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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

IN RE CELGENE CORPORATION SECURITIES LITIGATION

Case No. 18-cv-04772 (MEF) (JBC)

**FOURTH AMENDED CONSOLIDATED CLASS ACTION COMPLAINT**

# TABLE OF CONTENTS

## GLOSSARY OF TERMS

| | |
|---|---|
| AAN | American Association of Neurology |
| ADME | Absorption, Distribution, Metabolism, and Excretion |
| AMF | Lead Plaintiff AMF Tjänstepension AB |
| AUC | Area Under the Curve |
| CD | Crohn's Disease |
| CDER | FDA Center for Drug Evaluation and Research |
| CELG | Celgene ticker symbol |
| CFR | Code of Federal Regulations |
| CPMAC | Corporate Pricing and Market Access Committee |
| HEOR | U.S. Health Economics and Outcomes Research |
| I&I | Inflammation & Immunology |
| IBD | Inflammatory Bowel Disease |
| IIEC | Inflammation & Immunology Executive Committee |
| MS | Multiple Sclerosis |
| NDA | New Drug Application |
| NICE | National Institute for Health and Care Excellence |
| PsA | Psoriatic Arthritis |
| PsO | Psoriasis |
| PBM | Pharmacy Benefits Manager |
| PD | Pharmacodynamics |
| PDUFA | Prescription Drug User Fee Act |
| PK | Pharmacokinetics |
| RML | Regional Medical Liaison |

| | |
|---|---|
| RMS | Relapsing Multiple Sclerosis |
| RTF | Refuse To File |
| S1P1 | sphingosine-1-phosphate receptor-1 |
| S1P5 | sphingosine-1-phosphate receptor-5 |
| SEC | Securities and Exchange Commission |
| SOPP | Standard Operating Policy and Procedure |
| UC | Ulcerative Colitis |

Lead Plaintiff AMF Tjänstepension AB ("AMF" or "Lead Plaintiff"), by and through its undersigned counsel, brings this action individually and on behalf of all other persons and entities who purchased or otherwise acquired the common stock of Celgene Corporation ("Celgene" or the "Company") between April 27, 2017 and April 27, 2018, both dates inclusive (the "Class Period"), and were injured thereby (the "Class").

Lead Plaintiff alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Lead Plaintiff's information and belief is based upon, among other things, the investigation conducted by and through its attorneys, which included, among other things, interviews with numerous individuals, including former employees and consultants of Celgene, a review of Celgene's public documents, conference calls concerning Celgene, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by Celgene, analyst reports and advisories about the Company, media reports concerning Celgene and information obtainable on the Internet, as well as documents and deposition testimony adduced in discovery.

## I. INTRODUCTION

1. By 2015, Celgene confronted a major problem. The Company knew that in just a few years, it would lose its single largest source of revenue. Celgene's blockbuster multiple myeloma drug, Revlimid, was going to lose patent exclusivity in 2022. As Celgene knew, when that happened, less expensive generic versions of Revlimid would immediately take much of the market share that had been Revlimid's alone since 2006. Celgene would no longer be able to lean on Revlimid to provide billions in annual revenues. For more than five years running, Revlimid had delivered well over half of the net product sales for the entire Company. In 2014, net product sales from Revlimid had accounted for $4.98 billion, or ***more than 65%*** of total net sales, for the Company as a whole.

2. The approaching threat to Celgene from "the Revlimid patent cliff" was recognized in 2015 and throughout the Class Period by investment analysts and national media outlets alike. For example, in July 2015, investment analysts at Morningstar discussed the Company's need to "reduce Celgene's reliance on cancer drug Revlimid beyond 2020." Celgene's over-dependence on Revlimid continued throughout the Class Period, leading one analyst to write in May 2017 that "investors have reason to be 'concerned' over the Company's revenue concentration from Revlimid."

3. Celgene needed something it could point to as the replacement for its multi-billion dollar blockbuster drug. It needed a major new source for the revenue and growth that investors had come to rely on from Revlimid. Celgene knew it. The industry knew it. Investors knew it.

4. The alleged fraud in this case begins in April 2016, when Celgene embarked on a campaign to fraudulently misrepresent that two drugs in its Inflammation & Immunology ("I&I") franchise were poised to be billion-dollar blockbusters and provide massive revenues after Revlimid went off-patent. As Defendants knew, that was nowhere near the truth.

5. The first drug was **Otezla**, a pill that treats psoriasis ("PsO") and psoriatic arthritis ("PsA"), which Celgene began to sell in 2014. Celgene marketed Otezla as the first oral therapy approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adults with active PsA.

6. Celgene added the second drug, **Ozanimod**, through a $7.2 billion acquisition of Receptos, Inc. ("Receptos") on July 14, 2015. Ozanimod was in development for the treatment of multiple sclerosis ("MS") and ulcerative colitis ("UC").

7. After the Receptos acquisition, on July 15, 2015, *The New York Times* reported that Celgene "has grown to be one of the most successful biotechnology companies, based largely on

its blockbuster cancer drug, Revlimid. But Revlimid will eventually lose patent protection, and the company has been aggressively looking to expand its business and diversify. . . . Celgene executives said that ozanimod could have peak annual sales of $4 billion to $6 billion and would complement . . . Otezla, a pill Celgene already sells to treat psoriasis and psoriatic arthritis."

8. Throughout the Class Period, Celgene again and again trumpeted the supposed multi-billion dollar "replacement" revenues that these I&I drugs—Otezla and Ozanimod—would deliver in the next few years, as Revlimid fell off the "patent cliff" and its revenues faded away. Unbeknownst to the market, however, Celgene and numerous Celgene executives materially misrepresented the true facts about Otezla and Ozanimod.

9. In their attempt to assure the market that Celgene could fill the revenue hole Revlimid would soon leave, Celgene and the other Defendants concealed the truth from investors at almost every turn. In particular, Defendants: (i) ignored warnings of flat sales, implacable barriers to market penetration, and explicit calls to change long-standing, publicly issued sales guidance for Otezla from Celgene's senior market access executives; and (ii) disregarded warnings and guidance from Celgene's senior scientists and its primary regulator, the FDA, confirming that the Company's publicly promised application for approval of Ozanimod by the FDA in late 2017 would be rejected without required study data. Instead, Defendants misrepresented to investors the true state of affairs surrounding the growth and development status of these drugs, no matter how bleak things appeared to those within the Company.

10. By the end of the Class Period, Defendants disclosed that: (i) the Company had reduced its revenue guidance for Otezla by over a quarter of a billion dollars; and (ii) the FDA issued a stunning "Refusal to File" ("RTF") rejection of Celgene's initial New Drug Application

("NDA") for Ozanimod. Defendants' fraud directly caused billions of dollars in losses to Celgene investors, which Lead Plaintiff seeks to recover on behalf of the Class through this action.

**A. Otezla**

11. On January 12, 2015, Celgene publicly unveiled a five year strategic growth plan. Celgene claimed that its I&I franchise would grow to deliver $3 billion in net sales by 2020—and that Otezla would lead the way. Specifically, Celgene stated that Otezla, which launched in 2014, would bring in $1.5 billion to $2 billion in net sales ***by 2017***. Robert J. Hugin ("Hugin"), the Executive Chairman of Celgene's Board of Directors, stated that the "progress achieved . . . with Otezla . . . gives us great confidence that we are on track to really again meet or exceed the 2017 guidance." Investment analysts cheered this representation of Otezla's strength, with SunTrust Robinson Humphrey writing that it "***should spur investor excitement***."

12. In multiple statements over the next year and a half, Defendants repeated the refrain that Otezla would achieve $1.5 billion to $2 billion in revenues by 2017, signaling to the market that the conditions necessary to hit those numbers—sustained and increasing market acceptance and sales growth—were firmly in place. Those statements were materially false and misleading when made. In reality, after the initial post-release excitement in 2014, Defendants knew that Otezla sales growth was flat, and numerous factors barred the way to further market penetration for the drug.

13. For starters, Otezla was trying to take market share away from well-established, proven PsO and PsA drugs, which doctors knew and trusted, and also faced competition from other new entrants into the space. More fundamentally, Otezla did not work as well as the other PsO and PsA treatments, and Defendants knew it. Reports from the field did not support competitive efficacy levels. Otezla also worked more slowly, and on a narrower range of indications, than its competitors, further limiting its potential patient population. Furthermore, while Celgene

promoted the fact that Otezla was an easy-to-take pill, as opposed to the inconvenient injections of its competitors, multiple former Celgene employees confirmed that its inferior efficacy overshadowed this convenience, contributing to lower prescription rates.

14. In addition, insurers and Pharmacy Benefits Managers ("PBMs"), who greatly influence whether and when treatments are covered by insurance plans, posed another major obstacle to the growth of Otezla sales. In 2015, these entities largely refused to cover Otezla as a first-line treatment. Instead, they imposed so-called "step-edits" – requirements that patients first try less expensive treatments before being covered for Otezla.

15. To get the step-edits removed and attempt to gain market share, Celgene decided to "pay to play" and offered steep discounts and rebates to insurers for Otezla. The discounts also drove down the price that Celgene could obtain from Medicaid. The discounts, however, did not buy Celgene enough market access to offset the lower revenue generated from the discounted Otezla sales.

16. Numerous former Celgene employees reported that throughout the Class Period, these and other fundamental barriers were recognized within the Company as blocking Otezla from selling sufficiently to achieve the 2017 sales guidance, which Defendants repeatedly and unwaveringly affirmed to the public without any reasonable basis.

17. The dismal Otezla growth trends from 2015 and 2016 were recognized and discussed at the highest levels of Celgene's I&I franchise, as was the fact that ***the publicly-issued 2017 net sales guidance for Otezla could not be met***. Indeed, former high-ranking Celgene employees specifically recounted that at multiple meetings of Celgene's I&I Executive Committee ("IIEC"), of which Defendant Curran and Scott A. Smith were members, in the third and fourth quarters of

2016, senior market access executives presented Otezla data and warned expressly that the 2017 net sales guidance for Otezla was not attainable.

18. By the fourth quarter of 2016, high-ranking Celgene employees, including Robert Tessarolo, the Senior Vice President of I&I, U.S., explicitly urged Curran, Smith, and the other members of the IIEC to lower the forecast, which impacts the guidance. Despite the fact that, according to a senior executive in the U.S. Market Access group, "***everyone knew that the actual stated forecast was not reasonable***" and could not be met, the IIEC insisted that the public guidance would not be changed. Indeed, this executive recounts that Smith and Curran "told" the forecasting team to ***"change" the numbers***—i.e., Celgene's internal forecasts—to make Otezla's sales growth appear better than it actually was. Moreover, Defendants continued to publicly reaffirm the guidance through the end of 2016, without any reasonable basis.

19. In a public filing in January 2017, Celgene again assured investors that it was on track to meet the 2017 guidance and represented that it expected Otezla to achieve approximately 57% year-over-year sales growth to meet that guidance. Former Celgene personnel recount, however, that by early 2017, it was again recognized and openly discussed by senior market access employees within the Company that there was no way 57% growth in Otezla sales was attainable in 2017.

20. Moreover, the IIEC was once again warned, in at least one meeting in early 2017, that the Otezla net sales guidance remained too high, was unattainable, and needed to be lowered. In response, Smith cut off the presentation, saying he had heard enough.

21. Throughout the first and second quarters of 2017, Defendants misrepresented and otherwise failed to provide complete and accurate information to investors regarding key Otezla sales and performance metrics, which formed the basis for Otezla's Budget and internal forecasts,

as well as its 2017 Otezla net sales guidance. After Defendants continued to falsely affirm the 2017 Otezla net sales guidance throughout the second and third quarters of 2017, on October 26, 2017, Celgene abruptly reversed course and admitted publicly that Otezla would not hit the net sales guidance the Company had long affirmed, and cut its Otezla guidance by a ***quarter of a billion dollars***. This disclosure blindsided investment analysts, and the market reeled in response to the news, with the price of Celgene's common stock ***falling $19.57***, or more than ***16% per share***, on October 26, 2017 alone.

**B. Ozanimod**

22. Defendants also fraudulently misrepresented the true facts about Ozanimod, when, starting in April 2017, they represented that this development-stage MS and UC drug was sailing towards regulatory approval (and subsequent product launch) in late 2017, based on successful, ongoing Phase III clinical testing.

23. In reality, by April 2017, Celgene had received results from Ozanimod tests (which Celgene had long deferred performing) that identified critical issues in areas known to be of high FDA concern. These test results were a huge setback for Ozanimod. They raised basic questions about how the drug worked in humans that would require many months, and even years, of additional testing to answer. The results virtually guaranteed that the FDA would not accept, much less approve, an Ozanimod NDA in 2017 as the Company had represented to investors. In formal written comments from the FDA, the agency explicitly told Celgene that further testing, which could not be completed by the end of 2017, was required with the Ozanimod NDA. Yet Celgene said nothing to the market and, instead, pushed forward with the doomed Ozanimod NDA in late 2017, without the additional test results. The FDA promptly rejected the NDA, revealing Defendants' fraud to a stunned marketplace.

24. Celgene acquired Ozanimod in July 2015, when it bought Receptos, the company that first developed the drug. Strong results from advanced clinical studies made Ozanimod the "crown jewel" of the $7.2 billion acquisition, and Celgene immediately projected FDA approval and launch by 2018, and potential Ozanimod sales of up to $6 billion per year. Post-acquisition, Celgene took complete control of Receptos, installing Defendant Philippe Martin (Celgene's Vice President of Leadership & Project Management – Immunology) as *de facto* CEO.

25. If Ozanimod won FDA approval, it would compete directly with the established MS drug, Gilenya. Just three months after Celgene bought Ozanimod, however, a major patent ruling against Gilenya fundamentally changed the market outlook. In October 2015, Gilenya lost a challenge to would-be generics. Cheap, generic versions of Gilenya would thus hit the market by 2019. This ramped up the pressure on Celgene to establish Ozanimod's market share well before 2019, when competition from Gilenya generics would kick in.

26. In 2015, Celgene repeatedly told the market that Phase III trials for Ozanimod were well underway, and that the drug was on track for submission for FDA approval (for MS indications) by 2017, and a projected launch by 2018. Analysts cheered Ozanimod's progress toward launch, with RBC Capital Markets analysts, for example, reporting that Ozanimod was "ahead in timing," as of November 2015. The Gilenya generics ruling left little margin for error.

27. However, through 2015 and much of 2016, Celgene's Ozanimod development portfolio was missing a crucial component. Namely, Celgene lacked complete and adequate testing of Ozanimod's metabolites. Metabolites are essentially the chemical byproducts of the body breaking down a drug. They can be inactive or active. Active metabolites produce their own effects on the body and can impact the functioning of drugs. New Drug Applications must address drug metabolism, and in guidance dating back to at least 2008, the FDA has made clear that testing

and understanding the properties of active metabolites associated with a drug is a priority that should be undertaken "as early as possible" in drug development. The FDA warns that a failure to ascertain metabolite effects can "cause development and marketing delays." Seminal drug development literature also urges that the importance of metabolite testing "cannot be overemphasized," and that it should be done "at an early stage of clinical development, such that issues of disproportionate human metabolites may be addressed ***prior to the initiation of large-scale clinical trials***."

28. Nevertheless, Celgene had pushed forward with large scale Phase III clinical trials of Ozanimod without the requisite metabolite testing. The Company had put off performing (among other tests) the critical test to conclusively identify all active metabolites and begin to study how these metabolites affected the body—the "human radiolabeled mass balance study," which is "generally accepted" in the field as the "gold standard." Working, in effect, out of order, Celgene sought to backfill clinical pharmacology testing of Ozanimod (including metabolite testing) only ***after*** it had publicized promising results from the efficacy phases of the drug's development.

29. Celgene did not begin the necessary "mass balance" testing for Ozanimod metabolites until October 2016—more than a year after Celgene acquired Ozanimod. Unbeknownst to investors, this testing detected the disproportionate presence of a highly active metabolite, named RP112273 by Celgene (the "**Metabolite**" or "**RP112273**"). Under FDA guidance, various forms of significant, additional testing on the Metabolite were required before submitting the Ozanimod NDA. Those tests, however, would take time.

30. These late metabolite test results sent shockwaves through Celgene. Defendant Martin and other Celgene senior management knew about the results and regularly received updates on the issue. Former employees with roles in the Ozanimod development process

immediately recognized the need for additional testing on the Metabolite before an Ozanimod NDA could be filed with the FDA. These former employees noted that filing the NDA without the testing would cause the FDA to issue an RTF letter—which is a rejection of the NDA as facially deficient—a fact that was conveyed to their direct management. One former clinical pharmacologist who had first-hand knowledge of the discovery of the Metabolite stated that ***the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file, and he thought other teams felt that way too from speaking with them***. A second former employee also recounted that the need for additional testing was raised in a meeting involving Celgene senior leaders, including Tran and Martin, in early 2017. However, Martin abruptly shut down the discussion.

31. Notwithstanding the discovery of the Metabolite and the need to conduct protracted additional ***Phase I*** testing, Defendants knowingly misrepresented that the NDA was on track to be submitted by the end of 2017 pending only the results of ongoing ***Phase III*** testing, and that Ozanimod remained on track for FDA approval in 2018. Specifically, Defendants told the market that Ozanimod was advancing through Phase III testing, and that, "contingent on that, we will file an NDA for Ozanimod in multiple sclerosis by the end of the year." And when the last Phase III trial was ultimately completed in the spring of 2017, Defendants touted the results, without ever mentioning the need to go back and perform basic Phase I testing on the Metabolite. In essence, Defendants told investors that Ozanimod was on the two-yard line for NDA submission when, ***in fact***, given the need to conduct the additional testing, it was back at the fifty-yard line.

32. In preliminary meeting comments provided to Celgene on November 21, 2017, the FDA explicitly informed Celgene that it needed to include certain data with the NDA—data that Celgene did not have and could not generate before the end of the year. Despite this clear directive

from the FDA, Defendants charged ahead and filed the deficient Ozanimod NDA in December 2017. This was a reckless gamble that was also financially motivated. Former Celgene employees report that Defendant Martin and other executives received lucrative bonuses upon mere submission of the NDA to the FDA—and that they "***just wanted to get the NDA out the door***." Furthermore, as noted above, Celgene was desperate to capture market share from Gilenya before it lost patent exclusivity in 2019—and delaying submission of the NDA to complete protracted testing of the Metabolite would prevent Ozanimod's launch until after the market was saturated with cheaper generic alternatives.

33. On February 27, 2018, Celgene shocked the market when it disclosed that it had received an RTF rejection of its Ozanimod NDA application from the FDA—just as Celgene employees had warned. Celgene disclosed that, "[u]pon its preliminary review, the FDA determined that the . . . pharmacology sections of the NDA were insufficient to permit a complete review." The FDA issues an RTF only where an NDA contains glaring, facial deficiencies, including "***scientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity or potency***." Notably, RTFs are exceedingly rare—industry observers estimate that RTFs have been issued just forty-five times in the past ***sixteen years*** and almost never to well-established pharmaceutical companies like Celgene.

34. Celgene's receipt of the RTF was a public debacle. Investment analysts decried Celgene's "self-inflicted wounds" and lashed the Company with criticism. When the dust settled on the February 27, 2018 disclosure, it had driven Celgene's common stock price down by $8.66 per share in a single day.

35. In late April 2018, Celgene disclosed additional information about the Metabolite. Based on this presentation, analysts from Morgan Stanley reported that completion of the required

metabolite testing would delay the refiling of the Ozanimod NDA by ***up to three years***, or until 2021. In direct response to this final disclosure, which concludes the alleged Class Period, Celgene's common stock price fell an additional $4.08 on heavy trading.

## II. JURISDICTION AND VENUE

36. The claims asserted herein arise under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

37. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and under 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States.

38. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b), because Defendant Celgene conducts business in this District and also maintains its administrative headquarters in this District.

39. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities exchange.

## III. PARTIES

### A. Lead Plaintiff

40. Lead Plaintiff AMF is one of the largest pension companies in Sweden. AMF manages the AMF family of mutual funds, as well as separate pension, private client, and fixed income portfolios. AMF was established in 1973 as the asset management branch of the Stockholm-based AMF insurance group, and manages approximately $65 billion in assets on behalf of more than four million pension customers. As set forth in the certification attached hereto

as Exhibit A, AMF purchased or otherwise acquired Celgene common stock on the NASDAQ at artificially inflated prices during the Class Period and was damaged as a result of the conduct alleged herein. On September 26, 2018, this Court appointed AMF as Lead Plaintiff for this litigation. AMF Fonder manages mutual funds in which particular investments are made, and has the legal authority to assert legal claims on behalf of these mutual funds with respect to the investments they hold. As set forth in the certification attached hereto as Exhibit A, AMF Fonder purchased or otherwise acquired Celgene common stock on the NASDAQ at artificially inflated prices during the Class Period and was damaged as a result of the conduct alleged herein. By an Assignment of Claims and Power of Attorney executed on November 11, 2024, AMF is the assignee and transferee of "all rights, titles, and interests in the claims, demands, or causes of action against any defendant relating to transactions by AMF Fonder and its mutual funds, AMF Aktiefond Global, AMF Aktiefond Världen, AMF Balansfond and AMF Aktiefond Nordamerika, in any security issued by Celgene Corporation."

**B. Defendants**

**1. Celgene**

41. Defendant Celgene, a Delaware corporation headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development, and commercialization of therapies for the treatment of cancer and inflammatory diseases. The Company operates two key divisions: (i) the I&I franchise, which focuses on developing drugs for treatment of inflammatory diseases, such as PsO, PsA, UC, MS, and CD; and (ii) the "Hematology & Oncology" franchise, which focuses on developing treatments for blood diseases and cancer. Celgene's common stock trades on the NASDAQ Global Select Market under the ticker symbol "CELG." For fiscal year 2017, Celgene reported earnings of $2.539 billion with annual revenues of $13 billion.

42. On July 15, 2015, Celgene entered into an agreement and plan of merger with Receptos, a San Diego, California-based biopharmaceutical company, pursuant to which Celgene acquired Receptos and its development-stage drug, Ozanimod, through a series of merger transactions for $7.2 billion. On August 27, 2015, Celgene closed its acquisition of Receptos, which resulted in Receptos becoming a wholly-owned subsidiary of Celgene.

**2. The Individual Defendants and Former Defendant Smith**

43. Former defendant Scott A. Smith ("**Smith**") served as Celgene's President and Chief Operating Officer ("COO") from April 1, 2017 until his departure from Celgene, on April 2, 2018. Prior to April 1, 2017, Smith was President of the I&I franchise. According to the Company's 2017 Proxy Statement, in this role, Smith was engaged in company-wide strategic planning and decision making aimed at delivering on short and long-term financial goals and continuing to innovate, develop, and commercialize Celgene's products. Smith also oversaw the clinical development, global registration, and commercial sales of drugs within the I&I franchise. Both in his positions as President and COO and his prior position as President of I&I, Smith actively participated in Celgene's process for preparing and making public disclosures to the market regarding the Company's financial performance and clinical development matters. In particular, in each fiscal quarter from at least 2016 through April 2, 2018, Smith was a core participant in the senior executive team that prepared, drafted, reviewed, revised and finalized: (i) Celgene's quarterly earnings call and Q&A script; (ii) the investor slide deck presentation that Celgene published on its website to accompany each quarterly earnings release; (iii) the press releases that Celgene published along with each quarterly earnings release and upon other important events; and (iv) the SEC Forms 10-Q or 10-K that Celgene filed and published for each fiscal period.

44. Defendant Terrie Curran ("**Curran**") was promoted to President of Celgene's Global I&I franchise on April 1, 2017. From March 2016 through April 1, 2017, Curran served as Head

of Worldwide Markets for Celgene's I&I franchise. From April 2013 to March 2016, Curran served as the U.S. Commercial Head of the I&I franchise. According to Celgene's Senior Management Team biographies, in this role, Curran built capabilities and recruited the teams that executed the U.S. launch of Otezla. As the President of I&I, Curran actively participated in Celgene's process for preparing and making public disclosures to the market regarding financial performance and clinical development matters in the I&I franchise. In particular, in each fiscal quarter during her tenure as President of I&I, Curran was a core participant in the senior executive team that prepared, drafted, reviewed, revised and finalized: (i) Celgene's quarterly earnings call and Q&A script; (ii) the investor slide deck presentation that Celgene published on its website to accompany each quarterly earnings release; (iii) the press releases that Celgene published along with each quarterly earnings release and upon other important events; and (iv) the SEC Forms 10-Q or 10-K that Celgene filed and published for each fiscal period. As President of I&I, Curran had particular responsibilities with respect to providing and reviewing language in Celgene's earnings call scripts, investor slide decks, press releases and SEC Forms 10-Q and 10-K that discussed clinical development matters within the I&I franchise and the financial performance of I&I products.

45. Defendant Philippe Martin ("**Martin**") has served as Celgene's Vice President of Leadership & Project Management - Immunology from January 2014 through early March 2018. Martin also served as Celgene's Corporate Vice President from January 2017 to March 2018. From June 2016 to March 2018, Martin also served as Managing Director at Celgene-Receptos. Martin was the highest-ranking employee at the Celgene-Receptos site in San Diego, California. Martin was a member of the IIEC (along with Smith and Curran). His responsibilities with regards to the Ozanimod NDA were (1) to ensure the development of Ozanimod and to

monitor the Ozanimod NDA team's progress toward the completion of the NDA submission, (2) to ensure that the IIEC was apprised of what the project teams at Receptos were working on, including the Ozanimod NDA team, and (3) to ensure that Celgene was involved in the decision-making process with respect to the NDA submission. Martin provided updates regarding the Ozanimod NDA to the IIEC at meetings of the IIEC, among other means. Martin also provided quarterly updates regarding the Ozanimod NDA to Celgene's Board of Directors.

46. The Defendants referenced above in ¶¶ 44-45 are referred to herein as the "Individual Defendants."

**C. Certain Relevant Celgene Employees**

47. Jay T. Backstrom, M.D. ("Backstrom") served as Celgene's Chief Medical Officer from 2017 to 2019 and reported to Smith.

48. Matthew Lamb ("Lamb") was Celgene's Vice President and Global Head of Regulatory Affairs in I&I from April 2015 to November 2019 and reported to Backstrom.

49. Jean Louis Saillot, M.D. ("Saillot"), served as Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos from November 2016 to November 2019. Saillot reported to Defendant Martin.

50. Maria Palmisano ("Palmisano") began working at Celgene in July 2010 and served as Celgene's Corporate Vice President of Clinical Pharmacology during the Class Period.

51. Jonathan Tran ("Tran") served as the Executive Director of Clinical Pharmacology at Receptos from July 2015 through November 2019 and reported to Saillot.

52. Esther Martinborough ("Martinborough") was the Executive Director of Research in Computational Chemistry at Receptos from 2015 to the end of the Class Period. Martinborough reported to Defendant Martin.

53. Susan Meier-Davis, Ph.D. ("Meier-Davis") was the Senior Director in Pre-Clinical Sciences at Receptos from April 2016 to 2018. She reported to Martinborough.

54. David Kao ("Kao") served as the Senior Director of Regulatory Affairs at Receptos from July 2015 to April 2016 and then as the Executive Director of Regulatory Affairs at Receptos from May 2016 through April 2020. In 2016 and 2017, Kao reported to Saillot. In 2018, Kao reported to Lamb.

55. Gerlee Thomas ("Thomas") was the Director of Regulatory Affairs at Receptos from July 2016 to March 2018 and reported to Kao.

56. Richard Aranda ("Aranda") was the Vice President of Clinical Development at Receptos from January 2015 to February 2018. Aranda reported to Defendant Martin.

57. Brett E. Skolnick ("Skolnick") began working for Celgene in April 2015 and served as the Director of Clinical Development at Receptos through the end of the Class Period. Skolnick reported to Aranda.

58. Ted Reiss ("Reiss") served as Celgene's Corporate Vice President and the Head of I&I Clinical Research and Development Management from September 2015 through the end of the Class Period. Reiss reported to Defendant Curran in 2017.

59. Karen Zoller ("Zoller") was the Senior Director of Project Management at Receptos from November 2014 through the end of the Class Period. Zoller reported to Saillot.

60. Paul Frohna ("Frohna") served as Vice President of Clinical Development and Translational Medicine at Receptos from December 2013 to October 2016 and reported to Defendant Martin.

61. Jeffrey J. Kopicko ("Kopicko") was the Executive Director of Biometrics at Receptos from June 2016 to May 2017 and the Senior Director of Biostatics from July 2015 to June 2016. Kopicko reported to Saillot in 2016.

62. A personnel matrix dated March 9, 2017 identifies the individuals involved in drafting, reviewing, and approving portions of the Ozanimod NDA. This document confirms that, among others, the following individuals were responsible for and involved in authoring, reviewing, and approving various sections of the Ozanimod NDA: (a) Martin; (b) Lamb; (c) Saillot; (d) Aranda, (e) Skolnick; (f) Reiss; (g) Tran; (h) Palmisano; (i) Kopicko; (j) Kao; (k) Thomas; (l) Meier-Davis; (m) Martinborough; and (n) Zoller. In addition, as Celgene's Chief Medical Officer, Backstrom had the final authorization to submit the NDA on the Company's behalf.

63. Betty Jean Swartz ("Swartz") was a Vice President of U.S. Market Access at Celgene from April 2016 to January 2018. Swartz reported to Robert Tessarolo, who reported to Terrie Curran, and to Thomas Cavanaugh.

64. Robert Tessarolo ("Tessarolo") served as a Vice President and General Manager of I&I at Celgene from September 2015 to April 2017 and reported to Curran.

### D. Certain Relevant Non-Parties

#### 1. Former Employees, Consultants and Scientists[1]

65. FE 2 worked in Clinical Research & Development in the Company's I&I franchise through late 2016 in Summit, New Jersey. FE 2's responsibilities included long-term planning of

[1] Former Employees, Consultants and Scientists ("FEs") will be identified herein by number (FE 1, FE 2, etc.). Plaintiff has not renumbered the FEs despite the removal of allegations in the Second Amended Complaint attributed to FEs 1, 3, and 4, who provided information related only to Plaintiff's claims based on GED-0301, which were dismissed by the Court. Regardless of gender, all FEs will be described in the masculine to protect their identities.

both organizational and project-related activities, and assisting the Vice President of the I&I Clinical Research and Development department with the management of the department. Additionally, FE 2 participated in clinical development planning for I&I's compounds and managed departmental activities to ensure on-time delivery of the clinical component for regulatory submissions. FE 2 also served as a member of the GED-0301 developmental team and participated in writing a protocol for one of the GED-0301 studies. Prior to his work with GED-0301, FE 2 worked on over five NDAs for various drugs.

66. FE 5 was employed as a Director at Receptos from mid-2015 to mid-2017. While at Receptos, FE 5 oversaw and performed statistical analyses for the Ozanimod CD and UC studies. In this role, FE 5 was a regular attendee at meetings related to Celgene's Ozanimod clinical trials, including meetings regarding the submission of Ozanimod for FDA approval as a treatment for Relapsing Multiple Sclerosis ("RMS"). FE 5 also reviewed the GED-0301 Phase Ib study results in connection with his work on Ozanimod. While at Receptos, FE 5 reported to Kopicko, the Executive Director of Biometrics. Kopicko reported to Defendant Martin, who in turn, reported to Smith.

67. FE 6 was a Regional Medical Liaison ("RML") for the Company's I&I franchise in the New England region from before May 2015 to late 2017. In this role, FE 6 was part of the Market Access team, where he worked with Account Manager teams to identify scientific and medical support needs for accounts with marketed and pipeline products in the I&I franchise. FE 6 was also responsible for maintaining a working knowledge of all the I&I franchise's products so that he could educate the Account Managers on a product's clinical data.

68. FE 7 was a Senior National Account Manager at Celgene from 2013 to 2016. FE 7's work encompassed Market Access, in which he had 18 years of experience. FE 7 advised

Celgene's senior executives on the pricing strategy and market access strategy for Otezla. These senior executives included Sal Grausso ("Grausso"), Executive Director of Market Access for I&I, Swartz, Vice President of U.S. Market Access, Tessarolo, Senior Vice President of I&I, U.S., Gordon Willcox ("Willcox"), Vice President of Market Access, and Defendant Curran. In his role as Senior National Account Manager, FE 7 reported to Defendant Curran and Grausso, who in turn reported to Smith.

69. FE 8 was an I&I Sales Representative at Celgene from before May 2015 to late 2017 in the Northeast Region and his focus was on selling Otezla.

70. FE 9 was a Dermatology Specialty Sales Territory Manager at Celgene from before May 2015 to early 2017 in the Southwest Region and his focus was on selling Otezla. He was also involved in Celgene's launch of Otezla.

71. FE 10 worked as a Rheumatoid Sales Specialist for Celgene from early 2015 to late 2016. FE 10 was responsible for Otezla sales in the Northeast Region.

72. FE 11 was a Celgene District Sales Manager for the Northeast Region from before May 2015 to late 2016. As District Sales Manager, he received weekly reports regarding Otezla sales volume and growth for the previous week, quarter, and half-year, and a year-over-year comparison. FE 11 had eleven Otezla sales representatives under his supervision—five rheumatoid representatives and six dermatology representatives.

73. FE 12 was a Sales Representative for Celgene from before May 2015 to late 2017. FE 12 was responsible for Otezla sales in the Northeast Region.

74. FE 13 was a Regional Sales Manager at Celgene from before May 2015 to early 2015. FE 13 was in charge of I&I sales for more than five states in the mid- and western U.S. FE 13 was responsible for the launch and sales of Otezla.

75. FE 14 was a Sales Representative at Celgene from before May 2015 to early 2017. FE 14 promoted Otezla to doctors in a large Northeast market, from the early days of Otezla's launch until he left Celgene. At least quarterly, FE 14 received a ranking report, which force ranked FE 14 against other Otezla sales personnel based on their volume of Otezla sales.

76. FE 15 was a senior member of the Pricing and Market Access group at Celgene from before May 2015 to late 2015. In this role, FE 15 developed market access models for various drugs, including Otezla. These models were based on the drug's efficacy compared to other medications already in the market space. FE 15 provided the models to Frank Zhang ("Zhang"), Celgene's Global Head of HEOR, who reported to Smith.

77. FE 16 was a high-ranking member of HEOR and Pricing for the U.K. and Ireland at Celgene throughout the Class Period. In this role, FE 16 was responsible for making reimbursement submissions to the National Institute for Health and Care Excellence ("NICE"), an organization in the U.K. that determines whether the government will reimburse a company for a new drug. FE 16 reported to the Head of Market Access and Corporate Affairs for the U.K. and Ireland, the Global Head of HEOR and Pricing for I&I in the U.S., who reported to Smith, and a high-ranking member of the Global Market Access group.

78. FE 17 was a senior executive in the U.S. Market Access group at Celgene from early 2016 to late 2017. In this role, FE 17 worked with the managed care team where he negotiated new contracts with health plans. FE 17 led the U.S. Market Access team responsible for optimal patient access, strategic development, and execution of Celgene's value proposition. FE 17 also prepared pricing recommendations for the IIEC, which included pricing recommendations for Otezla. FE 17 reported to Tessarolo. Tessarolo reported to Smith and Defendant Curran.

79. FE 18 was a senior executive in the U.S. Health Economics and Outcomes Research ("HEOR") group at Celgene from before May 2015 to early 2018. FE 18 reported to Swartz.

80. FE 19 was a senior executive in U.S. Field HEOR from mid-2016 through the end of the Class Period. FE 19 worked in external Market Access to guide key decision makers with respect to patient access to specific drugs and services, efficacy, and safety. FE 19 reported up through the Executive Director of U.S. HEOR.

81. FE 20 was a senior executive in Clinical Development at Receptos from before May 2015 to late 2016. FE 20 was responsible for conducting all the Phase II and Phase III studies for Ozanimod in MS and UC.

82. FE 21 was a Clinical Pharmacologist from late 2016 to early 2018 at Receptos and worked on the Phase I studies of Ozanimod. FE 21 contributed to the clinical pharmacology section of the Ozanimod NDA and had first-hand knowledge of the Metabolite starting at the time of its discovery. Following this discovery, FE 21 worked on studies regarding the Metabolite, including tests to identify and characterize the Metabolite.

83. FE 22 was a contractor for Receptos and worked as a Project Manager for the Ozanimod UC/CD team in San Diego between late 2017 and early 2018. As a Project Manager, FE 22 oversaw the Ozanimod UC/CD drug development through various clinical stages. FE 22's job responsibilities also required him to be kept apprised of the status of the MS Ozanimod project.

## IV. FACTUAL ALLEGATIONS

### A. Celgene Needed to Offset the Looming Loss of Revlimid's Patent Protection

84. After the launch of Revlimid in 2006, the drug quickly became a blockbuster for Celgene. By 2010, Revlimid accounted for ***$2.469 billion*** in annual product sales—roughly ***70.4%***

of Celgene's total annual net product sales—and, by the end of 2014, Revlimid accounted for ***$4.980 billion*** in sales.

85. Celgene's over-reliance placed significant pressure on the Company to diversify its pipeline away from Revlimid. Indeed, analysts often cited the risk inherent in Celgene's financial success being tied so closely to a single drug. On May 5, 2017, for example, Benzinga reported that "investors have reason to be 'concerned' over the company's revenue concentration from Revlimid. . . . During the recent quarter, sales of Revlimid accounted for 64 percent of total revenue and that proportion is only growing."

86. The Revlimid patent protects the drug from generic competition, but only until the year 2022. With Revlimid's patent expiration on the horizon, and given the frequent challenges to the validity of the patent by a number of generic drug manufacturers, Celgene was under intense pressure before and during the Class Period to create and maintain a drug pipeline (including through acquisitions) to offset the anticipated loss in revenues that would result from generic Revlimid competitors entering the market.

87. For example, on July 15, 2015, *The New York Times* recognized Celgene's need to replace the revenue it historically relied upon from Revlimid in an article discussing Celgene's recent acquisition of Receptos:

> Celgene agreed on Tuesday to pay $7.2 billion in cash to acquire Receptos, which is developing a potentially promising drug for autoimmune diseases. . . . Receptos, based in San Diego, is developing a drug called ozanimod that is now in late-stage clinical trials as a treatment for multiple sclerosis and ulcerative colitis, with an approval possible for multiple sclerosis as early as 2018 and for ulcerative colitis the year after. . . .
>
> [Celgene] has grown to be one of the most successful biotechnology companies, based largely on its blockbuster cancer drug, Revlimid. ***But Revlimid will eventually lose patent protection, and the company has been aggressively looking to expand its business and diversify***. . . .
>
> Celgene has earned a reputation as willing to pay top dollar either to acquire smaller companies or to license their drugs. . . . Last year it made an eye-popping initial payment

> of $710 million to an obscure company based in Dublin, Nogra Pharma, for rights to GED-0301, a drug being tested for Crohn's disease, which, like ulcerative colitis, is an inflammation of the bowel. . . .
>
> Celgene will be paying more than 16 times the $14 price at which Receptos went public two years ago. Celgene executives said that ozanimod could have peak annual sales of $4 billion to $6 billion and would complement GED-0301 and also Otezla, a pill Celgene already sells to treat psoriasis and psoriatic arthritis.

88. Celgene itself also told the market that it was diversifying its pipeline away from Revlimid and situating itself to offset the anticipated loss of Revlimid patent exclusivity and the accompanying reduction in revenues with the Company's I&I franchise. On May 31, 2017, for example, Mark J. Alles ("Alles"), Celgene's Chief Executive Officer, after referencing the Company's historical reliance on annual Revlimid revenues, told investors that GED-0301 (a developmental drug for the treatment of Crohn's disease), Ozanimod, and Otezla, would serve as a "replacement for it."

89. Internal Celgene documents confirm that the Company intended to use I&I franchise drugs like Ozanimod to offset expected revenue losses when the Revlimid patent expired. For example, a presentation from the October 25, 2016 IIEC meeting identified one of the "Objectives" for Ozanimod as "Addresses Revlimid loss of revenue through genericization."

### B. Defendants Made Fraudulent Statements About Otezla During the Class Period

90. One part of Defendants' plan to replace the Company's revenue stream from Revlimid was Otezla—the most commercially advanced drug in Celgene's I&I franchise. Otezla, which the Company touted as one of its "primary commercial stage products," is an oral medication that is used to treat PsA and PsO.[2] While many drugs used for the treatment of PsO

[2] Psoriatic arthritis (PsA) is a type of arthritis that affects some people who have psoriasis (PsO)—a chronic skin condition that speeds up the life cycle of skin cells, causing extra skin cells to build up on the surface of the skin in scales and red patches that are itchy and sometimes painful.

and PsA are biologics, Otezla is an oral medication. Celgene regularly promoted the convenience of Otezla to patients, emphasizing that Otezla is "not an injection, cream or biologic. It's a pill . . . ."

91. Otezla was approved by the FDA in March 2014 for the treatment of PsA, and Celgene began recognizing revenue from the sales of Otezla during the second quarter of 2014. As early as January 13, 2014, months before the Otezla launch, Defendants primed the market that Otezla sales were poised to sky-rocket, representing that Otezla net product sales would reach $1.5 billion to $2 billion by 2017.

**1. Celgene Issues 2017 Guidance for Otezla Without a Reasonable Basis**

92. On January 12, 2015, Celgene issued a press release unveiling the Company's five-year strategic growth plan. According to this plan, Celgene maintained that Otezla net product sales would grow to between $1.5 billion and $2 billion in 2017 and its net product sales from the I&I franchise as a whole would exceed $3 billion by 2020. During a presentation at the J.P. Morgan Healthcare Conference that same day, Hugin highlighted the Company's 2017 Otezla sales guidance, claiming that "the progress achieved in the fourth quarter [of 2014] with Otezla in our I&I franchise, gives us great confidence that we are on track to really again meet or exceed the 2017 guidance."

93. Analysts quickly seized on Celgene's reaffirmation of the 2017 Otezla and I&I guidance as well as Hugin's assurances that the Company would achieve these numbers. For example, SunTrust Robinson Humphrey wrote that "management's commentary that CELG is slated to 'meet or exceed 2017 guidance' . . . should spur investor excitement."

### 2. Celgene Internally Recognizes Multiple Barriers That Prevented Otezla From Achieving the 2017 Otezla Sales Guidance

94. Unbeknownst to investors, Defendants lacked a reasonable basis for their January 2015 statements reaffirming the Company's aggressive 2017 sales guidance for Otezla. In reality, after the 2014 launch, numerous barriers impeded Celgene from achieving those numbers, and Company sales representatives struggled and failed to grow their Otezla sales commensurate with the Company's projections.

95. According to FE 7, a Senior National Account Manager, as early as the March 2014 launch, Otezla's sales and revenue generating capabilities were severely impaired by several dynamics.

96. For example, FE 7 stated that, shortly after the drug's launch in 2014, Celgene offered excessive rebates and discounts to convince insurance companies to remove "step-edits"—the requirements put in place by insurers and PBMs that forced patients to try other, less expensive therapies before being permitted to use Otezla. Celgene's goal was to gain market share for Otezla by using the rebates and discounts to lower Otezla's effective price. However, according to FE 7, the plan was doomed from inception.

97. As FE 7 explained, one consequence of the Company's steep rebates and discounts on Otezla was additional downward pressure on Otezla sales revenues due to the impact of these rebates and discounts on Celgene's "best price calculation" for the drug. As FE 7 explained, rather than boosting net sales from Otezla by capturing market share through the large discounts and rebates, Celgene drove down the "best price" calculation, and was left selling the drug for what FE 7 illustratively described as one cent per pill—thus ensuring that the Company would never meet the 2017 Otezla net sales guidance.

98. In the pharmaceutical industry, a drug's "best price" refers to the price a drug manufacturer must offer to Medicaid. Specifically, the Medicaid "best price" policy requires drug manufacturers by statute to give Medicaid programs the lowest or "best" price offered to nearly all purchasers. Accordingly, because Celgene was repeatedly driving down the price of Otezla that it was offering to insurers and PBMs, it necessarily drove down the price it was required to provide to one if its largest payers, Medicaid.

99. The inherent flaw of this strategy was known to senior management, including Smith, who FE 7 stated had the final say with regard to Otezla and Market Access decisions. In fact, starting in 2014, FE 7 repeatedly warned Smith that the Company's pricing and discounting strategy for Otezla was fatally flawed and simply would not work to increase revenues. When Otezla launched, FE 7 informed Smith that he would be destroying the "best price" for the drug by offering large rebates and discounts, thereby setting Otezla up for consistently depressed net sales going forward. In response, Smith told FE 7 that Celgene would do "whatever it takes to get the business."

100. After the Otezla launch in 2014, FE 7 wrote multiple emails to Celgene's senior executive management, including Smith, documenting his concerns about the discounts and rebates that Celgene was offering for Otezla. FE 7 also told Smith that Celgene should never "pay to play"—i.e., offer rebates and deep discounts in exchange for market access—as that would prevent Celgene from maximizing its profits. Notwithstanding FE 7's warnings, Celgene pressed ahead with its ill-fated "pay to play" plan for gaining market access.

101. FE 7 also stated that, critically, Otezla was far worse than Humira, Amgen's Enbrel (etanercept)—a biologic treatment manufactured by Amgen that has been available to treat PsA since 2002 and PsO since 2004—and other competitors in terms of efficacy. The drug's inferiority

to numerous established competitors in the marketplace made market penetration, and thus any attempt to increase revenues from Otezla sales, even more difficult.

102. FE 7 added that these impediments to growing Otezla net sales were exacerbated by the fact that, from the date of the Otezla launch, Smith hired extremely inexperienced sales representatives to sell the drug.

103. Echoing the accounts of FE 7, former Celgene sales representatives from every corner of the country all told the same story: for several fundamental reasons that remained unchanged throughout 2015, 2016 and 2017, the growth rate of Otezla sales was essentially flat.

- FE 8, a Celgene Sales Representative in the Northeast Region, confirmed that his annual Otezla sales were flat the entire time he worked for Celgene, from early 2014 through late 2017.

- FE 9, a Sales Territory Manager in the Southwest Region, recounted that by 2015, the growth of his Otezla sales had flattened and were flat from 2015 until he left Celgene in March 2017.

- FE 10, a Celgene Sales Representative in upstate New York, stated that, during his entire time with Celgene (from early 2015 until the end of 2016), it was "certainly a struggle to sell" Otezla, particularly on the rheumatology side—i.e., for patients suffering from PsA. As FE 10 explained, "[o]nce the buzz [around Otezla] had dropped off by 2016, and once providers got a sense [Otezla] wasn't going to work that well," growing sales of Otezla "started to become a huge issue." Thus, FE 10 recalls that "the consensus was that the growth was not sustainable by 2016."

- FE 11, a District Sales Manager for the Northeast Region, stated that by 2016, his prescription sales had flattened for the entire year and there was a decline in annual growth (vs. 2016).

- FE 12, a Sales Representative in the Northeast Region, similarly noticed a slowing of Otezla prescription sales, particularly around October 2016.

- FE 13, a Regional Sales Manager, said that it was virtually impossible for Celgene to sell enough Otezla to meet its 2017 guidance. Specifically, FE 13 stated that the idea that Otezla could ever achieve 40% year-over-year growth in net product sales in 2017, let alone the 57% growth Defendants projected in January 2017, was absurd. FE 13 explained that he had seen no indication that would justify that kind of projection unless Celgene was expecting some huge

> shift in the managed care environment, and that it makes no logical sense to see those numbers domestically.

104. The Otezla sales representatives confirmed that Celgene's executives had access to information showing that the Company was unable to increase the growth rate of Otezla sales throughout the Class Period. FE 14 stated that Celgene management knew of Otezla's struggles because all of the sales results were available to management through a computer program called "Tableau." FE 12 explained that Tableau is a computer data tool that Celgene used to compile and analyze sales data that Celgene receives from IMS—a company that collects pharmaceutical data. During the Class Period, the data available through Tableau for Otezla included straight volume, volume growth, number of prescriptions by territory, number of prescriptions by provider, and number of prescriptions attributed to each salesperson. According to FE 12, anyone from the sales side at Celgene could log on to Tableau and view the Otezla sales data. The degree of access to the data increased as you went higher up in the Company.

105. The former sales representatives also confirmed FE 7's account, uniformly attributing their struggles to grow Otezla sales to three main issues: (i) Otezla's inferior efficacy compared to its competitors, including the fact that Otezla worked slower than other drugs and was only effective for certain indications; (ii) challenges with insurance coverage for Otezla, including step-edits and preauthorization requirements; and (iii) various other obstacles that made it difficult for patients to get Otezla or negatively impacted the ability of sales representatives to sell Otezla. These persistent and widespread impediments to growing Otezla sales rendered Celgene's 2017 Otezla guidance unattainable and Defendants' representations reaffirming that guidance materially false and misleading.

**(a) Celgene internally viewed Otezla's competitors as more effective, faster-acting, and covering a broader range of indications**

106. As numerous FEs recounted, the first fundamental barrier to growing Otezla sales throughout the Class Period was the fact that Otezla was not as effective as the other PsA and PsO drugs from which it was attempting to capture market share.

- FE 9 explained that Humira produced positive results more quickly than Otezla. In addition, Otezla was not as effective as Humira for individuals who only suffered from PsO.

- FE 8 stated that Otezla's main competitors, Humira and Enbrel were simply more effective products with broader indications than Otezla. Humira and Enbrel could be prescribed to patients with mild to severe symptoms and typically worked within two to three weeks, whereas Otezla was only approved for mild to moderate indications and required up to four months to produce noticeable results. FE 8 referred to Otezla as "training wheels" compared to Humira and Enbrel.

- FE 10 confirmed that Otezla was difficult to sell because it was not as effective as its competitors, stating, for example that PsA patients who had the disease for some time often did not respond well to Otezla. FE 10 received consistent feedback from rheumatologists that Otezla did not work well to treat PsA.

- FE 11 added that there was an increase in competitor products entering the market during the Class Period, and in contrast to Otezla's efficacy rate of approximately 33%, these new biologic competitors had efficacy rates between 50% and 75%. As FE 11 explained, these statistics made it difficult to convince doctors and patients to switch to Otezla.

- FE 13 likewise confirmed that the efficacy of Otezla was nothing groundbreaking and not nearly as efficacious as some of the other competitors.

- FE 12 and FE 14 also indicated that there were issues with Otezla's efficacy and FE 12 specifically stated that Otezla worked slower than other competitor products and that these competitor products had more efficacy data. FE 12 further noted that there were significant deviations between patients in terms of Otezla's efficacy.

**(b) Celgene understood internally that the market was oversaturated with entrenched competitor drugs**

107. Celgene's attempt to capture market share and increase Otezla sales during the Class Period was further stymied by the sheer number of competitors in the PsA and PsO treatment market and the fact that many of these drugs had been on the market for years and were well-accepted by physicians.

- FE 9 explained that the market for PsA and PsO medications was oversaturated with competitor treatments, including established drugs like Humira. Physicians had many choices and Otezla was not at the top of the list—other, better known treatments were.

- FE 8 stated Otezla had difficulty capturing market share from its main competitors, Enbrel and Humira, as they had been on the market since 2002 and 2005, respectively.

- FE 11 similarly recounted that Humira was the "big kid on the block" and was already entrenched in the Northeast Region.

- Echoing FE 11, FE 13 indicated that the growth of Otezla sales was limited by Humira's successful saturation of the market.

- FE 13 explained that while the Company wanted Otezla to be the first in-step therapy, in light of its safety profile, ***that was just a "pipe dream***" because Methotrexate (another competitor) was so much cheaper and had been in use for so long that ***it just was never going to happen***.

- According to FE 13, Otezla was always destined to be a niche product as compared to its previously launched competitors.

**(c) Insurance coverage for Otezla was limited and patients faced step-edits and preauthorization requirements**

108. Celgene's efforts to drive down pricing, in part, to avoid insurance step-edits and preauthorization requests, were largely unsuccessful until 2017, when several large PBMs finally agreed to cover Otezla as an initial PsA and PsO treatment. As such, insurance companies threw up roadblocks that constrained Otezla's ability to gain market share and increase sales from May 2015 through at least 2016.

- FE 9 reported issues with insurance companies, including that pre-authorization was routinely denied for Otezla and patients had to try other first-line drugs due to insurers' step-edit requirements. Insurance companies initially would not budge on coverage for Otezla.

- FE 14 stated that Otezla suffered from challenges with insurance coverage, including step-edits.

- FE 10 stated that insurance providers were unwilling for an initial period to reimburse patients for Otezla.

- FE 11 explained that several of the managed care groups in the Northeast Region had step-edits in place that required patients to use and reject Humira and Enbrel before they would approve Otezla, and the appeals process was cumbersome, so most doctors and plans opted to take the easier route by prescribing other drugs.

**(d) Other barriers to growth**

109. The growth of Otezla sales was also constricted by the fact that some patients experienced difficulties in trying to fill their Otezla prescriptions and the fact that Celgene lacked experienced sales personnel. FE 9 recounted that Otezla was considered a specialty drug, and had to be ordered from specialty pharmacies, unlike Humira and Enbrel, which were readily available in traditional pharmacies. This limit on access made it harder for patients to obtain Otezla even if their doctors prescribed it and insurance companies covered it. In addition, like FE 7, FE 14 also reported that Celgene's Otezla sales representatives were very inexperienced, which adversely impacted their ability to sell Otezla.

**(e) Otezla faced barriers to growth in the European markets**

110. Former Celgene employees involved with Celgene's efforts to expand Otezla into European markets similarly reported challenges to introducing Otezla into these markets and growing Otezla sales to meet the Company's unrealistic sales guidance.

111. FE 15, a senior member of the Pricing and Market Access group throughout 2015, was charged with creating pricing and market access models for reimbursement applications that

Celgene submitted to foreign national healthcare organizations in conjunction with efforts to obtain approval to market Otezla in Europe. As FE 15 explained, during the Class Period, there were two main hurdles before a drug could be marketed outside the U.S.: (i) the drug must be approved by the foreign counterpart to the FDA; and (ii) a reimbursement application must be accepted by the national healthcare organization charged with evaluating, among other things, the efficacy, cost and potential patient base for a drug.

112. In developing the models for Celgene's reimbursement applications, FE 15 struggled with Otezla's lack of compelling efficacy data because the models are usually driven by a drug's efficacy compared to other medications that are already in the market space. As he explained: "Otezla is worse than other things on the market so there was very little for me to work with." Because the data for "Otezla wasn't any better and was much worse than all of the competitors, it was very difficult to find the value" to support the reimbursement application models. FE 15 provided the Otezla models for the reimbursement applications to Zhang, Celgene's Global Head of HEOR, Pricing and Market Access, who in turn presented them to Smith.

113. Based on his review of the Otezla Phase II and Phase III trial data, FE 16, a high-ranking member of HEOR and Pricing for the U.K., stated that Otezla was inferior to its biologic competitors in terms of response rate and efficacy. It was his understanding that Otezla had a response rate that was 50% of the rate of biologics. Otezla's main advantage was that it was an oral medication, but the response rates for patients taking Otezla were "nowhere near" a biologic like Humira.

114. FE 16 confirmed that, in the U.K., Celgene's strategy was to discount Otezla to just below the price of its biologic competitors to stimulate sales and capture market share. However, clinicians and patients were not swayed by the discount because the clinician would put the two

drugs side by side, and the modest discount was not enough to make a difference with such an inferior efficacy. As FE 16 further explained, it was aggressive and foolish to assume that clinicians would use Otezla over biologics—clinicians just want to use the best product with the best data. As a result, FE 16 recounted that the Otezla sales and uptake forecasts compiled by Celgene for the U.K. and Ireland were overly aggressive. FE 16 added that his colleagues in other parts of Europe shared the same feeling that the Company's targeted sales figures were quite aggressive. FE 16 and his European counterparts at Celgene participated in discussions with independent advisory boards comprised of clinicians, local payers and various stakeholders. The advisory board members would consistently criticize Celgene, stating: "You're offering a biologic-like price without [] biologic-like efficacy."

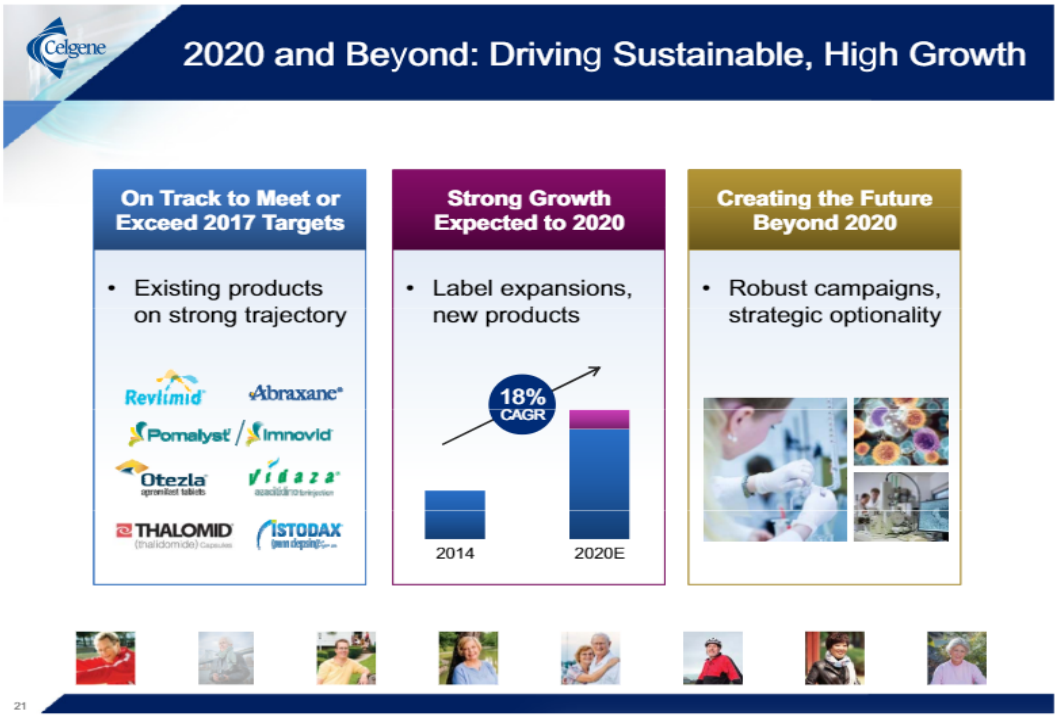
115. According to FE 16, once approval was granted by the relevant U.K. regulatory body, the NICE, in late 2016, and Otezla was introduced into the U.K. marketplace, sales and uptake were "very slow and very low." FE 16 stated that they missed sales targets for five or six quarters and were continuing to struggle as late as the middle of 2018. The early sales targets were missed by close to 50%. FE 16 confirmed that both Celgene's European and U.S. leadership were well aware of the missed targets. Indeed, there was "business review meeting after business review meeting" concerning the missed targets, including, at one point in late 2016 or early 2017, a meeting in London between Smith and Business Unit Director Rob Moore.

### 3. Defendants Reaffirm the 2017 Guidance and Tout Otezla's Net Product Sales Prospects Throughout 2015 and Into 2016

116. Notwithstanding the numerous barriers that were impeding Otezla's net product sales and market share growth by the beginning of the Class Period, Defendants repeatedly represented that Celgene was on track to meet its 2017 Otezla guidance—net product sales of $1.5 billion to $2 billion—over the course of the next year and a half. For example, during the May 12, 2015

Bank of America Merrill Lynch Healthcare Conference, Smith lauded the purportedly "phenomenal" "acceptance of [Otezla]" for PsO and PsA by new patients, claiming that Otezla was "off to a great start" and that Celgene was "very, very encouraged."

117. Defendants also presented nearly identical versions of the slide set forth below discussing "sustainable, high growth" and reassuring investors that the Company was "***on track*** to meet or exceed" its 2017 Otezla sales guidance at no fewer than five separate investor conferences—on March 4, May 12, June 10, September 17 and November 10, 2015:




118. At the May 11, 2016 Bank of America Merrill Lynch Healthcare Conference, Alles claimed that Otezla's "terrific launch" gave Celgene confidence in the Company's ability to hit the Otezla 2017 guidance. Alles went on to downplay certain impediments to growth such as the step-edits imposed by the insurance companies on new users of the drug, stating, "we understand the access environment very well, so some of those barriers that gave us all a little bit of caution for the uptake of Otezla early have started to present themselves in ways where we can manage it,

understand it, and in many cases, we have great advantaged positions now because of the profile of the drug."

#### 4. Defendants Ignore Explicit Warnings From Celgene's Market Access Team That the 2017 Otezla Net Product Sales Projections Are Unachievable

119. Despite (i) Celgene's continuing struggles to grow Otezla net sales in light of insurance barriers and Otezla's inferior efficacy vis-à-vis its competitors, and (ii) management's receipt of explicit warnings regarding the Company's doomed "pay to play" strategy for gaining market access, Defendants maintained Celgene's aggressive 2017 sales guidance throughout 2016 and 2017. Furthermore, as discussed below, between July and December 2016, Defendants disregarded explicit warnings from high-ranking finance personnel within the Company who voiced grave, specific and unequivocal concerns that the 2017 Otezla sales guidance was unachievable.

120. According to FE 17, a senior-level U.S. Market Access executive between early 2016 and late 2017, there was no Otezla revenue growth anywhere by 2016. FE 17 recalled that the lack of growth in Otezla sales and its fundamental causes were expressly communicated to the IIEC by no later than the third quarter of 2016. At this time, the IIEC was comprised of at least the following individuals: Smith; Defendant Curran; Tessarolo; Hunter Smith (Vice President, Finance); Tom Tomayko (Vice President, Commercial Development & Strategy, I&I); and Celgene's Head of Medical.

121. FE 17 and his team presented to the IIEC one to three times during each of the third and fourth quarters of 2016. Jim Kilgallon, Executive Director, U.S. Market Access, Pricing and Contracting, who worked with FE 17 and maintained much of the supporting Otezla payer and pricing statistics, presented with FE 17 at these meetings. During these presentations, which focused on payers and pricing, FE 17 and his team expressly warned the IIEC that the 2017 Otezla

guidance could not be met. FE 17 explained that the detailed research he reviewed and presented regarding payers and pricing showed that the forecasted Otezla sales for 2017 were not attainable. According to FE 17, Tessarolo also warned the IIEC in weekly meetings by the third quarter of 2016 that the 2017 Otezla guidance could not be met.

122. In the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered. FE 17 also specifically recalls that he and Kilgallon told Tessarolo directly that the guidance needed to be lowered. Tessarolo agreed and later confirmed to FE 17 that he, too, warned the IIEC that the guidance should be lowered, but the other members of the IIEC, which included Smith and Curran, insisted that the guidance would not be changed. Thus, FE 17 confirmed that by the third and fourth quarters of 2016 the IIEC was acutely aware that Celgene was not going to hit the repeatedly reaffirmed 2017 Otezla sales guidance numbers. According to FE 17, "***everyone knew that the actual stated forecast was not reasonable***" and could not be met.

123. FE 17 further recounted that the Forecasting team (which included Doug Bressette, Senior Director, Global Business Planning and Analysis for I&I) was "***told to change***" ***the numbers*** (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth.

124. FE 18, a direct report to Swartz, Celgene's Vice President of U.S. Market Access, confirmed that Smith and other Celgene executives were aware that Celgene was not going to meet its 2017 Otezla sales guidance by no later than the fourth quarter of 2016. FE 18 explained that Swartz made recommendations to the Corporate Pricing and Market Access Committee ("CPMAC")—the committee charged with monitoring and approving pricing and market access decisions—that the Company needed to reduce the 2017 guidance numbers, but she was ignored.

The CPMAC was chaired by Smith, and other members of Celgene's senior executive management would sit in as well.

125. When FE 18 first saw the 2017 Otezla sales guidance, his reaction was "***wow, there is no way in the world we were going to make [it] . . . it was crazy***." FE 18 described the guidance as a "moon shot." FE 18 indicated that the aggressive Otezla guidance did not even account for the introduction of new competition to the PsA and PsO market—Defendants simply ignored this factor. FE 18 further explained that the guidance figures were based on the assumption that insurance reimbursement hurdles would be removed. To meet the Otezla sales numbers set by the CPMAC, Otezla would have had to completely transform the market space in less than twelve months—but this kind of transformation is unheard of, unless a company introduces a curative drug. Otezla just did not have the efficacy or novelty to bring about the market change needed to meet the Company's sales guidance. FE 18 also confirmed that Otezla sales in the fourth quarter of 2016 were very flat and had been flat for quite some time before that.

126. The admonitions of Swartz, FE 18, and their colleagues responsible for pricing concerning the unachievability of Celgene's Otezla sales guidance were outright ignored by Smith, Defendant Curran and other members of Celgene's senior management. According to FE 17, Defendants refused to lower the guidance and instead put pressure on the salespeople to hit the impossible numbers.

127. Indeed, Defendants repeatedly reaffirmed the 2017 Otezla net product sales guidance to the market. During the September 12, 2016 Morgan Stanley Global Healthcare Conference, Smith claimed: "Otezla is moving along very nicely at this point in time. Looks like $1 billion in sales this year [2016]. . . . I feel really great about where we are going and the numbers both in 2017 and 2020 that we put out there." Later, during Celgene's October 27, 2016 third quarter

conference call, Smith expressed a "high degree of confidence" in Celgene's ability to meet the 2017 Otezla sales guidance, adding that "we feel very good about the targets that are out there."

128. According to FE 18, Swartz was fired in late 2017. FE 18 had reported to Swartz for a year and a half and never had any issues with her, stating that she was always very professional and was a great boss to work for. The consensus among FE 18 and his colleagues was that Swartz had been fired due to her consistent pushback regarding the unachievable Otezla sales guidance that Celgene repeatedly provided to the market. According to FE 18, Swartz was "scapegoated" and her termination was an attempt by Celgene to "pivot around her."

### 5. Defendants Marginally Lower the Upper Range of 2017 Guidance But Forecast Impossible 57%+ Growth in Otezla Sales

129. In January 2017, even after Smith and Curran were expressly advised by Swartz, Tessarolo and others that Celgene's publicly-stated 2017 Otezla guidance could not be met, Defendants refused to revise the low end of the range and only modestly lowered the top end from $2 billion to $1.7 billion. Critically, Defendants also misleadingly projected 57% year-over-year growth in Otezla net product sales for 2017 compared to 2016. Specifically, on January 9, 2017, Celgene filed a Form 8-K with the SEC signed by Peter N. Kellogg ("Kellogg"), Celgene's Chief Financial Officer ("CFO") and Chief Accounting Officer, attaching a press release with the Company's 2016 preliminary results and its outlook for 2017. In this press release, Celgene stated that it expected Otezla net product sales of "approximately $1.5 [billion] to $1.7 [billion]" for 2017, representing 57% year-over-year growth.

130. Analysts reporting on Celgene's press release, including BTIG Equity Research, wrote that the "biggest driver" of the Company's overall 2017 guidance was Otezla, "which is expected to grow ~58% YoY." SunTrust Robinson Humphrey wrote that even the narrowed Otezla guidance range "calls for significant growth." In addition, several analysts noted that

Celgene's reaffirmation of the $1.5 billion low-end of the guidance range was in line with the market's expectations. For example, RBC Capital Markets was focused on the low end of the range, writing on January 9, 2017 that the $1.5 billion figure was "already expected." Evercore ISI wrote in a January 9, 2017 report that "CELG took the top end of Otezla guidance down from $2B to $1.7B, and the midpoint of Otezla guidance now tracks with consensus 2017 estimates of $1.54B." Similarly, J.P. Morgan stated in a January 9, 2017 report discussing Celgene's updated 2017 guidance that the consensus guidance for Otezla was $1.53 billion.

131. Multiple former employees confirmed that Defendants' forecasted 57% year-over-year growth was both unrealistic and unachievable. FE 19, a senior executive in U.S. Field HEOR, recounted that based on what his Market Access group was seeing in their interactions with and analyses of large payers, there was no way that the projected 57% year-over-year Otezla sales growth for 2017 was attainable. According to FE 19, in late 2016, when Smith was assessing the 2017 Otezla market access and setting the targets, the market did not support anything close to 57% growth. FE 19 continued, "even if Market Access was able to obtain 100% coverage [from insurance companies], it was unrealistic to obtain the kind of growth in Otezla sales that Smith was forecasting for 2017."

132. As FE 19 explained, Otezla's competitors, including Humira and Remicade, were deeply entrenched in the market space, which made it increasingly difficult for the sales team to come anywhere close to Smith's projections. FE 19 stated that in light of physicians' reluctance to prescribe Otezla over well-established competitor drugs, reaching the sales projection was "not going to happen." FE 19 recalled having conversations with Swartz and Claudio Faria, Executive Director and Group Lead of U.S. HEOR, concerning the unrealistic sales projections given what Market Access was reporting to management. According to FE 19, there was no way Smith could

have interpreted what his Market Access team was saying and translated that into 57% sales growth for Otezla in 2017. In other words, Smith ignored the Market Access team's warnings.

133. FE 17 also detailed multiple impediments to Celgene meeting the Company's 2017 Otezla sales guidance, and achieving the publicly-stated 57% year-over-year growth. FE 17 attributed the overall lack of growth in Otezla sales observed throughout 2016 and into 2017 to three main factors: (i) managed care was "underwater" by April 2016; (ii) as early as April 2016, new Otezla prescriptions and patients were down; and (iii) Celgene allowed wholesalers to buy in above their demand in late 2016. With respect to managed care being "underwater," FE 17 explained that when Celgene enters into a new PBM contract that requires Celgene to issue rebates, the Company ends up paying rebates for all existing prescriptions—i.e., the rebates apply both to new prescriptions and existing prescriptions. By virtue of the massive rebates due on the existing prescriptions, the PBM contracts are deemed "underwater" and undermine sales revenues. As early as April 2016, the rebates due on existing Otezla prescriptions covered by these "underwater" contracts were "significant" and amounted to millions of dollars. FE 17 stated that Celgene management should have given a warning to investors in the fourth quarter of 2016 because the IIEC knew about the rebate issue and the impact that it was going to have on the Company's 2017 Otezla revenues. However, no warning was given.

134. Further compounding the adverse effect from the "underwater" managed care contracts in the first quarter of 2017, at the end of 2016, Celgene permitted wholesalers to buy Otezla at reduced prices in excess of their demand. As FE 17 explained, in anticipation of a planned 2017 price increase for Otezla, many wholesalers asked to purchase in December 2016 the quantities of Otezla they were slated to purchase in January 2017, in order to take advantage of the lower price. Celgene could have refused the requests and required the wholesalers to comply

with their contracts to purchase the goods in 2017, but they chose not to do so. This decision, which FE 17 stated was motivated by management's desire to make the fourth quarter 2016 Otezla numbers look great, had a negative impact on the revenues in the first quarter of 2017, and thus Celgene's ability to meet its 2017 Otezla sales guidance.

135. FE 7 likewise confirmed that achieving a 57% increase in Otezla net product sales was "***impossible***" given Celgene's "pay to play" strategy (*see supra* ¶ 100). FE 7, who identified multiple barriers to Otezla's ability to capture market share (*see supra* ¶¶ 99-102), added that "there isn't any way to grow [Otezla] revenue by 57%." FE 7 was very vocal to senior management (i.e., Alles, Smith, Curran) and specifically told them that he did not think Otezla's growth would continue because of the step-edit hurdles and the saturation of competitor drugs in the market. FE 7's warnings, however, were ignored.

136. Consistent with FE 7, FE 8 stated there was no way Celgene could meet the 57% year-over-year growth forecasted as part of the January 2017 Otezla guidance. FE 8 stated that Otezla sales continued to be flat into April 2017 and, as a result, he and his Regional Business Manager were "banging their heads against the wall."

137. The disappointing sales results and other issues rendering the 2017 Otezla guidance unachievable were again communicated to the IIEC in early 2017. However, Defendants again refused to heed the warnings. Specifically, FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that the Company needed to downgrade its 2017 Otezla sales guidance. During this presentation, Smith cut off Tessarolo, stating that he had heard enough of the negative information.

### 6. Defendant Curran and Other Celgene Executives Received Information Showing Declining Sales, Inventory, Demand, and Market Share Metrics Throughout the First Quarter of 2017

138. In an April 27, 2017 conference call with investors discussing Celgene's results for the first quarter of 2017, Curran addressed a question from an analyst for UBS asking that the Company "walk through what gives you confidence [that Otezla] growth will bounce back" from disappointing results in the first quarter of 2017. In response, Curran stated:

> I think there was really 3 key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased [gross to net] as a result of the contracting. But importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw a minimal drawdown in inventory. Importantly, if we look at the underlying dynamics of the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients. And these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter 1 and into quarter 2, we do see the net sales rebounding and on track to deliver our 2017 guidance.

139. As discussed in more detail below, Curran's response contained numerous materially false and misleading claims. As a general matter, her response addressed several specific sales, inventory, demand, and market metrics that comprised the forecast outputs used by Celgene to formulate Otezla's 2017 Budget and the quarterly forecast "Latest Estimates" ("LEs"), and which served as the basis for determining Celgene's public guidance regarding Otezla's net revenue. Those included: (i) the size of the overall PsO and PsA markets (and whether those markets were growing or contracting, according to forecast); (ii) the size and impact of any inventory held by Otezla wholesalers and specialty pharmacies exiting 2016 that may have impacted sales in the first quarter of 2017 and, by extension, Budget and public guidance assumptions through the remainder of the year; (iii) Otezla's total unit sales and net revenue in the first quarter of 2017, and the impact of a sales and net revenue shortfall on the full-year Budget and public guidance; (iv) the performance of Otezla's PBM contracts, including whether those contracts (touted by Curran as

providing access to new patients) actually met Budget assumptions in the first quarter of 2017; and (v) Otezla demand, as determined through unit sales to date and growth assumptions, and whether any of those assumptions changed materially throughout the first quarter of 2017.

140. As set forth herein, Curran knowingly or with reckless disregard for the truth misrepresented the status of the Otezla sales, inventory, demand, and market metrics she discussed in her response to the UBS analyst, and/or otherwise failed to provide complete and accurate information to make her statements not misleading.

141. By as early as October 20, 2016, Curran and other Celgene executives received and discussed information regarding the methodology Celgene used to calculate the 2017 Otezla Budget and subsequent LEs and other internal forecasts. The "outputs" that formed the basis of those broader Celgene forecasts consisted of (1) Units, Gross Revenue, and Net Revenue; (2) Demand & Inventory; and (3) Otezla Market Shares (PsO and PsA), which also relied on assumptions relating to the size and growth of the overall PsO and PsA markets involving other competitors.

142. Throughout the first quarter of 2017, Curran and other senior Celgene executives internally received, discussed, and shared internally presentations and other information showing that the performance of the Otezla business, as assessed through sales, inventory, demand, and market metrics, substantially underperformed the forecasted 2017 Otezla Budget, and that there was no reasonable basis to represent to investors that Celgene would meet its full-year 2017 Otezla public guidance.

143. Specifically, throughout the first quarter of 2017, Curran and other senior Celgene executives received, discussed, and shared internally presentations and other information showing the large amount of Otezla inventory on hand that Celgene had with distributors at the beginning

of the first quarter of 2017, which depressed Otezla sales demand. Curran and senior Celgene executives also received, discussed and shared internally presentations and other information showing multiple declining, or flat, Otezla sales metrics, which ultimately led to a significant downward variance between actual Otezla sales and net revenue and those forecasted in the 2017 Budget. Curran and other Celgene executives further received, discussed, and shared internally presentations and other data showing that there was an overall contraction in the PsO and PsA drug markets, which posed a risk to Otezla's shares of those markets and comprised material risks to Otezla's 2017 net sales and revenue.

144. Early in the first quarter of 2017, Celgene executives recognized that Otezla's sales were disappointing and underperforming the Budget forecast. For example, on January 31, 2017, Mark Kreston, the I&I franchise's Head of Global Marketing, emailed Hunter Smith, the I&I franchise's Vice President of Finance, regarding a regular "Otezla Invoiced Shipments" report, for which Curran and other I&I executives were members of the distribution list. Kreston wrote, "We are lagging big time – any feel for why? Strong December buy-in?" The phrase "December buy-in" referred to larger-than-normal inventory levels that Otezla wholesalers had accumulated at year-end 2016, which equaled approximately 20 days of inventory on hand ("DOH") – well in excess of normal ranges of 10-13 DOH. Hunter Smith responded that "the answer is that we are long past digestion of the December buy-in so the issue is demand."

145. On February 8, 2017, Celgene's Executive Director of Corporate Financial Planning and Analysis, Steven Rosen, emailed Celgene CFO Peter Kellogg with the subject "Revenue Update – US Otezla Q1 QTD." Rosen's email referenced "the discussion at last week's EBR [Executive Business Review] meeting regarding U.S. Otezla trends" and stated that "we wanted to give you a forewarning regarding the ongoing trend which continues to be soft." He

characterized the sales trend as being "significantly below where we would expect," and that "a 73% increase on the average daily sales to date is needed to achieve the Budget." Rosen declared that it would thus "take a very significant uptick to meet the budget."

146. On February 14, 2017, Celgene's Senior Vice President of Finance Jurg Oehen sent an email to Celgene CEO Alles and CFO Kellogg entitled "Q1 trends and forecast considerations." The email, which purported to provide "a brief update on our thoughts on the Q1 trends and the related forecast," stated that "Otezla sales have been very soft so far." Oehen stated that "[t]o make the Q1 forecast, we would need to see a very significant revenue acceleration in the remainder of Q1 (US sales would need to increase by roughly 100% above the levels we have seen until now)." CFO Kellogg responded to Oehen (and included Alles) that it was "important to note that the Street is well ahead of this Budget/forecast for Otezla, so that will be the main issue for Q1, even if we get back to Budget." He remarked further that "we should plan our verbal commentary, and whether there should be some pre-emptive signaling during the Quarter to get the street better aligned." In a subsequent email, Kellogg wrote that "[w]e should start with [Defendant] Scott [Smith], to get his sense of where he feels the business will land in the Quarter. Shipments this week didn't pick up."

147. On February 21, 2017, Curran received an email from Robert Tessarolo that attached a slide presentation "[f]or review in our 9am meeting," which Curran requested to be printed. A slide in that presentation, entitled "Latest Thinking Summary," reduced the total number of forecasted Otezla unit sales for the first quarter of 2017 from 141,776 units (as set forth in the 2017 U.S. Budget) to 117,300 units (a greater than 17% reduction) – while retaining the budgeted forecasted units for the remaining three quarters. The slide reflected I&I's "latest thinking" that Otezla's total unit sales for 2017 would miss the 2017 U.S. Budget forecast by approximately

24,500 units. That same presentation further indicated that I&I's "latest thinking" was that full-year 2017 net revenue would be 1,279.6 million, a $29.6 million downward variance from the 2017 U.S. Budget.

148. On February 24, 2017, Jurg Oehen emailed Hunter Smith and asked him to provide "an updated forecast to Senior Management for discussion." Hunter Smith responded that "Terrie [Curran] has updated numbers and can talk to them," stating that the latest thinking for the Global I&I franchise was "$258 net (-$34 million vs. budget)." Oehen replied to Hunter Smith that "we need more regular automatic updates from I&I and one source of the truth." Oehen thereafter forwarded the email exchange to CFO Kellogg, stating that the "updated forecast seems very ambitious and I have serious doubts on whether we will get there."

149. The Otezla outlook continued to worsen over the next few weeks. In an IIEC meeting on March 7, 2017, Curran received and discussed the I&I franchise's "latest thinking" that Otezla's net revenues would significantly underperform the 2017 U.S. Budget. The presentation proposed that the March 2017 LE be downgraded from the first quarter of 2017 U.S. Budget forecast of $255.7 million to $215.2 million, a reduction of $40.5 million against the U.S. Budget. That same presentation stated that Otezla's EMEA (Europe Middle East Asia) sales were lagging 18% behind the 2017 EMEA Budget for the first quarter of 2017.

150. On March 8, 2017, members of the I&I Finance team prepared a draft slide presentation that included another "Latest Estimate Summary." That summary forecasted a further decrease in units for the first and second quarters of 2017 (down to 116,600 and 152,400, respectively), but increased the units forecasted for the fourth quarter of 2017 – raising the fourth quarter units forecast from 193,052 to 200,900 units. The next day, March 9, 2017, Finance team members prepared and emailed an updated slide deck to Curran, entitled "Q117 LE Review Slides-

post Terrie_Huntermeeting.pptx." The "post Terrie_Huntermeeting" presentation also included an updated "Latest Estimate Summary." That updated version further increased the fourth quarter of 2017 forecasted units (from the presentation the day before) by an additional 8,000 units to 208,800 units – an increase of over 15,000 total units added onto the fourth quarter of 2017 forecast from the 2017 U.S. Budget.

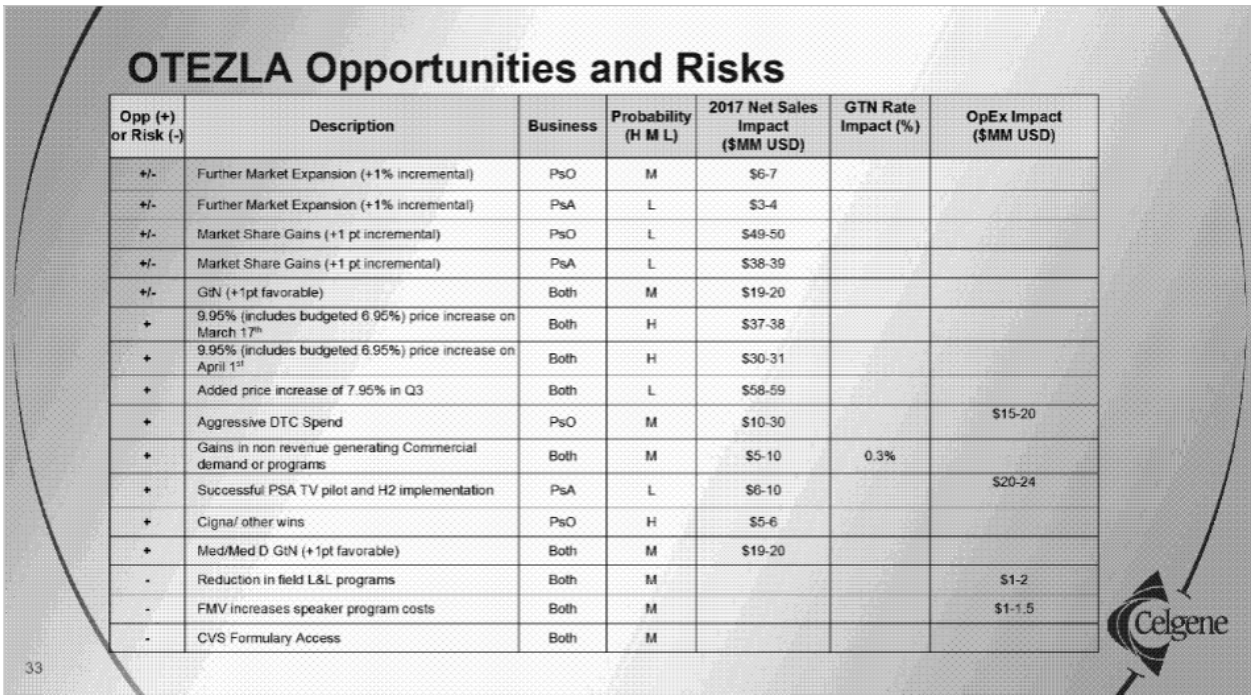
151. Senior Celgene executives, including Curran, and including during the first quarter of 2017, also regularly received updates regarding the overall PsO and PsA markets and Otezla's market shares, which they reviewed in connection with monitoring and assessing Otezla's performance throughout 2017 and in developing the forecast LEs. Through those updates and presentations, Celgene I&I executives, including Curran, learned during the first quarter of 2017 that the overall market for PsA and PsO drugs was contracting. During a presentation to the IIEC on or about March 7, 2017, Celgene executives received and discussed a slide entitled "Market Growth Appears to be Cooling – PsA and PsO." Three days later, on March 10, 2017, Curran emailed Smith, stating: "Interesting. As [I] [ ] look more closely, market growth does seem to be cooling in both segments." That same day, Curran received the "post Terrie_Hunter meeting" presentation, a subsequent version of which she forwarded to Celgene executives in connection with a meeting to discuss Otezla's actual and forecasted 2017 performance. A slide from that presentation, including the version that Curran forwarded to Smith, stated that "Market Growth in both PSO and PSA is cooling," "PsA Market Growth has slowed," and "[g]rowth [was] already decelerating in 2016."

152. On March 15, 2017, Curran emailed a slide presentation from a March 13, 2017 EBR meeting with Celgene executives entitled "Q117 LE Review Slides_TC_Deck march 13 v02.pptx." That presentation referenced a "Q1 shortfall of 25k units vs. Budget." The March 13

"TC-Deck" presentation also included a "Latest Estimate Summary," which assumed a 9.95% price increase for Otezla as of April 1, 2017 – an increase that was 3% higher than the price built into Celgene's 2017 Budget and never adopted by Celgene.

153. Celgene executives, including Curran, received additional information that Otezla would not achieve the net revenue necessary to meet the 2017 U.S. Budget absent a price increase. As Douglas Bressette, Senior Director, Global Business Planning and Analysis for I&I, recognized in an email to a colleague in March 2017, "Without 9.95% price, we were never going to hit the [$]1,309 [billion]"—i.e., Celgene's forecast for 2017 U.S. Otezla sales that was built into the 2017 Budget.

154. The "TC-Deck" also included an "OTEZLA Opportunities and Risks" slide, which quantified the "2017 Net Sales Impact" based on a variety of opportunities and risks, including market expansion (or contraction), market share gains (or losses), and price. As shown below, the presentation quantified the risk of an overall market contraction at approximately $6-7 million per each percentage point contraction in the PsO market and $3-4 million per each percentage point contraction in the PsA market. The presentation further quantified the risk of decreased Otezla market share at approximately $49-50 million per each percentage point reduction in Otezla's market share of the PsO market and at approximately $38-39 million per each percentage point reduction in Otezla's market share of the PsA market:



## OTEZLA Opportunities and Risks

| Opp (+) or Risk (-) | Description | Business | Probability (H M L) | 2017 Net Sales Impact ($MM USD) | GTN Rate Impact (%) | OpEx Impact ($MM USD) |
|---|---|---|---|---|---|---|
| +/- | Further Market Expansion (+1% incremental) | PsO | M | $6-7 | | |
| +/- | Further Market Expansion (+1% incremental) | PsA | L | $3-4 | | |
| +/- | Market Share Gains (+1 pt incremental) | PsO | L | $49-50 | | |
| +/- | Market Share Gains (+1 pt incremental) | PsA | L | $38-39 | | |
| +/- | GtN (+1pt favorable) | Both | M | $19-20 | | |
| + | 9.95% (includes budgeted 6.95%) price increase on March 17th | Both | H | $37-38 | | |
| + | 9.95% (includes budgeted 6.95%) price increase on April 1st | Both | H | $30-31 | | |
| + | Added price increase of 7.95% in Q3 | Both | L | $58-59 | | |
| + | Aggressive DTC Spend | PsO | M | $10-30 | | $15-20 |
| + | Gains in non revenue generating Commercial demand or programs | Both | M | $5-10 | 0.3% | |
| + | Successful PSA TV pilot and H2 implementation | PsA | L | $6-10 | | $20-24 |
| + | Cigna/ other wins | PsO | H | $5-6 | | |
| + | Med/Med D GtN (+1pt favorable) | Both | M | $19-20 | | |
| - | Reduction in field L&L programs | Both | M | | | $1-2 |
| - | FMV increases speaker program costs | Both | M | | | $1-1.5 |
| - | CVS Formulary Access | Both | M | | | |

33

Celgene

155. On March 23, 2017, CEO Alles's Chief of Staff sent an email to Smith and Curran with the subject "Monday's EBR Meeting," writing: "At Monday's EBR meeting, in addition to an LE update, we would like to discuss Otezla sales/market trends, etc." Curran forwarded the email to Hunter Smith and other I&I executives. Hunter Smith thereafter referenced a conversation he had with Scott Smith, stating: "Based on conversations w Scott yesterday, I think it's key to understand both volume and price sensitivity of the full year LE."

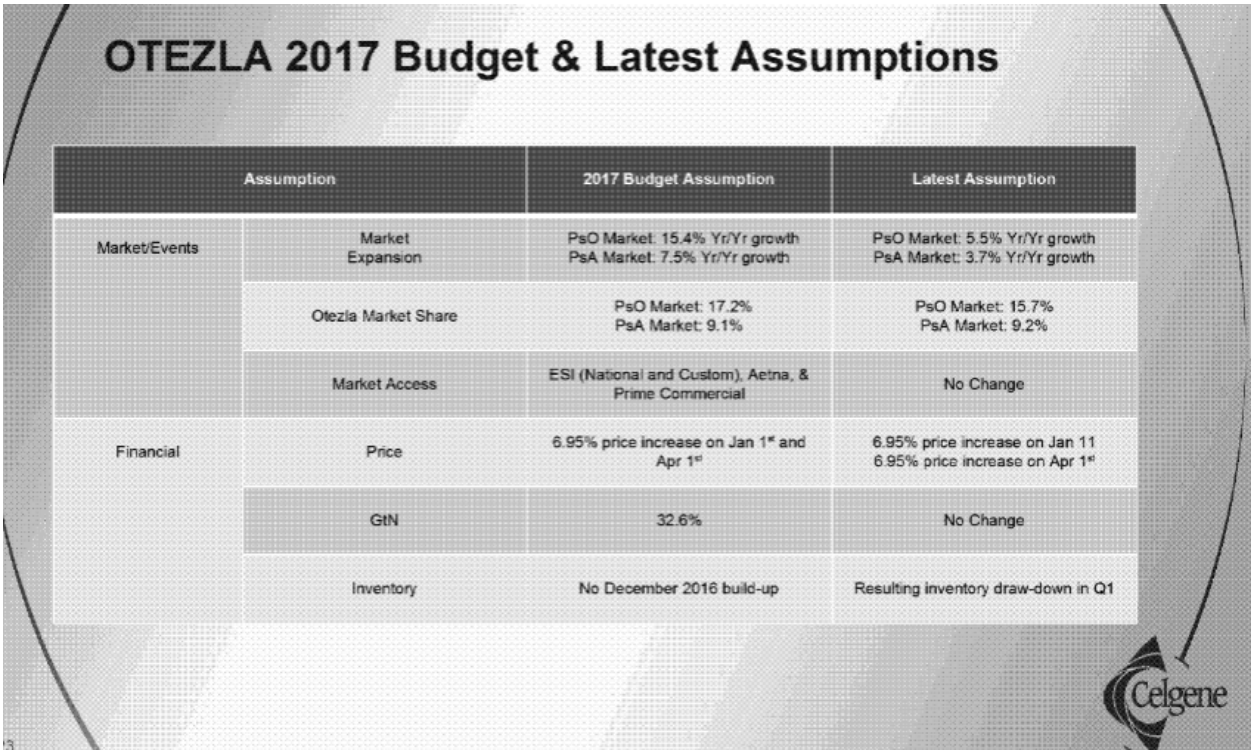
156. Later that day, I&I Finance executives exchanged several emails regarding the unit sales run rate out of the first quarter of 2017 and whether the run rate could support achieving the second quarter of 2017 Budget. Those emails showed that I&I Finance executives first determined the amount of weekly sales necessary to achieve the March 2017 LE – and then calculated the growth rate that would be necessary to support it. For example, on the morning of March 23, 2017, Douglas Bressette sent an email to other I&I Finance executives noting that the "Q2 LE is $308M. How much unit growth is necessary for each scenario to get to the $308M." Later that afternoon, Bressette emailed Hunter Smith with the title "Q1 Run rate build to Q2." Bressette explained that

he had "modeled the units needed each week to hit forecast. I then modeled revenues based on different price assumpts. Last column to the right is the number of additional unit[s] needed to hit Q2 revenue LE at each price." The attached spreadsheet showed that Bressette had not relied upon any of the forecast methodologies underlying the 2017 Budget to forecast unit sales; rather, he simply created a basic mathematical formula to calculate the necessary week/week growth rate to satisfy the pre-established March 2017 LE units forecast.

157. On March 27, 2017, Curran received an email with an attachment entitled "EBR SLIDES for Terrie March 27, 2017," referencing an EBR meeting that same day with Celgene executives. The presentation set the March 2017 LE at $201 million for U.S. net revenue, a reduction of approximately $55 million from the first quarter of 2017 Budget; and at $43 million for Rest of World (ROW) net revenue, a reduction of approximately $7 million from the first quarter of 2017 Budget – for a total reduction of $62 million from the 2017 Global Otezla Budget, or 25%. The presentation acknowledged that "[i]nventory adjustment" was one of the leading factors "driving Q1 weakness."

158. The March 27 EBR presentation also referenced the overall PsO and PsA market, stating that overall PsO and PsA market prescription "Volumes Show Consistent Weakness in Q1." One slide provided to Curran prior to that presentation set forth I&I's latest assumptions regarding the overall PsO and PsA markets, which showed a significant downward variance from the original 2017 Budget. As depicted below, the slide assumed that, rather than the 15.45% year-over-year PsO market growth rate that Celgene had incorporated into the 2017 Budget, the PsO Market would experience the far lower growth rate of only 5.5% year-over-year. The slide further assumed that the PsA market would contract from the 7.5% year-over-year growth rate built into the 2017 Budget down to only 3.7% year-over-year growth. And it assumed that Otezla's PsO

market share would decrease by approximately 1.5% from the assumption built into the 2017 Budget.



OTEZLA 2017 Budget & Latest Assumptions

| Assumption | | 2017 Budget Assumption | Latest Assumption |
|---|---|---|---|
| Market/Events | Market Expansion | PsO Market: 15.4% Yr/Yr growth<br>PsA Market: 7.5% Yr/Yr growth | PsO Market: 5.5% Yr/Yr growth<br>PsA Market: 3.7% Yr/Yr growth |
| | Otezla Market Share | PsO Market: 17.2%<br>PsA Market: 9.1% | PsO Market: 15.7%<br>PsA Market: 9.2% |
| | Market Access | ESI (National and Custom), Aetna, & Prime Commercial | No Change |
| Financial | Price | 6.95% price increase on Jan 1st and Apr 1st | 6.95% price increase on Jan 11<br>6.95% price increase on Apr 1st |
| | GtN | 32.6% | No Change |
| | Inventory | No December 2016 build-up | Resulting inventory draw-down in Q1 |

Celgene

159. Altogether, the 9.9% contraction in the PsO market growth rate, the 3.8% contraction in the PsA market growth rate, and the 1.5% decline in Otezla's expected PsO market share reflected an approximately $140 million risk to the 2017 Budget and the Company's public guidance based on I&I's self-established "Opportunities and Risks" assessment.

160. Curran and other Celgene executives also recognized that the Company's Board of Directors could view negatively the existence of a "flat" Otezla market share. For example, in response to a draft slide deck that Curran received for an upcoming Board of Directors meeting in April 2017, Curran wrote on April 14, 2017, "Just met re Q1 and Bod messaging…Feedback re BOD deck – don't like market share as it looks flat."

161. Otezla sales in April 2017 did not increase at a level to make up the substantial first quarter 2017 shortfall. After receiving a copy of the April 10, 2017 Daily Sales Report on April

11, 2017, Oehen forwarded it to Rosen, commenting, "Otezla is on track to … again miss the forecast." Nor did sales improve appreciably the next week, either. On April 18, 2017, Rosen forwarded the Daily Sales Report to Oehen, writing, "Another challenging Monday for Otezla." He stated that "we are falling further behind every Monday." Oehen replied, "Indeed very disappointing sales and hard to belie[ve] that they will get close to their Q2 forecast."

162. During an internal presentation to Celgene executives on April 24, 2017, Curran confirmed that Otezla's market share was not growing in either the PsO or PsA markets through a slide that read "Q1 Otezla market shares relatively flat in both PsO and PsA."

163. Two days later, on April 26, 2017, Curran and other Celgene executives received a presentation with Otezla U.S. Performance data showing that Otezla's actual net revenue was only 83% of the 2017 U.S. Budget for the year-to-date. The presentation further confirmed that April sales were at the level forecast originally in the 2017 Budget, and that they thus had not made up any ground from the 27,000 sales unit shortfall in the first quarter of 2017. In addition, Otezla's new prescription ("NRx") metric was negative for the 4-week/4-week period and was -2.02% below NRx growth year/year. The presentation also indicated that the overall market had contracted, with declines of approximately 4% in the PsO market over the 4-week market volume metric and approximately 3% in the PsA market over the 4-week market volume metric.

164. In addition, Celgene executives had also internally recognized that, given the "pay-to-play" rebates that Celgene was offering, and providing, to PBMs, Celgene's achievement of the 2017 Otezla Budget was dependent on significantly increasing Otezla's market share. For example, on September 16, 2016, Tessarolo wrote to Smith and Curran, and Hunter Smith, that achieving even an Otezla sales "neutral" scenario in 2017 "will require us to drive significantly more demand in these plans in 2017," and that "[f]ailing to deliver an inflection in market share

would risk performing to our currently submitted 2017 Budget." But internal Celgene data in the first quarter of 2017 showed that Otezla's share of the market it accessed through managed care contracts with each of the critical PBMs – Aetna, ExpressScripts ("ESI"), and Prime – tracked lower than budgeted and forecasted over the first half of 2017. In the first quarter of 2017, total prescription volume for each of the three PBMs underperformed the forecasted amount built into the 2017 Budget; and ESI and Prime each underperformed Otezla's within-plan forecasted market share comprised of an eight-drug market basket.

165. Thus, as of April 27, 2017, Curran and other Celgene executives received, discussed, and shared internally presentations and other information and data showing that the forecast outputs that formed the basis of the 2017 Budget and March 2017 LE – which were used to determine the Company's public guidance – had significantly underperformed, that Curran's April 27, 2017 claims to the contrary regarding specific Otezla metrics were knowingly or recklessly false when made, and that there was no reasonable basis to believe that Otezla's 2017 net revenue would achieve the Company's public guidance.

166. Otezla's total sales units, gross revenue, and net revenue far underperformed the 2017 Budget forecast for the first quarter of 2017, and April sales, which were flat as against the 2017 Budget forecast, did not make up any ground from the unexpected sales miss in the first quarter.

167. Otezla's inventory exceeded 20 DOH at year-end 2016, which was well-above normal levels, and Curran and other executives learned and discussed that "inventory adjustment" was one of the key factors "driving Q1 weaknesses." Otezla's NRx demand metric was also negative and trending downward.

168. The overall PsO and PsA markets contracted in the first quarter of 2017, and internal assessments, shared with and discussed by Curran and other Celgene executives, recognized that

the PsO and PsA markets would continue to contract well below 2017 Budget forecast assumptions and through year-end. Otezla's market share was flat to declining in both the PsO and PsA segments in the first quarter of 2017 through April, and Curran and other Celgene executives received and discussed information acknowledging that Otezla's share of the PsO market would decline by over 1.5% from 2017 Budget forecast assumptions through year-end. These market-based assumptions alone equaled approximately $140 million in net revenue risks, as reflected in presentations and assessments received and discussed by Curran and other Celgene executives throughout the first quarter of 2017.

**7. Despite Continued Headwinds and Recognized Impediments, Defendants Reaffirm the Aggressive 2017 Guidance**

169. On April 27, 2017, Defendants announced that Celgene's Otezla net product sales for the first quarter of 2017 fell short of the Company's expectations, with just a 14% year-over-year increase and a 1% sequential decline from the fourth quarter of 2016. Rather than disclose the true cause of the decline in sales, Celgene ***reaffirmed*** the forecasted 57% year-over-year growth for Otezla sales, stating that the "Updated 2017 Guidance" for Otezla was "Unchanged."

170. During the April 27, 2017 first quarter conference call, Kellogg represented that "sequential performance from Q4 to Q1 is always impacted by several items . . . Otezla is impacted by managed care dynamics that drive lower total marketplace prescriptions for psoriasis therapies in Q1." Kellogg also tried to excuse the poor first quarter results by citing to the "higher gross-to-net adjustment related to new contracts with several large payers that were implemented in January," reassuring investors that the new PBM contracts and elimination of step-edits would improve market access, and by extension, Otezla net product sales for 2017: "These new contracts approximately doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy, which has already improved OTEZLA's market share

in these accounts." Smith further claimed that "[w]e initiated a number of activities that will expand the addressable population for OTEZLA worldwide, laying the groundwork for a highly successful year ahead," stating that "[w]e can see that early gains are already evident after only 1 quarter from this contracting strategy."

171. When asked by an analyst that the Company "walk through what gives you confidence [that Otezla] growth will bounce back," Curran claimed—contrary to all data and other information received and discussed by herself and other Celgene executives—that there was only "a minimal drawdown in inventory." Curran further characterized the "underlying dynamics of the business" as "exceptionally strong," when, as discussed above, the key forecast outputs had either underperformed or had been flat, and where she and other Celgene executives had been warned that the Budget forecast, which formed the basis of the Company's public guidance, was unattainable.

172. Curran further falsely claimed on April 27, 2017 that "OTEZLA continues to grow market share," when, in fact, and undisclosed to investors: (1) Otezla's market share remained relatively flat throughout the first quarter of 2017; (2) Otezla's PsO market share actually declined within a particular six-drug market basket used by Celgene to assess Otezla's performance; and (3) internal presentations and information received and discussed by Curran and other executives recognized that Otezla's market share would underperform 2017 Budget estimates, creating a significant and material risk (as quantified in internal presentations) to Otezla's ability to meet the 2017 Budget and the public guidance.

173. Curran further provided incomplete and materially false and misleading information regarding the level that the PsO and PsA markets had contracted in the first quarter of 2017, and she failed to disclose that Celgene internal presentations received and discussed by Curran and

other executives recognized that Celgene had substantially overestimated the level of growth in the PsO and PsA markets in creating the 2017 Budget, which created a significant and material risk (as quantified in internal presentations) to Otezla's ability to meet the 2017 Budget and the public guidance.

174. On the April 27, 2017 call, Curran also referenced the new PBM contracts that would give Celgene "access to an additional pool of patients moving forward," yet she omitted and failed to disclose that each of those PBM contracts underperformed forecasted unit sales, and that two of the PBM contracts (ESI and Prime) underperformed their forecasted within-plan market shares.

175. In addition, Curran referenced "exit run rates out of quarter 1 and into quarter 2," but she omitted and otherwise failed to disclose how badly unit sales underperformed in the first quarter of 2017 (by over 27,000 units), how that poor performance caused Celgene to downgrade unit sales estimates in the second quarter of 2017, and how Curran and other Celgene executives added 15,000 of those missed forecasted units onto the fourth quarter of 2017 absent any reasonable basis to do so given Otezla sales, inventory, demand, and market metrics to date.

176. Given Curran's multiple false and misleading statements, she had no reasonable basis to misrepresent to investors that "we do see the net sales rebounding and on track to deliver our 2017 guidance."

177. In truth, Defendants had no reasonable basis for representing that new PBM contracts and the removal of step-edits would improve Otezla sales and help the Company hit its 2017 guidance. As detailed below by multiple former employees, the removal of step-edits and the newly negotiated contracts with the insurance companies and PBMs did not offset Otezla's struggling sales in light of the myriad other issues depressing the sales numbers and, thus, would not suffice to make up the significant gap in sales.

**(a) Removal of step-edits was not a panacea for Otezla's lackluster sales**

178. Defendants acknowledged internally that Celgene needed a corresponding increase in Otezla sales to counterbalance the increased expenses and lower margins associated with the new contracts to remove the step-edits imposed by the insurance companies. According to FE 12, after Celgene spent a lot of money for "payer wins" (i.e., the removal of step-edits and other requirements by insurance companies), there was a push from corporate and District Managers to increase the sales volume to offset the higher expenditures and lower margins. As discussed above, however, a laundry list of additional issues, including the lack of efficacy and increased competition, continued to negatively impact Otezla sales (*see supra* § IV.B.2) despite the increased removal of step-edits by insurance companies. As FE 9 confirmed, even if Celgene managed to remove the step-edits, it would not solve the sales issues for Otezla because, among other things, physicians had been working with competitor drugs for many years and it was easier for them to prescribe medications they were used to and knew worked well.

179. During meetings in November or December of 2016 with Defendant Curran, Tessarolo, Swartz, Grausso, Willcox, and Ronald Owen ("Owen"), National Sales Director, FE 7 continued to warn these executives that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges.

180. FE 7 indicated that while Celgene did remove some step-edits for Otezla in 2017, Celgene's leadership had previously made decisions that hampered Otezla's market access and destroyed its "best price" beginning as early as the 2014 launch (*see supra* ¶¶ 95-99). In addition, not all payers agreed to remove step-edits, including United, Aetna, Cigna and Blue Cross Blue Shield. Furthermore, FE 7 stated that even if 10 million individuals obtained access to Otezla through the removal of step-edits, not all of them would actually buy Otezla. In short, the removal

of the step-edits was too little too late, and could not spur on Otezla sales enough to close the widening gap between the actual Otezla sales and the Company's knowingly unreasonable 2017 guidance.

**(b) Many of the new PBM contracts were "downgraded" in 2017**

181. Unbeknownst to investors, Defendants' April 27, 2017 representation that the newly-entered PBM contracts would help drive the Company's 2017 Otezla sales was undermined by the fact that many of the PBM contracts took several months to generate revenues and, as a result, the Company reduced the revenue expectations associated with these contracts.

182. Specifically, FE 18 stated that several of the new PBM contracts Celgene entered into in 2017 covered patients who were receiving their Otezla prescriptions for free or at a reduced cost through various forms of patient assistance and other initiatives, such that Celgene was earning only minimal revenues related to these patients' prescriptions. Even after the new PBM contracts became effective, these patients continued to receive their Otezla prescriptions at little to no cost until their prior entitlements expired, at which point they were brought under the new reimbursement scheme. FE 18 explained that it was not until this process was complete—which could take one or two years—that Celgene started to earn revenues on these prescriptions. In other words, just because new PBM contracts went into effect in 2017, Celgene did not see increased revenues from prescriptions for many covered patients until months later.

183. FE 18 said that his Market Access team worked closely with the pricing team to assess how the new PBM contracts were performing throughout 2017. FE 18 stated that it was clear from the beginning of 2017, based on the models that his team was running monthly, that the PBM contracts were not meeting revenue expectations. FE 18 communicated the fact that the contracts were underperforming to his boss, Swartz, and he understood that she reported this information to the CPMAC. According to FE 18, Celgene did not lower expectations for the PBM contracts even

when presented with data showing that the contracts were underperforming; by contrast, when his team presented data showing that some contracts were outperforming, Celgene quickly raised the revenue expectations for those contracts.

184. Celgene eventually internally lowered the expectations on many of these PBM contracts. FE 18 recalled seeing a bar graph that depicted the original expectations, the actual numbers, and a revised, lowered expectation. The original expectation was "through the roof." While the revised expectations were closer to the current performance, this was after they had been significantly lowered—by amounts that "took [him] aback." Rather than communicate this to investors, Defendants left the market with the false impression that the new PBM contracts would help drive Otezla's 2017 sales.

#### 8. The Psoriasis and Psoriatic Arthritis Markets Continued to Contract in the Second Quarter, and Neither Otezla's Market Share Nor Prescriber Adoption of Otezla "Increased Significantly," as Curran Falsely Misrepresented to Investors

185. On July 27, 2017, during Celgene's second quarter of 2017 earnings conference call, Curran knowingly or with reckless disregard for the truth, falsely communicated to Celgene investors that "Q2 was an outstanding quarter of Celgene I&I, highlighted by significant sequential growth for OTEZLA. Key OTEZLA performance indicators continue to strengthen, and market share and prescriber adoption increased significantly in both U.S. and internationally." To the contrary, as discussed in detail below, neither Otezla's market share nor prescriber adoption of Otezla "increased significantly," as Curran falsely misrepresented to investors.

186. As in the first quarter of 2017, Otezla's market share did not experience any meaningful or sustained growth in the second quarter of 2017. Curran internally recognized that Otezla had not increased its market share in the second quarter of 2017, as she wrote in an email on July 25, 2017, that Otezla's market share was "flat" over the quarter. In response, I&I Senior

Director of Global Business Planning and Analysis Doug Bressette confirmed that Otezla's market share was "relatively flat." In a separate email to Celgene executives later that same day, Curran again wrote that "Overall Otezla's demand growth v. Q1 on relatively flat market share generally tracked the systemic/biologic market basket growth over the same period."

187. Those internal conclusions by Curran regarding the "flat" Otezla market share were consistent with information that she and other Celgene executives received and discussed throughout the second quarter of 2017. For example, a May 22, 2017 presentation (including underlying data that was attached to, and incorporated into the slide deck itself) provided to Curran and other Celgene executives in advance of an EBR meeting showed that Otezla's PsO market share had declined from year-end 2016 through the end of the first quarter and into April 2017. Similarly, a slide prepared as of June 12, 2017, in advance of a June 2017 meeting with Celgene executives, including Curran, stated that "Market TRx volumes in April and May (MTD) indicate PsO/PsA market is flat."

188. In fact, Otezla's shares in the PsO and PsA markets were not just "flat"; they decreased over the second quarter of 2017 under internal metrics used by Celgene to assess Otezla's market share. Otezla performance slides, received by Curran and other Celgene executives on April 20, 2017, and July 19, 2017, respectively, showed that the PsO 4-week market share metric (which included seven competitors, including Otezla) fell from 18.1% to 17.1% between March 31, 2017 and June 30, 2017. Similarly, those same performance slides, also received by Curran and other executives on April 20, 2017, and July 19, 2017, respectively, showed that the PsA 4-week market share metric (which included seven competitors, including Otezla) dropped from 7.8% to 6.9% between March 31, 2017 and June 30, 2017.

189. On July 24, 2017, Curran's assistant emailed a copy of "Terrie's slides" in connection with Celgene's upcoming earnings call on July 27, 2017, which "reflect[ed] edits from today's prep session." A graphic in Curran's presentation depicted Otezla's overall PsO market share on a month-to-month basis in the United States. Although that graphic did not quantify Otezla market share by specific percentages, the underlying data for the graphic (which was attached to, and incorporated into, the slide deck itself) demonstrated that Otezla's overall market share for a six-drug market basket decreased over the second quarter of 2017, from 22.5% as of March 31, 2017, to 21.7% on June 30, 2017.

190. On July 26, 2017, Curran received feedback and suggested edits on a draft script that she had prepared in connection with her remarks and accompanying presentation at Celgene's July 27, 2017 earnings conference call for the second quarter of 2017. One of the edits, from CEO Alles's Chief of Staff, changed the meaning of Curran's presentation in a way that was directly contrary to what Curran knew to be the truth. Specifically, Alles's Chief of Staff suggested, contrary to internal Otezla data and Curran's own characterization of second quarter market share as "flat," that Curran should instead describe Otezla's performance in the second quarter of 2017 in the following terms: "Key OTEZLA performance indicators continue to strengthen and market share and prescriber adoption increased significantly in both the U.S. and internationally."

191. As set forth above, Curran had received information over the quarter consistently demonstrating that Otezla's market share was not growing. Despite being aware of those facts, Curran knowingly, or with reckless disregard for the truth, accepted the edits proposed by Alles's Chief of Staff that misstated the true state of Otezla's market share. Then, on July 27, 2017, during Celgene's second quarter of 2017 earnings conference call, Curran knowingly, or with reckless disregard for the truth, falsely communicated to Celgene investors that "Q2 was an outstanding

quarter of Celgene I&I, highlighted by significant sequential growth for OTEZLA. Key OTEZLA performance indicators continue to strengthen, and market share and prescriber adoption increased significantly in both U.S. and internationally."

192. Consistent with Otezla's poor performance throughout the month of July, Otezla's financial metrics continued to worsen throughout the third quarter of 2017. A September 8, 2017 presentation forwarded from I&I executives to Celgene's Finance Department and entitled "2017-2018 Executive Business Review.pptx," listed the "Latest Assumptive Scenario" for U.S. Otezla sales at a full-year "Run Rate" of $1.094 billion, which was well below the $1.309 billion forecast for U.S. net sales built into the 2017 Budget. The September "Current Forecast" (at $1.12 billion) and "Upside" (at $1,145 billion) also trailed the June latest forecast and 2017 Budget significantly.

193. In September 2017, Celgene's Finance Department asked several specific questions of the I&I franchise about Otezla performance metrics to date. In a September 11, 2017 email response to a list of items, Curran again internally recognized that Otezla's "[o]verall national market share [was] running flat vs increase forecasted in 2017." Curran noted multiple factors contributing to the flat growth in 2017, including that new entrants had entered the market (which the 2017 Budget had not adequately accounted for), "[m]arket growth [is] slowing more than expected," and the managed care plans on which Defendants relied to drive uptake—and which Celgene had entered into substantially more expensive contracts in late 2016 in order to increase market access—were "having lower & slower uptake than forecasted."

### 9. Other Key Performance Indicators Also Showed Declining Otezla Performance Throughout the Second Quarter of 2017

194. As in the first quarter of 2017, other key Otezla performance indicators declined throughout the second quarter of 2017. As set forth herein, Curran received information over the

second quarter of 2017 demonstrating that multiple Otezla performance indicators underperformed in the second quarter of 2017 as against the 2017 Budget.

195. As in the first quarter of 2017, Otezla's net revenues also underperformed Celgene's 2017 Budget in the second quarter of 2017 (by $7 million). U.S. Otezla sales also had a negative variance of over 6,000 total unit sales from the 2017 Budget in the second quarter of 2017. In addition, as depicted in a slide contained within a July 19, 2017 presentation received by Curran and other Celgene executives, Otezla's rate of new patient growth decreased throughout the second quarter of 2017. Otezla's market share of New-to-Brand patients, as also expressed in presentations and internal Company data throughout the quarter, as well as in a presentation received by Curran and other Celgene executives on June 26, 2017, also remained relatively flat over the quarter. A presentation dated July 31, 2017, entitled "Otezla LE Update Q3-Q4 2017," further showed a decrease in the "New Patients by Month End" through June 30, 2017. Confirming the disappointing results for the first half of 2017, Ronald Owen, Celgene's Executive Vice President of National Sales stated in an email to fellow sales professionals on June 27, 2017 that "We just didn't get it done against goal the first half – scripts and revenue."

196. Throughout at least the second quarter of 2017, Curran and other Celgene executives also received information regarding the negative impact that two new-to-market competing drugs, Cosentyx and Taltz, were having on Otezla sales. Celgene had built into its 2017 Budget the forecast assumption that the launch of Taltz, an IL17 inhibitor, would have "no impact to Otezla" and that Taltz's "share gains" would come "mostly from biologics" rather than from Otezla (a non-biologic). However, a May 9, 2017 presentation, received by Curran, stated, "After the launch of IL17s, Otezla's new patients [sic] growth is down in Q1 2017 compared to Q1 2016." An accompanying slide depicted Otezla's "New to Product TRx" as having decreased by 2,099 total

prescriptions, or 12%, over the period of December 30, 2016 through April 7, 2017. In contrast, the two new IL17 inhibitors, Cosentyx and Taltz, grew by 97% and 35%, respectively, over the same period.

197. That same presentation, received by Curran and other I&I executives on May 9, 2017, also contained slides referring to an Awareness, Trial, and Usage ("ATU") study conducted by a third-party to measure patient and physician satisfaction regarding Otezla. The study concluded that "Fewer than half of [dermatologists] are confident that patients will be satisfied with Otezla, putting it well below all other therapies but MTX [methotrexate]." According to that presentation, Otezla ranked the lowest of all of its competitors in the same market basket for PsO and PsA.

198. The May ATU study results regarding Otezla's efficacy as against its competitors were consistent with those prepared by governmental agencies in Canada (CDEC) and the United Kingdom (NICE), as well as by an American independent research organization (ICER). An October 27, 2016 CDEC Report—received by Curran on the same date—approved Otezla, but with multiple, stringent conditions, finding that the drug "appears to be associated with lower efficacy" than its competitors. A November 2016 NICE Report similarly found Otezla to be "less effective" than its competitors with the "lowest" probability of response to treatment. The NICE approved Otezla for the treatment of PsO (and for PsA in February 2017, in a report received by Curran on February 22, 2017), but only under limited circumstances. And a December 2, 2016 ICER Report found that Otezla "had the lowest relative effectiveness" across all possible treatment outcomes and determined further that Otezla was either "comparable or inferior" (C-), or "negative," as compared to its competitors. The ICER Report also included the results of a vote of its public advisory council on several issues covered by the Report, which had voted

unanimously (14-0) that the net health benefits of Otezla were not as favorable as those provided by its competitors.

199. In addition, as stated in internal reports and communications that Curran and other senior Celgene executives received, discussed, and circulated, all three of the critical PBMs, Aetna, ESI, and Prime underperformed their forecasted amount both in terms of total prescription volume and Otezla's within-plan market share of an eight-drug market basket.

200. In an email dated July 26, 2017, Ronald Owen informed sales personnel that Celgene entered the third quarter of 2017 requiring sales and prescriptions to "dramatically increase" given the "flat lined" prescriptions to date.

201. There was, however, no dramatic increase in sales in the third quarter of 2017. In fact, sales through the first few weeks in July were dismal as compared to the prior quarter, which itself had failed to meet the 2017 Budget and subsequent forecasts.

202. Otezla U.S. Performance slides dated July 19, 2017, which Curran received that day, depicted declining growth metrics in new and total Otezla prescriptions and average net sales trends. Otezla experienced a net revenue decrease of 10.6% over the preceding 6-week-over-6-week period. The full-year run rate for U.S. Otezla net sales was estimated at $1.078 billion, which was approximately $300 million less than the 2017 Budget. The slide deck showed that Otezla sales were tracking at approximately 84% to the June forecast latest estimate, and approximately 82% to the 2017 Budget—a figure that was virtually identical to the April 26, 2017 presentation received by Curran a day before her false and misleading statement on April 27, 2017, which represented that Otezla's net revenue was approximately 83% to the 2017 Budget. Thus, between Curran's public statements on April 27 and July 27, 2017, there were no positive changes to

Otezla's sales outlook—Otezla sales consistently tracked well below the 2017 Budget, which was the basis for the Company's public guidance.

203. Moreover, as in 2016, in 2017, Celgene achieved higher-than-usual weekly Otezla sales in the week preceding July 4, 2017. In 2016, Celgene accounted for pre-July 4 sales in the third quarter. But in 2017, Celgene recognized the pre-July 4 Otezla sales in the second quarter. Yet, even incorporating those pre-July 4 Otezla sales into the second quarter of 2017, Otezla underperformed Celgene's 2017 Budget forecast in the second quarter of 2017. In fact, on July 19, 2017, Curran and other Celgene executives received slide presentations, including the presentation referenced in ¶ 202, which included sales trends with a disclaimer stating that "[t]he peaks and valleys in recent weeks represent fluctuations around holidays," including two holidays in the second quarter of 2017: Memorial Day and July 4th. The fluctuation in sales around July 4th and the week thereafter was so pronounced that the two weeks (one in the second quarter of 2017 and one in the third quarter of 2017) were averaged together for purposes of quantifying week-over-week growth—which still remained negative over a 6-week-over-6-week period at the end of July 2017. Thus, Celgene executives, including Curran, further knew, or were reckless in not knowing, that without the pre-July 4 sales in the poorly-performing third quarter of 2017, Otezla sales would fall far short of the 2017 Budget and the June latest forecast estimate, and, thus, that Otezla would not achieve its public guidance.

204. Moreover, Curran received weekly wholesaler inventory reports, which showed that Celgene exited June 2017 with suppliers holding an abnormally high Otezla inventory, measured by the "days on hand" (DOH) metric (representing the number of days' worth of Otezla that the wholesalers held at a given point in time). As referenced in ¶ 157 above, Defendants, including Curran, had received internal communications and presentations in the first quarter of 2017

discussing that "inventory adjustment" was one of the key factors "driving Q1 weakness." Curran and other Celgene executives thus knew, or were reckless in not knowing, that given the higher levels of inventory exiting the underperforming second quarter of 2017 into the third quarter of 2017, there was no reasonable basis to maintain the third quarter of 2017 Otezla forecast and the Company's public year-end guidance.

205. Celgene's global "Daily Sales Reports" further demonstrated the Company's inability to meet its 2017 Otezla Budget and forecasts. Each day, global finance personnel circulated broadly an internal Daily Sales Report that included, on a drug-by-drug basis, (1) sales data providing month-to-date, quarter-to-date and year-to-date sales, and (2) a percentage comparison of those sales figures to the Company's latest forecast estimate.

206. The July 27, 2017 Otezla Daily Sales Report, with data through July 26, 2017, showed that Otezla sales were lagging significantly in July 2017 and were far behind the June 2017 forecast LE for the third quarter of 2017 and the full year. Although 86% of the selling days in July had elapsed to that date, Otezla sales had achieved only 53% of the June forecast LE for July 2017. Through 29% of the Otezla selling days for the third quarter of 2017, Otezla sales achieved only 18% of the June forecast LE for the third quarter. And with 57% of selling dates having elapsed in the year to date, Otezla sales achieved only at 44% of the June LE for full-year 2017.

207. Despite all of this information, which Curran possessed, she accepted and provided false and misleading remarks to investors that "Key OTEZLA performance indicators continue to strengthen" in the second quarter of 2017.

### 10. Defendants Slash Otezla and I&I Guidance, Blaming Market-Wide Effects

208. It was not until the end of the third quarter of 2017 that Celgene finally admitted to investors what Defendants had known for years—the 2017 Otezla guidance could not be achieved.

On October 26, 2017, Celgene stunned the market by announcing that, in light of the dismal Otezla sales numbers, the Company had slashed the 2017 guidance by more than $250 million—providing updated guidance of $1.25 billion compared to the $1.5 billion to $1.7 billion range Defendants reaffirmed just weeks earlier. Defendants also revised the 2020 I&I guidance down from over $4 billion to between $2.6 billion and $2.8 billion, due to the grim Otezla sales.

209. During the third quarter 2017 conference call that day, Defendants tried to blame the dramatic reduction of the Otezla guidance on slowing growth across the dermatology market and other market-wide challenges. Alles claimed: "[O]ur 2017 forecast assumptions did not adequately anticipate the deep and persistent slowing growth of the psoriatic arthritis and psoriasis markets, especially during the entire third quarter. When combined with the discounts tied to the execution of our ongoing managed-care contracting strategy, we missed our third quarter OTEZLA sales target." Kellogg similarly attributed the reduction in the Otezla guidance to the "market-wide challenges in the U.S. dermatology market," and Curran cited the "market deceleration" and characterized the Otezla market as "increasingly dynamic and competitive."

210. Curran further explained that Otezla's global net sales were only $308 million for the quarter—which was approximately $100 million below the 2017 Budget. Curran also acknowledged that Celgene missed its optimistic budget assumptions for Otezla, stating that Otezla instead experienced "lower-than-expected revenue due to market deceleration, increase in gross-to-net discounts to drive biologic step free access and inventory fluctuation." In addition, Curran stated that Otezla's market share "has been somewhat impacted in patients previously exposed to biologics." Pointedly, Curran did not reference Otezla's underperforming market and market share assumptions, nor did she characterize Otezla's market share as increasing; rather, she claimed that Otezla was able to "maintain" market share over the quarter.

211. Curran also stated that "declined script volume became more prominent" in the third quarter of 2017. According to Curran, declining script volume, combined with "the market's softening, increased competition, as well as the impact from GTN" led to disappointing third quarter of 2017 results.

212. Former Celgene employees knowledgeable about the real reason for the slashed guidance reported that these explanations were not accurate. FE 18, for example, rejected Defendants' claims that the Otezla miss was due to a slowing of the PsO and PsA markets, particularly during the third quarter of 2017, as well as increasing competition, calling this purported explanation "***bullshit***." FE 18 explained that there was no way that Celgene's leadership was unaware of the fact that there would be more products entering the market in 2017. In addition, FE 18 confirmed that the market did not change rapidly in the third quarter of 2017. As he explained: "***We saw what was happening way before then***. ***We had monthly meetings with the contract and pricing teams . . . very early on in 2017***." FE 18 stated that there was "worry" and "concern" at these meetings. As FE 18 further stated: "We were in trouble with our Otezla contracts. You heard that from a lot of the pricing and contract people." Thus, according to FE 18, there was no way that Celgene's leadership was unaware of the looming guidance miss long before the third quarter of 2017.

213. The accounts of the other former Celgene employees discussed above similarly confirm that the 2017 Otezla guidance was unattainable (*see supra* § IV.B.2).

214. Analysts reacted quickly and negatively to the Company's guidance reduction and expressed a lack of confidence in Celgene's ability to execute going forward. As J.P. Morgan wrote in an October 26, 2017 report:

> A week after a high-profile (albeit also high-risk) Phase 3 asset failed [GED-0301], the company reported a big miss for Otezla and a sizable cut to overall 2020

> guidance. This is clearly not a recipe for success for an over-owned stock in a skittish market. The question now is what happens from here? . . . . Sentiment has taken a tremendous hit, management faces a major credibility issue (at least based on our investor conversations), and generalists may be running for the hills after this week that more closely resembled a Halloween horror film than a typical 3Q biotech earnings season.

215. Raymond James commented that "today's update substantially alters our outlook and confidence in the company's ability to execute":

> We previously viewed Celgene's immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a "show me" story[.]

216. On the news of Celgene's steep guidance reduction, the price of the Company's common stock declined $19.57 per share, or more than 16%, on heavy trading volume from a close of $119.56 per share on October 25, 2017 to a close of $99.99 per share on October 26, 2017.

### C. Defendants Fraudulently Concealed the Need to Complete Additional Testing That Jeopardized the Ozanimod NDA

217. An additional component of Defendants' plan to replace Celgene's revenue stream from Revlimid was Ozanimod. Ozanimod was initially developed by Receptos to treat RMS and UC.[3] MS is the most common autoimmune disease of the central nervous system, affecting an estimated one million people in the U.S.

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[3] MS disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss, causing communication problems between the patient's brain and the rest of the body. Most people with MS have RMS, which is characterized by a relapsing-remitting disease course, whereby a patient's symptoms may remit for a period of time but then relapse.

### 1. Celgene Acquires Receptos and Installs Celgene Personnel to Oversee the NDA Submission for Ozanimod

218. On July 14, 2015, Celgene agreed to purchase Receptos for $7.2 billion. In its press release announcing the acquisition, Celgene trumpeted that "[t]he transaction adds Ozanimod" which, based on clinical studies, "demonstrated several areas of potential advantage over existing oral therapies for the treatment of [UC] and [RMS] . . . ." Celgene projected potential annual Ozanimod sales of up to ***$6 billion***, and analysts commenting on the Receptos acquisition zeroed in on the drug's anticipated power to generate revenue. As one commentator later remarked, Ozanimod was "the crown jewel in Celgene's $7.2 billion acquisition of Receptos, Inc." In light of the Receptos acquisition, Celgene revised its 2020 revenue guidance for the I&I franchise up from $3 billion to over $4 billion.

219. Immediately upon acquiring Receptos, Celgene installed its own personnel at Receptos' headquarters in San Diego. As FE 20, a former senior executive in Clinical Development at Receptos, explained, after the acquisition, Celgene moved in and took over Receptos: "They [Celgene] were in charge. Receptos was not." FE 20 stated that Receptos was brought under the control of Celgene's New Jersey headquarters. From that point forward, Receptos was out of the decision-making loop and important decisions were made by Celgene in New Jersey or by on-site Celgene personnel. FE 21 stated that after the acquisition, Receptos' leadership was not allowed to make any decisions that had the potential to impact Celgene's stock price, and there were constant discussions between senior Receptos personnel and their counterparts and superiors at Celgene.

220. According to FE 20, Defendant Martin came from Celgene to Receptos to oversee the Ozanimod NDA filing. Martin formerly served as the Vice President, Head of Project Leadership, for Celgene's I&I franchise. FE 2, who worked in Clinical Research & Development

in the Company's I&I franchise, described Martin as a "control freak" and Smith's right hand man, and confirmed that Martin was sent to San Diego as Managing Director for Receptos in late 2015 or early 2016. FE 2 recounted that Martin operated as the *de facto* chief executive at Receptos. FE 5, a former Director at Receptos, likewise described Martin as the CEO of Receptos after the acquisition, adding that Martin was in charge of the entire Receptos organization and reported directly to Smith.

221. FE 5 explained that once he was in power, Martin pushed out Receptos' previous upper management and replaced them with his friends from Celgene in New Jersey. Martin's best friend, Saillot, was brought in to serve as Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos. FE 5 also recounted that Gary Cline, Head of Strategic Research and Innovation at Celgene, was another individual sent by Smith to San Diego to keep tabs on Ozanimod for Smith. FE 22, a Project Manager on the Ozanimod UC/CD team, corroborated that Martin reported directly to Smith and further confirmed that Saillot was Martin's second in command.

**2. Celgene Touts Ozanimod's Advantages Over Gilenya**

222. When Celgene acquired Receptos in 2015, the Company knew that if Ozanimod received FDA approval, its main competitor would be Gilenya (fingolimod), a drug manufactured by Novartis for the treatment of RMS. The Company therefore immediately embarked on an aggressive campaign to hype the purported advantages of Ozanimod over Gilenya and to rush Ozanimod through the FDA approval process.

223. Gilenya has a mechanism of action that is similar to Ozanimod. Celgene, however, claimed that Ozanimod had the advantage of a much shorter half-life than Gilenya. Gilenya has a long half-life of 168 hours, or seven days—that is, half of the drug remains in a patient's body for

seven days after it is taken. By contrast, Celgene claimed that Ozanimod had a much shorter half-life of just nineteen hours.

224. As one scientific paper from 2015 explained: "Having a shorter half-life and rapid peripheral lymphocyte recovery may provide [Ozanimod] with ***significant advantages***, including flexibility in treatment with other immune-modulating agents as needed or allowing for a rapid switch to alternative therapies if the patients [sic] disease flares while on therapy."

225. Immediately after acquiring Receptos, Celgene began touting the supposed advantages of Ozanimod over Gilenya and other oral RMS medications, including the drug's purportedly shorter half-life. For example, during the Robert W. Baird & Company, Inc. Healthcare Conference on September 9, 2015, Smith pointed to the "different half-life . . . that you see with the S1P1 with Ozanimod, that you don't see with Gilenya," noting that this "could potentially be some reason to differentiate."

226. Armed with this supposed competitive advantage, Celgene sought to capture Gilenya market share following FDA approval of the Ozanimod NDA, which was expected in 2018. In a landscape-altering ruling, however, in October 2015, the U.S. Patent and Trademark Office ("PTO") quashed Novartis's Gilenya patent claims in response to a challenge by generic competitors, paving the way for the entry of fingolimod generics into the RMS market by the end of 2019. As one publication characterized the PTO's decision and its impact on companies like Celgene: "***[I]t's not good for rival pharma companies, either***. They'll also have to contend with copycat versions of Gilenya, the first oral treatment for MS."

227. Thus, despite Ozanimod's purportedly superior half-life and safety profile, the availability of cheaper generic alternatives with a similar efficacy starting in 2019 would make it more difficult for Ozanimod to gain widespread acceptance among RMS patients. As a result,

Celgene was highly motivated to file its Ozanimod NDA and seek FDA approval before the end of 2017, in hopes of establishing market share before the wave of generic fingolimod competitors hit the market in 2019.

### 3. Celgene Disregards FDA Guidance and Industry Practice and Fails to Undertake Critical Testing for Ozanimod Metabolites

228. In announcing the Receptos acquisition, Celgene represented that it anticipated no obstacles to FDA approval. For example, the Company told investors on July 14, 2015 that the data from the two ongoing Phase III clinical trials, the RADIANCE and SUNBEAM RMS studies, "are expected in the first half of 2017 to support a RMS approval in 2018." Defendants continued to make identical representations throughout the Class Period. However, unbeknownst to investors, after Celgene discovered the Metabolite, it failed to conduct and report critical testing required to receive FDA approval of Ozanimod in early 2018, thus dooming the drug's prospects for this rapid approval timeline.

#### (a) FDA guidance and industry practice standards on metabolite safety testing

229. Pursuant to FDA guidance, in order to avoid significant delay in the review and approval of a new drug application, drug companies are directed to identify all metabolites early on in the drug development process and to conduct extensive safety testing of any active metabolites that are discovered during the course of these pharmacological analyses. When a drug is administered to a patient, the drug can be metabolized (i.e., chemically altered) by the patient's body, resulting in the formation of one or more metabolites. Metabolites are characterized as either "active" or "inactive." Active metabolites continue to produce effects in the body after their formation, whereas inactive metabolites do not. Active metabolites can accumulate in the body following multiple doses of a drug and may ultimately alter both the safety and the therapeutic effects of the drug. Thus, according to a seminal article on the subject, understanding "the

metabolic fate of a drug candidate in preclinical species and humans is a ***key factor*** in new drug development, registration and ultimate use."[4]

230. The importance of metabolite identification and testing has long been recognized. Since 1985, federal regulations have ***required*** that NDAs include "[a] section describing the human pharmacokinetic data" (i.e., information about how a drug moves through the body), including "[a] summarizing discussion and analysis of the pharmacokinetics and the metabolism of the active ingredients . . . of the drug product."

231. In 2002, Dr. Thomas A. Baillie (Professor of Medicinal Chemistry and Dean *Emeritus* for the University of Washington School of Pharmacy, and former Vice President and Global Head of Drug Metabolism and Pharmacokinetics at Merck & Co.), et al. authored a paper entitled "Drug Metabolites in Safety Testing" that summarized the deliberations of a multidisciplinary committee regarding the critical importance of identifying and testing metabolites as early as possible in the drug development process.[5] In this paper, often referred to as the "MIST" paper, Baillie and his co-authors recognize "the increased attention being paid by both pharmaceutical companies and regulatory agencies to the role of metabolites as potential mediators of the toxicity of new drug products."

232. Baillie, et al. highlight the fact that the early identification of metabolites in drugs at the development stage is critical to evaluation of the drug's safety. The MIST paper also stated

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[4] Human Radiolabeled Mass Balance Studies: Objectives, Utilities and Limitations, Natalia Penner, Lewis J. Klunk and Chandra Prakash, May 2009. At the time of this paper, Penner, Klunk and Prakash were employed in the Department of Drug Metabolism and Pharmacokinetics at Biogen, a pharmaceutical company focused on discovering, developing and delivering therapies for people affected by serious neurological and neurodegenerative diseases.

[5] Drug Metabolites in Safety Testing, Toxicology and Applied Pharmacology 182, 188-196 (2002).

that "it seems reasonable to expect that the sponsor would wish to develop an understanding of the metabolic fate of the drug candidate in humans ***prior*** to the initiation of large Phase III clinical trials." Baillie, et al. further stress that "the importance of the animal and human ADME [Absorption, Distribution, Metabolism and Excretion] studies [used to identify metabolites] ***cannot be overemphasized***, the results of which need to be viewed in the context of all available pharmacology and toxicology data."

233. Relying on Baillie's 2002 MIST paper, the FDA published industry guidance for the Safety Testing of Drug Metabolites in 2008 and reaffirmed this guidance in November 2016. The FDA's guidance calls for "the identification of differences in drug metabolism between animals used in nonclinical safety assessments and humans ***as early as possible*** during the drug development process." The FDA warns that "[t]he discovery of disproportionate drug metabolites late in drug development can potentially ***cause development and marketing delays***." Thus, the FDA "encourage[s] contacting the FDA early in drug development to discuss these issues."

234. As Baillie subsequently explained in a 2009 paper, the FDA's metabolite testing guidance "underscores the need for sponsors to conduct studies on the metabolic fate of drug candidates ***at an early stage of clinical development, such that issues of disproportionate human metabolites may be addressed prior to the initiation of large-scale clinical trials***."[6]

235. Testing for the presence of metabolites in humans is conducted through so-called radiolabeled mass balance studies, wherein a radioactive "label" (typically Carbon-14) is added to the drug to allow for the tracking of metabolites in the blood, plasma, urine, and feces collected from patients. As Penner, et al. explain, radiolabeled mass balance studies are "viewed as the

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[6] Approaches to the Assessment of Stable Chemically Reactive Drug Metabolites in Early Clinical Trials, Chem. Res. Toxicol. 2009, 263-266.

primary source of data on human metabolites from which a decision can be made regarding the need for further safety assessment in preclinical species," stating that "[h]uman radiolabeled mass balance . . . studies are ***required*** by regulatory authorities for the registration of a new drug, and therefore, are an integral part of the majority of drug development programs." Baillie also acknowledges the importance of mass balance studies utilizing a "radiolabeled drug" in identifying metabolites, stating that these studies are "***generally [ ] accepted as the 'gold standard' method for defining the fate of a drug candidate in man***."

236. Following the identification of metabolites through appropriate studies, certain metabolites require additional testing. As the FDA explains, "when the metabolic profile in humans is similar to that in at least one of the animal species used in nonclinical studies," standard animal toxicology studies are generally deemed sufficient for FDA submission. In other words, if the metabolite is present in similar amounts in humans as in the animals used for toxicology studies, those animal toxicology studies can "stand in" for human toxicology studies. However, as the FDA guidance recognizes, there are cases when "the metabolite is formed only in humans and is absent in the animal test species or [ ] the metabolite is present at disproportionately higher levels in humans than in the animal species." In these cases where such an imbalance exists between the metabolite's presence in humans as compared to animals, the drugmaker should conduct additional testing of the metabolite ***before*** filing the NDA for the drug. In describing the type of metabolites subject to additional studies, the FDA guidance provides:

> Generally, metabolites identified only in human plasma or metabolites present at disproportionately higher levels in humans than in any of the animal test species should be considered for safety assessment.

The FDA guidance further provides that human metabolites can raise a ***safety concern*** when they "form[] at greater than 10 percent of parent drug systemic exposure at steady state."

237. Baillie likewise stresses the importance of determining whether any of a drug's metabolites are present at higher levels in humans than in animal test species. Baillie states that if an imbalance is detected, the next step is to determine whether "such 'disproportionate' human metabolites exceed 10% of the area under the plasma concentration vs time curve (AUC) of the unchanged parent"—a further red flag. The AUC, or "Area Under the Curve," percentage is significant as it reflects the actual body exposure to a drug after administration of a dose of the drug.

238. If a disproportionate metabolite is identified, the FDA guidance sets forth multiple categories of studies "to be conducted to assess the safety" of such a metabolite. This battery of tests includes: general toxicity studies, genotoxicity studies, embryo-fetal development toxicity studies, and carcinogenicity studies.

239. Penner, et al. recognize the need for further tests regarding disproportionate metabolite levels identified during drug development and, thus, the importance of early metabolite identification: "Additional toxicological testing on metabolites that display higher exposure in humans than preclinical animal species may be required. ***For such metabolites, the [FDA] Guidance recommends that they be synthesized and evaluated by direct administration to test animals and the study reports be submitted prior to commencement of large-scale clinical trials***."

240. As the FDA sets forth in its Guidance for Industry, ICH M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals, "[n]onclincial characterization of a human metabolite(s) is only warranted when that metabolite(s) is observed at exposures greater than 10 percent of total drug-related exposure

and at significantly greater levels in humans than the maximum exposure seen in the toxicity studies."

241. The accompanying Guidance for Industry, ICH M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals, Questions and Answers, addresses the non-clinical (animal) toxicology studies that a drug developer must perform, including testing with respect to metabolites. This guidance provides that "characterization and metabolite toxicity would generally be considered adequate when animal exposure is at least 50 percent the exposure seen in humans," but further provides that "[i]n some cases, ***for example when a metabolite composes the majority of the total human exposure***, ***it is appropriate for exposure to the metabolite in animals to exceed that in humans*** []. In this latter case it is important to achieve a higher exposure to the metabolite in animals because this metabolite constitutes the bulk of human exposure."

**(b) Celgene fails to conduct critical metabolite testing in contravention of governing guidance and industry standards**

242. Notwithstanding the need for additional, time consuming safety studies with respect to any disproportionate metabolites that are identified, Celgene pushed forward with large-scale Phase III clinical (i.e., human) trials of Ozanimod after the Receptos acquisition in an effort to expedite submission of the Ozanimod NDA. In doing so, the Company delayed administration of the "gold standard" radiolabeled mass balance study.

243. After the Receptos acquisition, Celgene disregarded the applicable FDA guidance and forged ahead with the Phase III SUNBEAM and RADIANCE trials and only later circled back to finish the necessary Phase I testing. Indeed, Saillot (Martin's direct report) subsequently acknowledged in a draft Q&A document prepared for Martin in July 2017 that "***[t]here is clear regulatory guidance on when such studies should be done, which was not followed***."

244. As FE 21 explained, Celgene reported to the market the "sexier" efficacy findings for Ozanimod first, and then sought to backfill the results from the "non-sexy" clinical pharmacology testing that must be conducted throughout drug trials. These "non-sexy" tests examine aspects such as how a drug impacts the body or absorption rates and are typically completed during Phase I (i.e., the first in-human studies). With respect to Ozanimod, however, FE 21 reported that Celgene was still undertaking many Phase I Ozanimod studies in 2016, notwithstanding that the Company had been proceeding with large-scale Phase III clinical trials for more than a year.

245. The Code of Federal Regulations ("CFR")—a codification of the rules established by U.S. Federal Government agencies, including the FDA—confirms that Celgene's decision to push forward with the Phase III trials without first completing the threshold Phase I studies was out of sequence. As these regulations explain, "the clinical investigation of a previously untested drug is generally divided into three phases," Phase I, II and III, and "***in general the phases are conducted sequentially***." 21 C.F.R. 321.21. Phase I studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans," among other things. Phase III studies, by contrast, "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained."

246. Celgene's acceleration of the Ozanimod Phase III testing—despite not having completed Phase I testing, including the "gold standard" radiolabeled mass balance study—conditioned the market that the Company was in position to file the Ozanimod NDA by the end of 2017. For example, Celgene represented in a November 5, 2015 slide presentation given during the Company's third quarter conference call that "Ozanimod Clinical Development Continues to Progress on or Ahead of Schedule." Unaware that Celgene had not yet completed Phase I testing, analysts reporting on the conference call repeated Defendants' representations regarding the timing

of the NDA for Ozanimod. Jefferies Group LLC listed the "potential launch in MS" for Ozanimod as mid-2018. Morningstar similarly reported that Ozanimod is "poised to reach the market in 2018" and also referenced Ozanimod's "potential approval in multiple sclerosis" in 2018. An RBC Capital Markets analyst also wrote that Ozanimod was "ahead in timing."

#### 4. Celgene Belatedly Conducts the Mass Balance Study and Acknowledges the Significant Risks Posed by the Discovery of a New Metabolite

247. Celgene did not undertake the testing necessary to identify all of Ozanimod's metabolites until October 2016—fifteen months after acquiring Receptos. On October 17, 2016, Celgene began recruiting study subjects for a "**Phase I**, Single-Centre, Single Dose Oral Excretion Balance Study of [14C]-RPC1063 in Healthy Male Adults" (the "Mass Balance Study"). One of the stated primary objectives of this study was "[t]o determine how the drug [Ozanimod] moves through the body [i.e., is metabolized] and how fast it is removed from the body."

248. According to an October 2016 Receptos Executive Committee presentation that went to Martin, Celgene's belated initiation of the Mass Balance Study was particularly significant, as Celgene recognized even before the study began that the plan necessary to meet the December 2017 NDA filing commitment was "heavily back-loaded" and put a "[h]uge workload on [the] team with little time for delays/errors." Thus, Celgene was aware that the consequences of a late-discovered metabolite would be severe.

249. Indeed, while awaiting the results of the Mass Balance Study, in December 2016, the Ozanimod project team identified the risk that a new metabolite would be discovered, as Saillot later acknowledged in a draft Q&A document prepared for Martin in July 2017.

250. The problems caused by the belated discovery of a new metabolite were discussed at the regular Ozanimod MS Team meetings that were attended by Saillot, Tran (Executive Director of Clinical Pharmacology at Receptos), Meier-Davis (Senior Director, Preclinical Sciences at

Receptos), Kao (Executive Director, Regulatory Affairs at Receptos), Thomas (Director, Regulatory Affairs at Receptos), and Skolnick (Executive Director, Clinical Development, Receptos), among others. For example, the minutes from the January 12, 2017 meeting of the Ozanimod MS Team reflected that Celgene was planning a formal risk assessment for the first quarter of 2017, and the first item to be addressed in this assessment was: "Identification of a new metabolite in the human mass balance study." As these minutes confirm, Celgene knew by no later than January 2017 that "[i]f a significant new metabolite is identified, ***then we will not have sufficient toxicology [studies] to support the [NDA] submission***." The minutes further noted that the "[t]eam is putting a mitigation plan together to address."

251. In addition to acknowledging the need for additional toxicology studies for any significant metabolite, Celgene understood that the FDA would require full clinical study reports at the time of the NDA submission. On March 2, 2017, the FDA sent a letter to Celgene stating unambiguously that "several Phase 1 studies are still ongoing," including RPC01-1001, RPC01-1904, PRPC01-1906, and RPC01-1910, and advised Celgene that "***[f]ull Clinical Study Reports are needed for these clinical pharmacology studies at the time of the NDA submission***." This correspondence was distributed to Martin, Saillot, Thomas, Kao, Skolnick, Meier-Davis, and Tran, among others.

252. The MS NDA Submission Dashboard for the week of March 27, 2017, which was distributed to Martin, Saillot, Kao, Skolnick, Kopicko, Martinborough, and Aranda, among others, confirmed that Celgene viewed the "[p]otential to identify a new metabolite" through the Mass Balance Study as a "key issue[]" and noted that "[p]reliminary (chromatographic) data from plasma samples in the [Mass Balance Study] is expected by the end of this week to possibly provide a clue about any potential new metabolite for [Ozanimod]."

253. A March 28, 2017 presentation sent from Zoller, Senior Director, Program Management, to Saillot confirmed that the "***[c]urrent tox data package would not be sufficient*** if a new metabolite is identified in the [Mass Balance Study]," acknowledging this as a "***Potential Risk[] to the Ozanimod Submission***."

**5. Data From the Mass Balance Study Confirms the Existence of a New Metabolite That Imperils the Company's Timeline for FDA Approval**

254. In April 2017, emerging data from the Mass Balance Study suggested that there was, in fact, a previously unknown Ozanimod metabolite that required further testing prior to the submission of the Ozanimod NDA to the FDA. The results from the Mass Balance Study also revealed that the half-life for the Metabolite was significantly longer than Ozanimod's half-life of nineteen hours, which Celgene had repeatedly promoted as a competitive advantage for Ozanimod over Gilenya during the Class Period. As later reflected in a July 2017 Q&A document prepared by Saillot for Martin, the previously-held "assumptions around PK [pharmacokinetic] and PD [pharmacodynamics] advantages compared to other S1P modulators," like Gilenya, including "a shorter half-life and more rapid lymphocyte count recovery upon discontinuation of the drug . . . will need to be updated." Celgene would not publicly disclose that the half-life of the Metabolite was ***ten to thirteen days*** until after the Class Period.

255. On April 3, 2017, an Ozanimod MS Team Meeting was attended by Saillot, Skolnick, Tran, Meier-Davis, Kao, and Thomas, among others. The minutes of this meeting stated that "[c]hromatograph results from the plasma samples collected in the [Mass Balance Study] showed results that require follow-up activities, including whether this may be evidence for a metabolite that was not seen in the non-clinical studies." In light of these results, the Ozanimod MS Team was tasked with "track[ing] status of this work on a weekly basis," and a "new-cross functional

team" was "established led by [Martinborough] and [Meier-Davis] . . . to oversee investigation into this finding and mitigate any potential risks."

256. A PowerPoint presentation that Martinborough sent to Martin and Saillot following a meeting on April 24, 2017 stated the following with respect to the data from the Mass Balance Study: "It appears this new peak is real." The presentation further noted: "[W]e are assuming that it is a single peak >10% [of Ozanimod's systemic exposure]." This data signified a major metabolite that required further pharmacokinetic (PK) and toxicology testing per FDA guidance. The presentation expressly noted the possibility that Celgene would need to delay the NDA submission by ***eight months*** (to September 2018) in order to perform a non-clinical (animal) toxicology test on rodents for purposes of evaluating the Metabolite for carcinogenic effects (the "**rat carc study**").

257. On May 16, 2017, Saillot emailed Martin about the risks posed by the new data and implored him to inform Smith:

> You're going to be mad at me for this one . . . Sorry. But I feel really strongly about this. You need to let Scott know. For the following reasons: ***In the best case scenario the December timeframe [for filing the NDA] is extremely optimistic.*** Anything that slows down the progress (challenges in identification of the components of the peaks, etc…) will put that timeline in jeopardy. We can leverage his being brought up to speed to ask for the mobilization of the resource[s] that we talked about to be assigned to the project. As noted below, this can be position[ed] as a heads up – That we have this finding and we need to address it in the best way (ranging from being able to explain it away***, to putting this in the best context to negotiate any additional actions with the Agency***) . . . .
>
> I do not see any down side. ***Painful as the potential bad news is shared***, but better moving forward (just focusing on getting the job done and not being distracted). I can assure you that the team will not let this investigation slow down their progress (not on my watch). . . .

258. Martin responded to Saillot that they would discuss the Metabolite issue the following day with the Receptos Executive Committee. The Receptos Executive Committee meetings were

attended by Martin, Saillot, Tran, Thomas, Kao, Martinborough, Aranda, and Meier-Davis, among others.

259. In a May 30, 2017 email to Saillot, Martinborough, and Meier-Davis, among others, Tran requested additional information regarding the Metabolite and "emphasize[d] the importance and urgency of getting resolution to this issue because it could potentially require us to go back and amend the completed clinical study reports for 6 Phase 1 studies and making changes to the ongoing clinical study reports for 3 Phase 1 studies." As Tran explained: "This is a major task . . . . ***Most importantly, these changes could have a significant negative impact on the NDA deliverables and timeline***."

260. Multiple witnesses confirmed that Defendants knew that Celgene needed to conduct further testing on the Metabolite and examine previously-conducted studies prior to filing the Ozanimod NDA. FE 5 recalled that Tran, Receptos' Head of Clinical Pharmacology, confirmed the need for additional testing and studies of the newly discovered Metabolite during an Ozanimod meeting in March or April of 2017. This meeting was attended by Martin, Saillot (who reported to Martin), Frohna (Vice President of Clinical Development and Translational Medicine, Receptos, who reported to Martin), Kopicko (Executive Director of Biometrics, Receptos, who reported to Martin), Darryl Penenberg (Director, Receptos, who reported to Kopicko), Aranda (Vice President of Clinical Development, Receptos, who reported to Martin), Skolnick (Executive Director, Clinical Development, Receptos, who reported to Aranda), and others. FE 5 stated that, at this meeting, Tran, who worked on the radiolabeled Mass Balance Study and was responsible for analyzing the Metabolite and preparing the pharmacokinetic report, discussed the high amounts of the Metabolite that were found in humans (but not in animals) and the need to conduct further studies. According to FE 5, Tran directed his comments to Martin and Saillot, and Martin and

Saillot quickly shut down the conversation regarding the Metabolite and moved on to a separate testing discussion.

261. FE 21, who had first-hand knowledge of the discovery of the Metabolite, recounted that immediately after the discovery, he and others at Celgene began working on several additional studies. FE 21 characterized these efforts as "herculean" and "monumental," explaining that Celgene started new studies and went back and looked at closed findings to extract more data. FE 21 also indicated that Celgene's senior leadership was briefed on the discovery of the Metabolite and the ongoing characterization efforts "quite some time before the filing" of the NDA. Furthermore, FE 21 confirmed that, over time, the team working on issues surrounding the Metabolite grew.

262. FE 21 discussed the Metabolite with his manager and stated that its discovery was of great concern. As FE 21 explained, his manager told him not to tell anyone about the Metabolite finding—instead, FE 21's manager and the leader of Receptos, who other former employees have identified as Martin, would tell him who needed to know. FE 21 understood that the individual with his parallel role at Celgene and his manager's equivalent at Celgene both knew about the discovery of the Metabolite. FE 21 also learned that members of Celgene's senior leadership knew about the discovery of the Metabolite and received updates on the issue.

### 6. Celgene Knows That It Lacks Critical Long-Term Stability Data Required for the NDA Submission

263. Having discovered the Metabolite, Celgene needed to ensure that it had sufficient analysis of the Metabolite completed by the December 2017 target date for the NDA submission. However, by early June 2017, Defendants knew that Celgene lacked adequate "long-term stability" data required to validate the stability of the Metabolite in human plasma, and that the testing required to generate such data would not be completed for well over a year.

264. The relevant FDA Guidance on Bioanalytical Method Validation requires that, in connection with NDA submissions, sponsors adhere to specific processes for bioanalytical method validation in order to ensure that the methods used for quantitative measurement of a particular substance, such as a metabolite, are reliable and reproducible. One important validation parameter is stability, and specifically, long-term stability (or "**LTS**")—i.e., the stability of a chemical compound during long-term frozen storage. LTS data is necessary to show that a chemical compound has not deteriorated, degraded, or otherwise changed when stored at below-freezing temperatures over long periods of time. Data included in an NDA submission must be supported by sufficient LTS data in order to be considered validated by the FDA.

265. As the FDA Guidance on Bioanalytical Method Validation states: "Assays of all samples of an analyte in a biological matrix should be completed within the time period for which stability has been demonstrated."[7] Stated another way, if a clinical test sample of a metabolite (or any other analyte) is older than the period for which stability has been demonstrated, then that sample is not considered validated per FDA guidance. The Guidance further provides that:

> The validity of an analytical method should be established and verified by laboratory studies, and documentation of successful completion of such studies should be provided in the assay validation report. . . . Documentation for submission to the Agency should include (1) summary information, (2) method development and establishment, (3) bioanalytical reports of the application of any methods to routine sample analysis, and (4) other information applicable to method development and establishment and/or to routine sample analysis. . . . Documentation for method development and establishment should include . . . [a] description of ***stability studies and supporting data***.

266. In light of the FDA's stability requirement, if a new drug applicant opts to rely on samples from previously-conducted clinical studies to collect data for a later-discovered

[7] An analyte is a substance whose chemical constituents are being identified and measured.

metabolite, the applicant must demonstrate the stability of the metabolite over the period for which the samples were stored. For example, if an applicant relies on human plasma samples that were kept in frozen storage for two years to generate data for the metabolite, then it must demonstrate that the concentration of the metabolite in human plasma does not change (i.e., remains stable) when stored in a freezer for two years.

267. Typically, LTS data is generated in real time—in other words, after being placed in frozen storage, plasma samples are periodically taken out of storage and the concentration of the metabolite in those samples is measured to ensure that the metabolite has not degraded during the storage period.

268. However, in the case of a *later*-discovered metabolite (like here), the applicant must retrospectively generate LTS data because the applicant was unaware of the metabolite when the plasma samples were placed into storage and thus could not have collected the necessary concentration data for the metabolite.

269. To generate LTS data after the fact, an applicant takes blank human plasma samples, spikes these samples with the metabolite, and places the samples into frozen storage. The applicant then takes the plasma samples out of storage at specified intervals and measures the concentration of the metabolite in the samples in order to ensure that this compound is stable and has not degraded over time. If LTS data must be generated retrospectively (as it was in this case), the minimum amount of time required to generate this data is the amount of time for which the previously-collected samples have been stored—i.e., if an applicant needs to generate two years of LTS data, this will take a minimum of two years.

270. On June 1, 2017, Tran emailed David Wilson, the clinical bioanalytical lead at Receptos, and asked if there would be any issue using old plasma samples from the previously

conducted clinical studies to measure and analyze the Metabolite as required by the FDA Guidance—the alternative would have been to go back and re-conduct the clinical studies from scratch to generate new data for the Metabolite, a process that would take several years.

271. Wilson responded that Celgene lacked sufficient LTS data to validate the Metabolite for the RPC01-1001 clinical study (the "**1001 Study**") due to the age of the retained plasma samples collected during the study. He explained that if Celgene were to rely on RP112273 data from the 1001 Study, "LTS becomes a real concern" as the FDA "won't consider the data as validated." As Wilson explained to Tran:

> ***Right off the bat, stability would be a main concern*** . . . . if we use . . . [the] 1001 [Study], LTS becomes a real concern. There will be some samples that you won't get validated LTS for until nearly our anticipated PDUFA time (or beyond) [i.e., 12 or more months after the NDA submission]. ***So the agency won't consider the data as validated***. If stabilizers are required in the plasma to keep the compound from converting, no existing study will work.

272. The same day—June 1, 2017—a meeting of the Receptos Executive Committee was held. The meeting was attended by Martin and Tran, among others. During the meeting, Tran presented a series of slides entitled, "Impact of new peak on Clinical Pharmacology Strategy"—the "new peak" being a reference to the Metabolite. The presentation underscored the lack of LTS data as a problem: "***Primary concern: PK sample stability***. ***Regulatory agencies will not consider data as validated due to lack of long-term stability (LTS) data***."

273. On June 6, 2017, Wilson emailed Tran as follows:

> You had requested to know how much LTS we needed for a few studies to cover 2273 analysis. . . . Some thoughts for you:
>
> - Assuming M[ethod] V[alidation] completes in late September and we jump straight to [the] 1001 [Study], ***you'll need about 15 months LTS to cover this study***.
> - We don't have sufficient sample volume to analyze 201A.
> - ***[The] 201B and 301 [Studies] will need ~4 and 3 years LTS***.

- I've added a slide to my weekly update to track this stuff.

274. Importantly, Celgene did not anticipate completing the "method validation" process necessary to develop and validate a method for measuring the concentration of the new Metabolite until September 2017, meaning that the Company could not begin to generate the necessary LTS data for the Metabolite until September 2017, at the earliest. Thus, because Celgene would need at least 15 months of LTS data to validate the Metabolite results from the 1001 Study, the LTS data required to cover all of the samples from this study would not be available until December 2018 at the very earliest (i.e., 15 months from September 2017). Similarly, because Celgene would need at least 4 years of LTS data to validate the Metabolite results from the 201B Study, the LTS data required to cover all of the samples from this study would not be available until September 2021 at the very earliest (i.e., 4 years from September 2017). And because Celgene would need at least 3 years of LTS data to validate the Metabolite results from the 301 Study, the LTS data required to cover all of the samples for this study would not be available until September 2020 at the very earliest (i.e., 3 years from September 2017). All of these timelines rendered Celgene's aggressive December 2017 target date for the NDA submission unattainable.

275. In connection with an Ad Hoc Executive Committee meeting on June 15, 2017, Tran prepared a presentation titled "A Phase 1 study to evaluate PK and PD of Ozanimod and active metabolites following multiple dosing regimens (RPC01-1911)." The invitees for this meeting included Martin, Saillot, Martinborough, Aranda, Kao, Thomas, and Tran, and the presentation was sent to Martin prior to the meeting. One slide in Tran's presentation was titled "**Preliminary, very limited data on new metabolite (RP112273) as of 08June2017**" and stated that "RP112273 is pharmacologically active and more potent (> 10-fold) than Ozanimod." The next slide stated: "RP112273 is likely the major and active moiety accountable for most of ozanimod's efficacy and/or safety." This slide further stated that "***[a]dequate characterization of RP112273 PK and***

***PD properties are required by regulatory agencies***," including "***Analytical information on the stability of the analyte*** . . . ." Tran's presentation further emphasized that the test result must be "considered validated by regulatory (i.e., with long-term stability data)." The final slide in the presentation stated: "Note: while a validated clinical assay will be used, ***results are not considered validated due to lack of long-term stability data for PK samples at the time of filing [the NDA]***." This presentation to Martin and the Receptos Executive Committee confirmed that the required LTS data would not be available at the time of the planned NDA submission in December 2017.

276. On July 17, 2017, Tran gave a slide presentation to the Receptos Executive Committee, which Defendant Martin led, titled "Clinical Pharmacology Strategy for RP112273 to support NDA submission and review." Tran's presentation again confirmed that Celgene would not have the necessary LTS data at the time of the NDA submission. On a slide titled "Summary of available Clinical Pharmacology data for Ozanimod at NAD [sic] submission (Dec 2017) and during NDA review (2018)," Tran informed Martin and the Executive Committee that Celgene would have: "***Limited PK characterization of RP112273 in RMS patients (with no long-term stability data)***" at the time of the NDA submission in December 2017. This presentation was sent to Martin.

### 7. Celgene Recognizes That Its Non-Clinical Toxicology Data Is Also Deficient

277. In addition to the internally-recognized LTS data deficiencies, Celgene knew that there were deficiencies in its non-clinical toxicology testing of the Metabolite. As discussed above, Celgene recognized as early as January 2017 that it would have insufficient toxicology testing data if the Mass Balance Study revealed the presence of a significant new metabolite. *See supra* ¶ 250.

278. The inadequacy of Celgene's non-clinical toxicology data for the Metabolite only became clearer during the Class Period. In a July 6, 2017 email to Meier-Davis, among others, Tran acknowledged that Celgene would not have "the actual human exposure until end of August/early September." This "actual human exposure" data was needed in order to calculate the non-clinical "exposure multiples" for the animal toxicology studies.

279. In basic terms, exposure multiples are calculated by comparing the amount of a given compound (here the Metabolite) to which humans are exposed when taking a normal therapeutic dose of the drug to the amount of the compound to which animals have been exposed during the course of the toxicology studies. These multiples are used to ensure that the animal study results can be used to meaningfully extrapolate findings about the safety of the compound to humans.

280. Because Celgene still did have not actual human exposure data for RP112273 as of July 2017 and was working off of estimated data, Celgene did not know whether the animal exposure multiples would exceed the applicable threshold multiple of 1.0 set by the ICH Guidance, which provides that "when a metabolite composes the majority of the total human exposure, it is appropriate for exposure to the metabolite in animals to exceed that in humans" (*see* ¶ 241 *supra*).

**8. Concerns About a Refusal to File Intensify Internally at Celgene Given the Lack of Data for the Metabolite**

281. As early as July 2017, Celgene acknowledged the possibility that the FDA could refuse to file the Ozanimod NDA if the Company was unable to provide the FDA with the necessary information regarding the Metabolite. A "Q&A" document from July 17, 2017 drafted by Saillot for Martin acknowledged the following in response to the question, "[w]hat is the impact on the [NDA] submission [of the Metabolite discovery]?": "***Unaddressed this would lead to a Refusal to File by FDA***."

282. The July 2017 Q&A made clear that a critical aspect of Celgene's plan to address the data deficiencies stemming from the belated discovery of RP112273 was to conduct a "pre-NDA meeting" with the FDA in order to obtain agreement from the Agency that the Company could provide the additional required data for RP112273 ***following*** the NDA submission in December 2017. The purpose of a pre-NDA meeting is described in the FDA's Guidance entitled, "Refuse to File: NDA and BLA Submissions to CDER, Guidance for Industry":

> When discussing the planned submission of [New Drug Applications] at a pre-submission meeting, the FDA and the applicant reach agreements regarding the content of a complete application for the proposed indication(s) as well as agreements, if any, on submission of minor components that may be submitted not later than 30 calendar days after submission of the original application. ***Unless the applicant and the FDA have agreed at the pre-submission meeting to delayed submission of certain components of the application, the FDA expects applications to be complete at the time of submission***.

283. As the July 17 Q&A explained, "[t]he team is putting together a package with the available preliminary data and preparing for a meeting with FDA to negotiate submission of the NDA within the original timeframe, with agreement for additional data to be submitted during the review period [i.e., after the NDS submission date] without an impact on the PDUFA action date." The Q&A noted that the "[b]est case" scenario was that the FDA would "accept submission within original timeframe," but also acknowledged the "[p]ossible scenario" that the FDA would "request submission of additional Pharmacology and/or non-clinical safety data" with the result that the NDA submission would be "***delayed by 1-2 Quarters***" into the "1[st] H[alf] 2018."

284. Saillot, Thomas, and Kao were already working on draft language for the pre-NDA meeting request as early as July 5, 2017. This draft language establishes that Celgene believed it would not have sufficient data by Celgene's NDA submission target date of December 2017 and sought the FDA's permission to submit this data ***after*** the NDA submission. Kao wrote to Saillot

and Thomas: "As we discussed, here is some wording that we could consider to include in the Mtg Request Doc":

> **PURPOSE OF MEETING**. . . . Celgene is also seeking FDA feedback and agreement on our proposed plans for the nonclinical qualification and PK/PD characterization of 112273, a recently-identified, active major metabolite of Ozanimod. Specifically, Celgene would like to obtain FDA confirmation that it would be acceptable to provide certain data regarding 112273 during the NDA review period without delaying the PDUFA performance goal date, on the basis that Phase 3 clinical trial data are already available and support the safety and efficacy of Ozanimod in RMS patients.

285. On July 25, 2017, Martin sent an email to Curran updating her on the status of Ozanimod and the discovery of the Metabolite. Martin's email confirmed that the Mass Balance Study "revealed a new disproportionate metabolite RP112273 which was not previously detected in preclinical species." Martin made clear that "[a] lot of work remains to be done in a very short period of time in order to keep the submission on schedule." He explained that "the human mass balance study is typically conducted early in drug development, so that results are available prior to the start of Phase 3 and non-clinical carcinogenicity studies," but that an "Ozanimod human mass balance study had not been conducted at the time of due diligence" for Celgene's acquisition of Receptos. Martin continued:

> The potential risk of new metabolite(s) was identified by the team in December 2016 and tracked by the team . . . . As per FDA guidance on safety testing of metabolites (2016), metabolites present at disproportionately higher levels in humans than in any of the animal test species should be considered for (non-clinical) safety assessment. Human metabolites that can raise a safety concern are those formed at greater than 10 percent of parent drug systemic exposure at steady state. ***Since RP112273 is the major (<10-fold higher in exposure compare[d] to the parent ozanimod) and pharmacologically active [metabolite], adequate characterization of Clinical Pharmacology properties of RP112273 is required by regulatory agencies***.

286. Confirming the importance of the pre-NDA meeting, Martin further stated that one of the "[n]ext steps" was a "Pre-NDA meeting in early November." Martin forwarded this email to Smith later the same day.

287. On August 1, 2017 Wilson sent Tran a slide deck with updated information on the amount of LTS data Celgene needed to cover the samples from several Phase I and Phase II clinical pharmacology studies. According to Wilson, Celgene needed between approximately one and three years of LTS data to cover the samples from these studies—data that Celgene would not have by December 2017 when it planned to submit the NDA.

288. On the same day (August 1, 2017), Dr. David Jacobson-Kram ("Jacobson-Kram"), a consultant retained by Celgene, emailed Meier-Davis that the situation Celgene was facing with respect to the Metabolite was "***somewhat unprecedented***." Jacobson-Kram noted that Celgene was "dealing with a very conservative division" at the FDA and that the division may require Celgene to demonstrate an adequate exposure of RP112273 "in ***all species tested***" (i.e., a multiple that exceeded that in humans) —yet Celgene could not demonstrate such coverage for several non-clinical toxicology tests.

289. In or around August 2017, FE 21 discussed with his colleagues the likely outcome of the Company's decision to file the NDA without the full results of the additional Metabolite testing. Specifically, FE 21 and his colleagues concluded that Celgene would receive an RTF letter due to the absence of the requisite test results. As FE 21 explained, ***the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file, and he thought other teams felt that way too from speaking with them***. FE 21 shared his concerns with his direct management. FE 21 and his colleagues also discussed the likelihood that the Company would blame Receptos personnel and the clinical pharmacology team for the RTF, and there would

be massive layoffs as part of the fallout. As FE 21 stated, he and his colleagues were concerned that an RTF would cause "heads to roll locally and up top at Celgene."

290. Beginning in early August 2017, Martin, Saillot, Kao, Backstrom, and Lamb, among others, participated in regular "touch base" teleconferences to discuss the progress of the Ozanimod NDA submission.

291. On August 7, 2017, the *Journal of Clinical Pharmacology in Drug Development* published a paper sponsored by Celgene and authored by Tran and several other Celgene employees entitled "Cardiac Safety of Ozanimod, a Novel Sphingosine-1-Phosphate Receptor Modulator: Results of a Thorough QT/QTc Study." In this paper, Tran stated: "Metabolism studies in animals identified 3 pharmacologically active metabolites (RP101988, RP101075, and RP101442) that have similar S1P selectivity and potency in vitro to ozanimod" and described the characteristics of these three metabolites. The article also included a Figure 1 that purported to identify the "Chemical structures of ozanimod ***and its active metabolites***." Tran's paper made no mention of RP112273 or the requisite additional testing, and through this omission, misled the scientific and investor community and perpetuated Defendants' concealment of the impact of the Metabolite on Celgene's submission of the Ozanimod NDA.

292. On September 18, 2017 Wilson sent Tran a slide presentation with updated long-term stability calculations for the previously conducted studies of Ozanimod. As noted above, Celgene was required to submit LTS data for the Metabolite with the NDA covering all of the samples from the studies that it intended to rely upon to support the NDA. Wilson's presentation made clear that:

- Celgene needed 508 days of LTS data for Study 1904, which would not be completed until December 15, 2018;

- Celgene needed 384 days of LTS data for Study 1906, which would not be completed until August 13, 2018;
- Celgene needed approximately 3 years of LTS data for Study 301, which would not be completed until around January 2020;
- Celgene needed approximately 5 years of LTS data for Study 201A, which would not be completed until around August 2022;
- Celgene needed approximately 2 years of LTS data for Study 1902, which would not be completed until around June 2019;
- Celgene needed approximately 1.75 years of LTS data for Study 1905, which would not be completed until around March 2019;
- Celgene needed approximately 1.5 years of LTS data for Study 1908, which would not be completed until January 2019; and
- Celgene needed approximately 4 years of LTS data for Study 201B, which would not be completed until July 2021.

293. In a September 19, 2017 email, Tran provided Meier-Davis and Martinborough with the long-awaited updated human exposure value for the Metabolite. According to this new data, the human exposure for the Metabolite was 155,716 pg*h/mL, compared to the July 6, 2017 estimate of 75,410pg*h/mL. This updated exposure data was particularly significant as the near-doubling of the human exposure value reduced the non-clinical multiples for the toxicology by nearly ***half***, thereby elevating the risk that Celgene would not have adequate exposure levels of the Metabolite—i.e., a multiple of 1.0 or greater—for purposes of the non-clinical toxicology tests.

294. On October 19, 2017, Lamb forwarded to Florence Houn, Vice President of Global Regulatory Science at Celgene ("Houn"), a copy of the draft "Briefing Book" that is customarily submitted to the FDA in advance of the scheduled pre-NDA meeting with the goal of reaching agreement with the FDA on the planned course of action for submitting the NDA. The Briefing Book set forth Celgene's plan to submit certain data regarding RP112273 after the target NDA submission date of December 2017 because the data would not be available at the time of

submission. In his email, Lamb stated: "Personally, I don't feel the package is ready for submission and requires substantial rework." After reviewing the document, Houn provided her comments, noting: "I don't see the rationale for the delayed metabolite characterization submission by 4 months with the other late submissions."

295. In a separate October 19, 2017 email, Reiss, Corporate Vice President, Head of I&I Clinical Research and Development, provided his comments on the draft briefing book to Aranda, which were subsequently forwarded to Palmisano, Saillot, and Tran. Reiss expressed concerns about the description of the metabolite, stating: "***It seems like you are going over board to sell a concept that the FDA will not buy anyway***—be careful with your credibility. . . . From my point of view this would need a lot of work. There is a lot of 'happy language' and minimizing of tolerability issues." Reiss also mentioned that "Matt [Lamb] had delivered similar comments."

### 9. Celgene Formally Seeks the FDA's Agreement to Submit Critical Data Regarding the Metabolite After the NDA Submission Because the Testing Would Not Be Complete by the End of 2017

296. Despite the fact that Celgene had belatedly discovered the Metabolite and internally recognized deficiencies and potential problems with both the clinical and non-clinical testing for RP112273 needed for the NDA, Defendants concealed that information from investors during Celgene's third quarter 2017 conference call on October 26, 2017. Celgene, through Smith, painted a rosy picture for the investing public by presenting a slide touting Celgene's "***Ozanimod FDA filing in RMS by YE:17***" as an "***inflection point***" to drive growth for the Company.

297. The next day, October 27, 2017, Celgene submitted the Briefing Book to the FDA and requested that the pre-NDA meeting originally scheduled for November 28, 2017 be rescheduled for November 27, 2017. The Briefing Book set forth its purpose, in relevant part, as follows:

> Celgene is also seeking feedback and agreement on the data for the nonclinical qualification and clinical pharmacokinetics (PK) and exposure-response characterization of RP112273, a disproportionate active metabolite of ozanimod. Specifically, Celgene would like to obtain FDA agreement that it would be acceptable, given the scope of the information included in the initial NDA, to provide additional clinical pharmacology data regarding RP112273 early in the NDA review period, on the basis that phase 3 clinical study data are already available that support the safety and efficacy of ozanimod in patients with RMS."

298. Celgene requested that the FDA permit the Company to submit certain data regarding RP112273 required for the NDA submission ***after*** the initial submission targeted for December 2017—i.e., during the NDA "review period"—including LTS data for the clinical studies. Accordingly, the Briefing Book set forth three critical questions regarding the acceptability of the incomplete data Celgene proposed to submit with the NDA by the end of the year:

- **Question 3:** Does the Agency agree that the proposed nonclinical package, including the evaluation of major metabolites, is adequate to support the filing for the registration of ozanimod?

- **Question 4:** Does the Agency agree that the overall proposed clinical pharmacology package, including the additional information planned to be provided early in the NDA review, is acceptable and supports the filing for the registration of ozanimod?

- **Question 5:** Does the Agency agree with Celgene's proposed timing for the bioanalytical [LTS] data package for the recently-identified major and active metabolite RP112273?

299. The "**Supportive Information for Question 5**" included in the Briefing Book made clear that Celgene would not have the required LTS data completed by the time of the anticipated NDA submission in December 2017:

> A liquid chromatography-tandem mass spectrometry (LC-MS/MS) method for the analysis of RP112273 has been developed and validated. . . . The method was validated according to the FDA Guidance on Bioanalytical Method Validation (2001) with consideration that samples from the previously completed clinical studies will be analyzed for RP112273 concentrations. For this reason, validation with greater short-term stability than is typical (ie, ≥ 5 freeze-thaw cycles and ≥ 24 hours bench top stability) ***and long-term storage stability (LTS) assessments (-20°C and/or -70°C, as appropriate) is ongoing as required to cover samples from***

> ***the previously completed clinical studies.*** A method validation report will be provided following completion of core validation activities, ***which only excludes the ongoing LTS***, freeze-thaw beyond 5 cycles, and co-administered drug interference assessments. ***Validation report addenda will be prepared following completion of LTS assessments at intervals of approximately 1, 6, 12, 15, 18, 24, 30, and 36 months***. . . .
>
> Celgene plans to provide bioanalytical data as follows:
>
> **In the NDA Submission:** . . . ***As noted above, the validation report for RP112273 . . . will not include LTS Assessments*** . . . .
>
> **By the 120-day safety update:** . . . Addendum to RP112273 plasma assay validation report . . . to include . . . some ongoing LTS assessments . . . .
>
> **Subsequent updates**: ***Ongoing LTS assessments to cover required analysis*** . . . .

300. On October 28, 2017, the day after Celgene submitted the Briefing Book, the Company held an Investor Event at the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis. During this event, Defendant Martin stated:

> [T]he RADIANCE study and the SUNBEAM study will form the basis of our submission to the FDA and to [the] EMA. ***For the FDA, we are working hard as we speak to get ready to file by the end of the year***.

301. During this same event, Smith stated:

> ***We announced positive top line data to ozanimod and SUNBEAM and RADIANCE earlier in the year***, and we've been very anxiously awaiting, getting to this meeting and being in a position to really get in and dig in and talk about the data. ***We're tremendously thrilled with the data and satisfied and happy***.
>
> ***
>
> So it's very, very exciting for us to be heading off in this new venture in neurology, but heading off with such an amazing, potential cornerstone product as ozanimod with what we think is a ***very, very, very positive data***.
>
> ***
>
> ***Since we went and made the acquisition and we've just continued to get more excited and more excited as we've continued to have data*** and whether that data was in MS and pivotal data, you see data firming up long term in the Phase II data,

Crohn's data coming in. ***The data around this asset is very, very solid, and it's really, really exciting***.

302. Not once during this conference did Defendants make any reference to the Metabolite, the fact that Celgene was lacking critical data regarding the Metabolite, or the resultant risks posed to submitting the NDA by the end of the year before the required data and testing was completed. At this point in time, Defendants had no idea whether the FDA would accept Celgene's proposal to submit the NDA by the end of 2017 without all of the required data and permit Celgene to provide this additional data after the initial submission.

303. In reporting on Defendants' statements at the MSParis2017 meeting, Oppenheimer focused on Defendants' repeated representations regarding the Phase III trial data and NDA submission timeline, stating: "Celgene has previously announced that further analyses of the RADIANCE trial are ongoing and it plans to submit an NDA to the FDA, based on the combined SUNBEAM and RADIANCE trials for relapsing MS by the end of 2017." Had Defendants disclosed the Metabolite, the need for additional testing, and the complete uncertainty surrounding whether the FDA would accept Celgene's proposal to "backfill" the required data after the submission date, Oppenheimer would not have issued such a positive report.

**10. Trepidation About the NDA Submission Escalates Within Celgene**

304. As Defendants awaited the FDA's response to Celgene's proposal for the NDA set forth in the Briefing Book, several individuals, including both Celgene's Ozanimod team members and external consultants, expressed grave concerns about the FDA's reaction to the proposal and whether the agency would bless the Company's plan, enabling Celgene to file the NDA by the end of the year.

305. On November 13, 2017, Saillot emailed Dr. James MacDonald ("MacDonald"), a consultant retained by Celgene to give advice regarding the non-clinical issues surrounding the

Metabolite. Saillot provided MacDonald with a "run-down of the ongoing activities" regarding the Metabolite testing and the draft NDA submission. Saillot recognized the likelihood that the FDA would reject Celgene's proposal: "The bottomline anyway will be whether FDA buys our 'total active structurally similar' approach . . . and if not and they require more [nonclinical] tox[icology] work, whether a post marketing commitment will suffice. Some folks mention that FDA's willingness to accept post-marketing commitment for these types of issue[s] is less than in the past."

306. On November 16, 2017, Saillot provided MacDonald with a copy of the previously-submitted Briefing Book. Saillot also sent MacDonald a copy of the draft Toxicology Written Summary for the NDA submission and asked for MacDonald's "reactions/suggestions." Following a telephone call, Saillot followed up with MacDonald by sending him "some of the comments [he] provided on the . . . non-clinical overview" section of the NDA. In response to these comments, MacDonald emailed Saillot on November 19, 2017, stating: "***The late discovery of RP112273 has had an impact on the non-clinical safety evaluation of ozanimod. A clear acknowledgement of this and the resulting deficiencies in the package will enhance the credibility of the submission***." Specifically, MacDonald noted that Celgene's claim that the nonclinical exposure multiples for RP112273 "are mostly above 1, and approach 1 . . . , which would be consistent with the ICH M3 guidance" "is the kind of argument that is a 'red flag' to me." MacDonald explained: "***The simple fact is that you have no exposure multiple to this major metabolite and you should simply acknowledge that***."

307. Later that evening, after reviewing MacDonald's comments and the most current draft of the NDA submission, Saillot emailed Martin with grave concern about the NDA submission, and particularly the description of the exposure multiples for the non-clinical studies:

> None of the comments from regulatory (including me, David, Tim and Matt) recommending stating exposure multiples including RP112273 and making the conclusions of each section consistent with the wording of the label have been taken into consideration . . . . The current text and positioning is at best confusing and at worse misleading and lacks credibility. ***I am now at a stage where I am very concerned about the approvability of the NDA unless these issues are addressed.***

308. On November 15, 2017, Jacobson-Kram, another consultant retained by Celgene, provided his "thought on the kind of issues one might expect FDA to raise" to Meier-Davis, who in turn forwarded this feedback to Martin, Saillot, Tran, Thomas, Aranda, Kao, Skolnick, and Martinborough, among others. Jacobson-Kram also had concerns about the deficient exposure multiples for the non-clinical toxicology studies:

> [T]he [ICH M3(R2)] guidance was designed to assure safety of metabolites of the API. In this particular instance RP112273 represents the overwhelming majority of drug related material and is responsible for the overwhelming majority of pharmacological activity. ICH M3(R2) states: 'In some cases, for example when a metabolite composes the majority of the total human exposure, it is appropriate for exposure to the metabolite in animals to exceed that in humans (see also Question 12). In this latter case it is important to achieve a higher exposure to the metabolite in animals because this metabolite constitutes the bulk of human exposure.' ***However, in the case of the rat carcinogenicity study and the segment 2 reproductive toxicology studies [Celgene] has less than the clinical [i.e., human] exposure for RP112273. Does the sponsor consider RP112273 to have be [sic] adequately tested in these studies?***

Through these comments, Jacobson-Kram specifically flagged that the FDA could question Celgene about the fact that the exposure multiples from two of the required toxicology studies did not meet the threshold of 1.0 established by the ICH Guidance. Jacobson-Kram noted that this question was among the "***major push back that you can expect from FDA***."

309. In another clear acknowledgment that the FDA could reject Celgene's proposal to submit the NDA by the end of 2017 and before all the required testing was completed, on November 20, 2017, Lamb emailed Curran about the possibility of using a priority review voucher

("PRV") which is a mechanism for a new drug applicant to expedite the FDA's review of the NDA:

> If . . . following the pre-NDA meeting, ***the FDA makes a strong recommendation that we shouldn't submit the NDA until we have all the information on the metabolite available and we decide to wait until March-April 2018 to submit the NDA***, then I think it is fair to utilize a PRV [Priority Review Voucher]. This would allow for an approval in a similar time frame as if we had submitted the NDA in Dec[ember 2017].

Six minutes later, Curran responded to Lamb: "***Agree***."

310. Lamb also shared his thoughts about the utility of a PRV with Martin, Curran, and Saillot in a separate email also sent on November 20, 2017:

> We've been approached about the potential sale of a Priority Review Voucher (PRV). . . . ***If*** . . . ***under the situation where the review division makes a strong recommendation to only submit the NDA when the additional information on the metabolite is available and the team decides to wait until early next year to submit***, I think it would be fair to consider [ ] a potential priority review . . . . Do you agree? If yes, and if FDA makes it clear what we should only submit once we have the complete metabolite information included in the NDA, it would be good to gauge the division's preliminary thoughts about the merits of a priority review . . . . this could then inform thoughts around the use of a PRV.

311. Saillot responded to Martin, Curran, and Lamb later that day:

> I must say that the team had discussed the option of trying to negotiate a priority review based on the same elements you highlight below in case the FDA were to ask us to delay the filing. . . . The writing of the briefing book was along these lines (addressing an unmet need), but short of mentioning the priority review. . . . ***I believe the highest risk is in our non-clinical safety argument (particularly the carcinogenicity)***. I am not sure how a priority review would best play in that scenario . . . .

312. That same day, Curran similarly acknowledged the possibility that the FDA would reject Celgene's proposal in an email to Smith:

> We have been approached about the opportunity to purchase a Priority Review Voucher (PRV). ***In the situation that the FDA doesn't accept the proposed Ozanimod strategy it would potentially enable us to keep the current timeline***.

> The team is working up some scenarios to assess the value over Ozanimod's lifetime.

### 11. The FDA Transmits Clear Feedback to Celgene and Requires It to Provide the Data for the Metabolite at the Time of the NDA Submission

313. On November 21, 2017, the FDA provided its Preliminary Meeting Comments, which responded to the questions and supportive information set out in Celgene's Briefing Book. These comments were reviewed by Martin, Smith, Curran, Lamb, Backstrom, and Saillot, among others. In its comments, the FDA clearly stated that the NDA must include complete RP112273 data at the time of submission and must ensure that the Metabolite has been adequately assessed, including (1) adequate exposure levels to the Metabolite in the non-clinical studies, and (2) long-term stability data for the Metabolite.

314. Specifically, in response to **Question 3**, which asked, "Does the Agency agree that the proposed nonclinical package, including the evaluation of major metabolites, is adequate to support the filing for the registration of Ozanimod?", the FDA did not agree, and cited the ICH M3(R2) guidance and Q&A, stating:

> You should ensure that all circulating major human metabolites (i.e., ≥ 10% of total circulating drug related material) have been adequately assessed in the nonclinical studies (see ICH M3(R2), January 2010; ICH M3(R2) Q&A, February 2013) . . . .
>
> Metabolite RP112273 is stated to account for 89% of total drug-related exposure in humans; ***therefore you will need to ensure that adequate exposure to RP112273 was achieved in a full battery of nonclinical studies, including chronic toxicity, reproductive and developmental, and carcinogenicity studies, in two species***.

315. In its response to Question 3, the FDA also informed Celgene that it could not rely on the "total agonist" approach to measuring metabolic exposure. Through this rejected approach, Celgene attempted to add up the exposures of several different compounds, including the Metabolite, in order to reach an exposure multiple above the required threshold of 1.0—a threshold

that the Metabolite exposure alone did not satisfy for some of the critical toxicology studies. Also on November 21, 2017, before Lamb learned of the FDA feedback, he wrote internally that, if the FDA did not agree with the total agonist approach, then "***RP112273 will not be qualified across all tox studies***." The FDA further stated that while Celgene had included mostly "***estimated***" nonclinical exposure multiples in the Briefing Book, ***actual*** "toxicokinetic data to document that RP112273 has been adequately assessed in the nonclinical studies" was required for the submission.

316. In response to **Question 4**, which asked, "Does the Agency agree that the overall proposed clinical pharmacology package, including the additional information planned to be provided early in the NDA review, is acceptable and support the filing for the registration of Ozanimod?", the FDA explicitly responded: "***No***. A ***complete*** clinical pharmacology package, including all relevant PK and PD studies and population PK and ER analyses is required at the time of submission." The FDA further stated that "***[f]ull [Clinical Study Reports] (including the bioanalytical and validation reports) for [the 1001 Study] and all relevant clinical PK and PD studies are needed at the time of the NDA submission***." The reference to "bioanalytical and validation reports" includes the long-term stability data required by FDA guidance (*see* ¶¶ 264-65 *supra*).

317. In response to **Question 5**, which asked, "Does the Agency agree with Celgene's proposed timing for the bioanalytical data package for the recently-identified major active metabolite RP112273?", the FDA instructed Celgene as follows:

> ***Include the Validation and Analytical Study Reports for all major active metabolites in the CSRs [clinical study reports] for all relevant PK and PD studies. These reports must be available at the time of the NDA submission***.
>
> State whether fresh or retained plasma samples were used to quantify RP112273 in the relevant clinical studies, including RPC01-1001, RPC01-1904, RPC01-1906,

RPC01-301, and RPC01-201B). ***If you used retained plasma samples to quantify RP112273 in the relevant Phase 1 studies, you will need to provide evidence that demonstrates the stability of RP112273 in human plasma at the time of the NDA submission***.

318. The same day Celgene received the Preliminary Meeting Comments, Tran sent an email to Wilson with the subject "Urgent - FDA response," asking Wilson "when he could talk . . . regarding the response." The next day, November 22, 2017, Tran asked Wilson "how much (if any) [of the data] in [Studies] 1904 and 1906 would be within the validated LTS" at the time of the submission. Wilson responded: "***None of the 1904/1906 are within stability. We need between a year to almost 2 years to cover the studies***." In a follow-up email, Tran asked Wilson to "create a table showing the required LTS and when [Celgene would have the LTS data] for each of these studies." The table that Wilson created for Tran provided dire news—Celgene needed between 382 and 1162 days of LTS data to cover the 1904, 1906, 1001, and 201B Studies.

319. After receiving the FDA's Preliminary Meeting Comments, Saillot emailed Martin and Tran on November 22, 2017 asking whether they should go forward with the November 27, 2017 meeting with the FDA. Saillot ran through the FDA's directives in his email, stating: "Question 3: ***No need for discussion – Feedback from Agency is clear*** . . . . Question 5-7: ***No need for discussion – Feedback from Agency is clear***." Saillot also confirmed that his "first reaction was we did not need a [pre-NDA] meeting" with the FDA given the clarity of the feedback. Tran weighed in expressing concern over whether a meeting with the FDA would "help or hurt," suggesting that meeting with the FDA likely would prompt further negative commentary from the Agency and/or a prohibition from filing the NDA by year's end. As a result, Celgene cancelled the face-to-face pre-NDA meeting with FDA in Washington, D.C. scheduled to take place on November 27.

320. Others within Celgene recognized that the FDA's comments upended the Company's ability to submit the NDA without the required Metabolite data and doing so would lead to an RTF. On November 27, 2017, Lamb asked Houn to review the FDA's Preliminary Meeting Comments, noting that he was assembling a "tracker" document to "help capture key gaps/challenges/etc related to the submission to ensure there is improved transparency and understanding of what will be included in the submission" and that he had "told Philippe [Martin] last week that [he] wanted to work on such a document . . . ." Houn responded to Lamb that the FDA's Preliminary Meeting Comments were "no surprise." Houn continued:

> ***I hope we do NOT submit without all the info as the risk for RTF is real. FDA has warned us. An RTF letter would state: "… on Nov. 21, 2017, we stated you must submit these data with the NDA…" . . . . In the grid, I recommend changing "Potential RTF issue" to "RTF issue." The FDA used "must submit with the NDA" for the missing info***. . . . I know this is a company disappointment but hopefully we don't compound our situation.

321. Houn testified that in addition to Lamb, she discussed her concerns about the NDA submission with Backstrom, Celgene's Chief Medical Officer.

322. On November 28, 2017, after receiving Houn's comments, Lamb emailed Backstrom and Palmisano, Corporate Vice President, Clinical Pharmacology, about documenting the deficiencies in the NDA—a topic he had discussed multiple times with Defendant Curran:

> Attached is a document that I have started to populate outlining ***data gaps, potential review challenges that could impact labelling and/or approvability and potential refusal to file concerns for the upcoming ozanimod RMS submissions***. ***Creation of this document follows a number of discussions with Terrie [Curran]*** with a goal of ensuring this information is appropriate [sic] captured and that franchise leadership and senior management have visibility and there is transparency leading up to the submission decision. . . . .
>
> The goal is to ensure we have as much transparency as possible around the program risks/challenges going into both the NDA and MAA submissions.

323. Backstrom responded to Lamb later that day following a discussion with Smith; he expressly acknowledged the prospect of an RTF letter and the potential need for additional time to prepare the NDA, and that he had discussed these issues with Smith:

> Thank you for taking the lead on this assessment. ***I spoke to Scott [Smith] and informed him of our discussions and of the effort to do a risk assessment with respect to quality of the application, potential RTF issues and my recommendation that we (you and me along with Terrie) provide this to Mark [Alles] and Scott [Smith] in advance of submitting the application***. I also highlighted the value of the [Priority Review Voucher] and that this could mitigate any delay in the approval timelines if we need some additional time for the submission.

324. Also on November 28, 2017, Curran emailed Smith, attaching a copy of Lamb's tracking document and stating: "I met with a small team this morning to review the FDAs feedback and will meet later today with the IIEC. Matt will be putting together a document [ ] to document the status of the submission, and mitigation of outstanding issues. ***I'll update you in person***."

325. On November 29, 2017, Saillot provided MacDonald with the text of the FDA's response to the nonclinical question (Question 3) from the Preliminary Meeting Comments. MacDonald responded to Saillot later that day: "An expected response from the Agency. The ***ominous*** wording I see is that the metabolite will be 'a review issue'." The FDA's draft guidance titled, "Refuse to File: NDA and BLA Submissions to CDER," provides that "[d]uring the filing review, FDA may also identify certain review issues that result in a refuse to file pursuant to § 314.101(d)(3) and other authorities . . . . some review issues may render an application incomplete and may therefore result in a refusal to file."

326. The next day, November 30, 2017, Saillot sent MacDonald a draft of the Nonclinical Overview section of the NDA filing for his review. MacDonald sent Saillot his comments to the draft section on December 3, 2017 and noted the following in the cover email: "***The document seems to suggest that everything is OK and the [compound] and metabolites have been well***

***characterized. The data simply don't support that statement*** and I think it will elicit a negative response in the mind of at least the [FDA] pharm-tox reviewer." MacDonald took issue with a statement in the draft NDA filing suggesting that RP112273 has been adequately assessed in non-clinical testing, stating: "Same comment as earlier – ***this metabolite has not been adequately evaluated*** by conventional rules of engagement and I believe this will elicit a negative response." He elaborated that RP112273 had not been qualified due to the inadequate exposure multiples for the toxicology tests and rejected Celgene's representation to the contrary: "Not sure how you [can] say this [i.e., that RP112273 was "qualified relative to repeated dose toxicity"] as the E[xposure] M[ultiple] in the carc and reprotox studies is <1 – ?" Saillot forwarded MacDonald's comments to Martin later that day. Meanwhile, MacDonald subsequently forwarded his response to one of his colleagues, stating that "Jean-Louis [Saillot] and Receptos have a problem—but their FDA/draft NDA docs only show an 'arm-waving' approach to dealing with the problem. Not the sort of client we want to be spending this much time with!"

327. On November 30, 2017, Lamb emailed Saillot, Backstrom, Tran, Kao, and Palmisano as follows:

> If we have almost 4-month stability at the time of NDA submission and amend the application during the review around the 8 month time point with additional data, we will have roughly 12-month sample stability in the NDA to support the RP112273 results from the impacted studies. Do we have a gap with samples from some studies being older than the stability that will be in the NDA and if so, which specific studies are impacted?

328. In response to Lamb's email, Tran summarized the LTS information Wilson had previously provided him on November 22, 2017, including that Celgene required over ***one to two years of long-term stability data to cover the Phase I clinical studies***:

> For the NDA, [11]2273 data are presented in 3 Clin Pharm studies and the Phase 3 (exposure-response analysis). Below is the table showing the required long-term

stability (LTS) for these studies. For the NDA, we have 4-month stability data. We plan to generate LTS data for 6, 12, 18, 24, 36, and 48 months on an ongoing basis.

| **Study** | **Maximum Samples Storage (Days)** | **When RP112273 LTS Ready** |
|---|---|---|
| RPC01-1904 (hepatic impairment) | 508 | Dec-2018 |
| RPC01-1906 (renal impairment) | 382 | Aug-2018 |
| RPC01-1001 (PK in RMS) | 393 | Aug-2018 |
| Phase 3 RPC01-201B, RPC01-301 | 1162 | Sep-2020 |

329. In addition to knowing that the deficiencies with the Metabolite testing likely would lead to an RTF, Defendants also knew that an RTF was all but certain without agreement from the FDA that Celgene would be permitted to submit certain data later than the December 2017 submission date—an agreement that Celgene did not have and could not enter into, after the Company cancelled the November 27, 2017 pre-NDA meeting with the FDA. For example, on December 13, 2017, Michael Faletto ("Faletto") Celgene's Executive Director of Regulatory Knowledge and Insights, circulated to Houn, Lamb and others the FDA's draft guidance titled, "Refuse to File: NDA and BLA Submissions to CDER." Faletto noted in his cover email that "***[g]iven the frequent discussions on potential for RTF, including asking the FDA at the pre-submission meeting***, it would be good for all leads to familiarize themselves with these requirements." The guidance provides that: "When discussing the planned submission of these applications at a presubmission meeting, the FDA and the applicant reach agreements regarding the content of a complete application for the proposed indication(s) as well as agreements, if any, on submission of minor components that may be submitted not later than 30 calendar days after submission of the original application." The guidance continues: "***Unless the applicant and the***

***FDA have agreed at the presubmission meeting to delayed submission of certain components of the application, the FDA expects applications to be complete at the time of submission***."

330. The next day, December 14, 2017, Faletto followed up on his prior email by circulating to the same recipients the CDER Manual of Policies and Procedures ("MAPP"), Good Review Practice: Refuse to File. The MAPP provided in relevant part:

> When discussing the planned submission of these applications at a presubmission meeting, the FDA and the applicant make agreements regarding the content of a complete application for the proposed indication(s) as well as agreements, if any, on submission of certain minor components that may be submitted no later than 30 calendar days after receipt of the original application. ***Applications are expected to be complete as agreed upon by the FDA and the applicant at the presubmission meeting. Incomplete applications, including applications with minor components not received within 30 calendar days after receipt of the original application, as agreed at the presubmission meeting, will be subject to an RTF decision.***

331. The MAPP further provided:

> The following policy statements emphasize CDER's expectation that applications are to be complete at the time of submission and that a piecemeal approach to building a complete application through amendments following initial submission is unacceptable. . . .
>
> CDER staff will refuse to file:
>
> Materially incomplete or inadequately organized applications that would not permit timely, efficient, and complete review by all relevant disciplines . . . .

332. The MAPP also cited several "examples of complex and significant deficiencies that may provide support for an RTF action," including: "***Failure to provide bioanalytical method validation***"—i.e., long-term stability data (*see* ¶¶ 264-65 *supra*).

### 12. Celgene Knowingly Submits a Facially Deficient and Incomplete NDA

333. The FDA had explicitly told Celgene in the Preliminary Meeting Comments that the Company must include as part of its NDA submission: (1) long-term stability data to cover all relevant clinical PK and PD studies; and (2) data demonstrating that adequate exposure to

RP112273 (i.e., an exposure multiple greater than 1.0) was achieved in a full battery of nonclinical studies, including chronic toxicity, reproductive and developmental, and carcinogenicity studies, in two animal species. The FDA's Preliminary Meeting Comments thus confirmed what Celgene had already recognized internally for months— Celgene needed to conduct further testing to fully characterize the Metabolite before submitting the NDA. Nevertheless, Celgene pressed ahead with its plan to file the NDA by the end of 2017—without the required data, and without telling investors that the submission was deficient.

334. FE 22 confirmed that Celgene moved forward and submitted the Ozanimod NDA without the required data in December 2017. FE 22 explained that one of the additional Metabolite studies was underway in December 2017, but results of that study were not to be received until April 2018—four months after the Company's self-imposed filing deadline. Celgene nevertheless chose to submit a facially incomplete NDA without the results rather than delay the filing. FE 22 had heard that Martin and Saillot "***just wanted to get the NDA out the door***." FE 20 echoed FE 22's account, explaining that the Ozanimod NDA had been "***hustled forward***."

335. Celgene's decision to push ahead with a facially deficient NDA submission which lacked the required Metabolite test results was motivated by three principal factors. First, Celgene was motivated to submit the NDA prematurely in order to begin marketing Ozanimod so that it could compete directly with Gilenya and capture market share before Gilenya went off patent in 2019. Accordingly, Celgene determined not to wait until the additional Metabolite testing was complete and instead forged ahead with the NDA submission, knowing that it was deficient and almost certain to be rejected by the FDA.

336. Second, Celgene had recently issued two negative I&I announcements regarding the failure of GED-0301, another I&I drug, and poor Otezla sales results. It could not disappoint the

market for a third time by advising investors that it was delaying the NDA filing date it had established and promised was on track for more than a year.

337. Third, many of Celgene's high-ranking employees were entitled to receive bonuses upon mere submission of the NDA to the FDA. FE 22 recounted that both Martin and Saillot received bonuses for submitting the Ozanimod NDA by year-end 2017. FE 20 similarly confirmed that the compensation for the Celgene and Receptos personnel, including Martin, was tied to the Ozanimod NDA filing. FE 20 explained that this was the "carrot" for the employees, and the higher one went up the corporate chain, the greater the amount of compensation tied to the NDA filing. Confirming these accounts, as set forth in Celgene's proxy statement filed with the SEC in 2017, Hugin, Alles, Kellogg and Smith were all entitled to performance awards based in part on the "filing of a new drug application." Notably, Hugin, Alles, Kellogg and Smith received lucrative performance awards for 2017 of $2,175,000, $2,144,623, $800,352, and $845,495, respectively, along with company stock.

338. FE 21 stated that he and his colleagues disagreed with Celgene's decision to push forward with the NDA, instead believing that the Company should wait and finish all of the necessary testing and other work before submitting the NDA. He explained that he and his colleagues could not understand why the Company would not invest the additional time to perform the necessary testing prior to submitting the NDA, especially when an RTF letter, which results from a deficient NDA filing, could severely damage Celgene's reputation. According to FE 21, there was no empirical reason for pushing ahead with the deficient filing. When FE 21 shared his thoughts with his managers, he was told to keep his views to himself.

339. In the months following Celgene's Ozanimod NDA filing, Defendants continued to tout the NDA submission and the purportedly expected FDA approval, while withholding from

investors material adverse information regarding the Metabolite and the Company's decision to submit the NDA without the requisite test results, even though the FDA told the Company in November 2017 that such results were required for approval. For example, on January 8, 2018, Celgene filed a press release in a Form 8-K with the SEC that identified the "FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)" as a "2018 Expected Operational Milestone[]." Similarly, despite the great concern that arose when Celgene found the Metabolite and Celgene's decision not to perform the required testing prior to its NDA submission, the Company highlighted other testing results in a January 25, 2018 Form 8-K, but made no mention of the Metabolite and the further Phase I testing required for FDA approval. As Celgene stated: "In December, a New Drug Application (NDA) was submitted with the FDA for ozanimod in relapsing multiple sclerosis (RMS) based on data from the phase III RADIANCE Part B and SUNBEAM trials evaluating ozanimod in patients with RMS." Finally, on February 7, 2018, Celgene filed an Annual Report on a Form 10-K with the SEC ("2017 10-K"), again representing that "***a New Drug Application (NDA) was submitted with the FDA for ozanimod in RMS*** based on data from the phase III trials evaluating Ozanimod in patients with RMS." The 2017 10-K also included a chart representing that the "Status" of Ozanimod for RMS was "Regulatory submission" and that Celgene "Entered current status" in the fourth quarter of 2017. Once again, Defendants did not make any mention of the Metabolite or the need for further testing in any of these filings with the SEC.

**13. The FDA Refuses to File the Ozanimod NDA**

340. On February 27, 2018, Celgene once again stunned the market by disclosing that it had received an RTF letter in response to its Ozanimod NDA submission.

341. The FDA can refuse to file an NDA and issue an RTF letter if it identifies clear and obvious deficiencies in a company's submission. As the FDA's Standard Operating Policy and Procedure ("SOPP") explains:

> ***[A]n RTF is based on omissions of clearly necessary information*** (e.g., information required under the statute or regulations) or omissions or inadequacies so severe as to render the application incomplete on its face and where the omissions or inadequacies are obvious, at least once identified, and not a matter of interpretation or judgment about the meaning of data submitted.

342. The SOPP provides that an RTF "[i]s not an appropriate vehicle for dealing with complex issues and close judgments on such matters as balancing risks and benefits, magnitude of clinical effect, acceptability of a plausible surrogate marker, or nuances of study design." Instead, an RTF is based on "***[s]cientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity and potency or provide adequate directions for use***." Thus, an RTF indicates the FDA's threshold rejection of an NDA based on facial inadequacies identified through a summary review of the NDA's contents, rather than an in-depth, all-encompassing review of the substantive data and information underlying the submission. In other words, receipt of an RTF letter sends a clear message that the identified deficiency is patently obvious and that the NDA should never have been filed in the first place.

343. The RTF letter, which the FDA issued to Celgene on February 23, 2018, identified both "Clinical Pharmacology" and "Nonclinical" deficiencies. With respect to the Clinical Pharmacology deficiency, the FDA stated:

> Clinical Pharmacology
>
> ***The long-term stability of RP112273, a recently identified predominant and active metabolite of ozanimod, has not yet been established***. Retained plasma samples were used to quantify RP112273 in studies RPC01-201 (Part A and B), RPC01-301, RPC01-1904, RPC01-1906 and for most of subjects in study RPC01-1001. ***The samples were analyzed outside of the long-term stability window (136 days) for RP112273, and more than one year after collection for some of the***

> ***samples. Long-term stability evaluations for RP112273 are ongoing. Per the Guidance for Industry on Bioanalytical Method Validation (2013), "Assays of all samples of an analyte in a biological matrix should be completed within the time period for which stability has been demonstrated". Because of the above issue, the clinical pharmacokinetics of RP112273 have not been adequately characterized***. The results of the pharmacokinetic analyses for RP112273 will inform critical assessments related to Zeposia dosing, e.g., the need for dosing adjustments for intrinsic or extrinsic factors that might affect the pharmacokinetic or pharmacodynamics of ozanimod. Without such information, labeling cannot be written to inform drug use in specific populations or patients taking concomitant medications.

344. With respect to the Nonclinical deficiency, the FDA stated:

> Nonclinical
>
> RP112273, an active metabolite with potency at the S1P 1 and 5 receptors similar to that of the parent compound, accounts for the majority (-90%) of drug-related material in circulation in humans. Therefore, ***you will need to demonstrate that RP112273 has been assessed in a standard battery of nonclinical studies***. To bridge to the existing nonclinical data, you would need to demonstrate adequate plasma RP112273 exposures in males and females, using the same dosing regimens used in the pivotal studies, in all species tested. ***Based on a preliminary examination, the available TK data are insufficient to allow a determination of the adequacy of the safety assessment for RP112273***.

345. There is little publicly available information regarding the frequency of RTF letters because the FDA does not release information on the subject and companies have no independent obligation to disclose RTFs. However, the available public information suggests that RTF letters are exceedingly rare. For example, using the subscription data service BioMedtracker, *Forbes* reported that the FDA issued just forty-five RTF letters in connection with NDA applications in the sixteen-plus years between December 31, 2001 and February 28, 2018. Moreover, receipt of RTFs by experienced and well-capitalized pharmaceutical companies like Celgene is virtually unheard of. As William Blair stated in a report entitled, "While Not a Crisis for Ozanimod, FDA's RTF Letter Represents Another I&I Franchise Setback and Could Lead to a One-Year Delay," published in the wake of the FDA's RTF for Ozanimod: "In our view, well managed and high

quality large-cap biotech companies do not make execution mistakes like the one disclosed on Tuesday [by Celgene]."

346. Celgene broke the news of the RTF letter to investors in a February 27, 2018 press release, stating: "Upon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review."

347. Analysts expressed both shock and concern upon the Company's revelation of the RTF. For example, Leerink Partners noted in a report entitled "How Many Self Inflicted Wounds Are Excusable? Ozanimod Delay at Least a Year," that the RTF "only adds to investors' growing unease with the company's direction and oversight of key activities" and observed that "***the company clearly made a decision to file this application at risk***, despite late information that might have been more thoroughly disclosed and explored in the application, had the filing been postponed by a few months." As Leerink Partners further explained:

> Celgene appears to have ***gambled on the ozanimod filing in December 2017*** while knowing about the unanticipated finding from a late-stage clinical pharmacology trial [i.e., the Mass Balance Study] after the two phase IIIs read-out successfully. ***This study seemed to duplicate the type of study that would originally have been completed by Receptos, and the completion of the study itself suggests some recognition of a deficiency in the early clinical package prepared by the prior owner***.

348. William Blair also wrote: "Obviously, investors are frustrated by another setback in the autoimmune franchise, especially in light of late last year's mongersen failure in Crohn's disease, clinical delay for ozanimod in ulcerative colitis, and soft third-quarter sales for Otezla."

349. In the wake of the RTF announcement, the price of Celgene's common stock fell from $95.78 per share on February 27, 2018 to $87.12 per share on February 28, 2018.

### 14. Celgene Admits Internally That It Failed to Provide the Data Expressly Requested by the FDA

350. In a February 27, 2018 email to Backstrom and Palmisano, Lamb re-forwarded Tran's LTS chart from November 30, 2017 (at ¶¶ 327-28 *supra*), stating:

> Some of the studies are complete but we don't have the required sample stability for the RP112273 metabolite. Please see the below table which provides dates for when we will have the required sample stability for some of the Clin Pharm studies in 2018. In the table you will see that we won't have the required stability data for the phase 3 samples until 2020. This is part of the equation. Once we have the stability data, we can consider the studies as "valid" as it relates to us having going back and used retain[ed] plasma samples for the RP112273 characterization.

351. In the same email, Lamb acknowledged that the FDA never agreed to permit Celgene to supplement the Ozanimod NDA submission with stability data following the submission in December 2017:

> ***FDA didn't agree to anything and they[]stated repeatedly that the CSRs [clinical study reports], BARs and stability data needed to be in the original submission***. Even in a subsequent email exchange FDA stated reports needed to be submitted at [] the time of the NDA submission (not within 30 days which we proposed via email).

352. Tran corroborated Lamb's comments in a February 27, 2018 email to Palmisano. Tran wrote: "[T]he FDA wanted LTS data and would not accept those during the NDA review. ***In the pre-NDA feedback, the FDA specifically requested LTS data for studies 1001 (PK/PD in RMS), 1904 (hepatic impairment) and 1906 (renal impairment)***."

353. On March 15, 2018, Faletto asked Lamb if he would address the audience at an upcoming Celgene Regulatory Affairs meeting. Lamb responded: "I will be happy to speak to ozanimod and the RTF in the opening and try to answer any questions folks may have. There isn't much to learn from a Regulatory Affairs perspective. ***FDA repeatedly stated what they expected, it was ignored and we got a RTF***."

354. A similar acknowledgment that Celgene ignored the FDA's directives was made to the Company's Board of Directors. On or about April 3, 2018, a presentation prepared by Backstrom and his team describing the circumstances leading to the RTF was given to the Board of Directors. One of the presentation slides, entitled "Ozanimod-Related Correspondence with the FDA," stated the following: "Feb 2018: . . . ***FDA issues Refusal to File Letter, identifying nonclinical and clin pharm deficiencies consistent with the pre-NDA meeting feedback***."

355. On April 3, 2018, Celgene had a Type A meeting with the FDA to discuss Celgene's proposal for addressing the deficiencies identified in the RTF. As reflected in the minutes from this meeting that were provided to Celgene on April 7, 2018, Celgene proposed to remedy its failure to include the necessary LTS data in the NDA submission by providing 17-month LTS data in the re-submission and the FDA generally agreed to this proposal, but noted the possibility that "unexpected issues" could "aris[e] during the review." With respect to the nonclinical deficiency, Celgene proposed a "bridging strategy" in an attempt to demonstrate adequate exposure to the Metabolite in the completed toxicology studies. The FDA indicated that "[o]n face, [Celgene's] proposed bridging strategy appears sufficient," but noted that "the plasma RP112273 exposures achieved in the mouse and rat carcinogenicity studies are not adequate, in the absence of data indicating higher RP112273 exposures would not be tolerated or feasible to achieve." As the FDA further stated: "Therefore, studies (in two species) to assess the carcinogenic potential of RP112273 may be needed, unless additional information can be provided that support the adequacy of the ozanimod doses tested in the completed studies."

### 15. Celgene Admits Publicly That the RTF Was Due to Its Failure to Fully Test the Metabolite

356. Smith, who had been promoted from head of I&I to Chief Operating Officer in April 2017, was ushered out of Celgene in April 2018. George Golumbeski, Celgene's head of business

development who was lauded as the chief architect of Celgene's acquisition strategy, also left the Company in April 2018. In addition, Defendant Martin was relieved of his responsibilities at Receptos in June 2018 and, according to FE 22, the employees within Martin's command at Receptos were let go after Celgene received the RTF. Furthermore, the 2018 proxy statement removed the "filing of a new drug application" as a factor in deciding upon senior management performance awards.

357. On April 25, 2018, several scientists gave a presentation at the American Association of Neurology ("AAN") 2018 Annual Meeting in Las Vegas, Nevada entitled "Safety of Ozanimod Versus Interferon β-1a in Two Multicenter, Randomized, Double-Blind, Parallel-Group, Active-Controlled, Double-Dummy Phase 3 Studies in Relapsing Multiple Sclerosis (SUNBEAM and RADIANCE Part B)." This presentation, which was partially funded by Celgene, disclosed to investors certain specifics of the Metabolite, dubbed CC-112273 by the Company, stating that: "Ozanimod is metabolized in humans to form one major active and other minor active metabolites"; "CC112273 accounts for the majority of the total activity of ozanimod in humans"; and "CC112273 is a minor metabolite in animal species."

358. Just days after the 2018 AAN annual meeting, the market learned that the additional preclinical work required to test the Metabolite could delay Celgene's refiling of its Ozanimod NDA for ***up to three years***. This is precisely the kind of significant delay that the FDA guidance cautions that drug companies should avoid by conducting the required metabolite safety testing early, before NDA submission. Specifically, on April 29, 2018, Morgan Stanley published a report entitled "More Bread Crumbs Yield Less Confidence In Ozanimod" that provided a detailed analysis comparing the recently disclosed information regarding the Metabolite to the data from the Company's earlier pre-clinical studies involving Ozanimod's other metabolites. This analysis

demonstrated that Celgene would need to run additional pre-clinical toxicology studies, which could take six months to two years. Thus, when combined with the time needed to start the studies, produce the study results and refile the NDA, these additional studies would result in a total delay of one to three years. In response to the news of a further delay, Celgene's common stock fell from $91.18 per share on Friday, April 27, 2018 to $87.10 per share on Monday, April 30, 2018, the next trading day.

359. During its first quarter 2018 conference call on May 4, 2018, Celgene confirmed that the RTF arose as a result of the Metabolite and that Celgene had belatedly discovered the Metabolite through the Mass Balance Study. Backstrom stated, in part: "***[T]he key issues for the Refusal to File centered on the completeness of the clinical pharmacology and the nonclinical portions of the NDA***. These issues relate to the major active metabolite, CC-112273." Specifically, Backstrom stated that Celgene conducted "a radio-labeled human mass balance study" that "identified CC-112273 as a major metabolite, accounting for approximately 90% of the activity" and that CC-112273 "disproportionately formed in humans and was not identified as a major metabolite in the nonclinical [i.e., animal] pharmacology studies." Backstrom further revealed that the half-life of the Metabolite is ***ten to thirteen days***, compared to the previously reported Ozanimod half-life of nineteen hours, thus confirming that Ozanimod had lost one of its key competitive advantages over Gilenya.

360. Celgene admitted that, upon review of the Ozanimod NDA, the FDA "requested further characterization of CC-112273." Alles claimed to be surprised by the FDA's decision, stating that: "[T]he hindsight view is that the characterization of [the] metabolite was something that we simply underestimated in the context of FDA's decision." FE 2, however, rejected

Defendants' claims, stating that, based on his experience with more than five NDA submissions, it was "incomprehensible" that Celgene was surprised by the FDA's interest in the Metabolite.

361. In explaining the Company's plan for Ozanimod going forward, Backstrom stated that after the Company's meeting with the FDA in early 2018, Celgene planned to utilize data from the existing and ongoing clinical pharmacology studies to provide the requisite safety assessment for the Metabolite. Backstrom also attempted to reassure investors: "***This work is well underway and will be incorporated into a new submission now targeted for Q1 2019***."

362. Following Celgene's first quarter 2018 conference call, analysts and other commentators condemned Celgene for its decision to file the NDA without adequate characterization of the Metabolite. An *In the Pipeline* article entitled "Finger-Pointing at Celgene," questioned: "[W]hy wasn't [the] issue [of the Metabolite] fully addressed for the FDA?" The article stated that Celgene should have discovered the Metabolite during Phase I testing:

> Analyzing blood levels of the parent compound and metabolites is one of the biggest points of Phase I, actually, so it's not like this could have been overlooked. If you find out that what you thought was your drug is apparently just a prodrug for what's really working *in vivo*, well, you have more work to do. ***But it appears that lack of data about the metabolite could have been one of the main reasons the FDA found the NDA unworkable, which just makes no sense***.

**16. Celgene Attempts to Blame Receptos for the RTF**

363. In an effort to deflect criticism for the RTF debacle away from Celgene itself, Defendants blamed Receptos for the deficient NDA filing, but in doing so, admitted that they knew the NDA was faulty upon submission. Specifically, Nadim Ahmed, President of Celgene's Hematology & Oncology Divisions ("Ahmed"), stated in a June 13, 2018 *Financial Times* article that "***I think that 99 percent of folk[s] at Celgene wouldn't have submitted [the NDA],*** but we had Receptos out on the West Coast and, for whatever reason, the decision was made to submit . . . . We learned a lesson of humility and that when you do an acquisition it's better to be

more integrated rather than be completely away from the mothership." Ahmed's comments, which confirmed that Celgene knew that its NDA filing was deficient prior to submission, thoroughly undermined Alles's representation to investors that the FDA's focus on the Metabolite was unanticipated and something that the Company "underestimated." Ahmed also stated that FDA officials were "actually quite surprised" with the deficient quality of the Ozanimod NDA and that "[the FDA] kinda said 'what happened guys, this isn't what we usually expect from Celgene?' And we had to say, you know, '***mea culpa, it's on us***.'"

364. The former CEO of Receptos, Faheem Hasnain ("Hasnain"), quickly disputed Ahmed's attempt to place all the blame on Receptos and leave Celgene unscathed. Hasnain emphasized to the market that "[i]t's important to know that ***Celgene had on-site control and oversight for two-and-a-half years before this filing took place***," and made clear that at the time of Celgene's acquisition of Receptos in mid-2015, Receptos "had mapped out the rest of the development and regulatory plans, with the rest of the pharmacology studies that needed to be done in a timely fashion." Hasnain's comments were echoed by Frohna, the former Vice President of Clinical Development and Translational Medicine at Receptos, who was "responsible for conducting positive Phase 2 clinical trials and two ongoing Phase 3 trials with Ozanimod in relapsing multiple sclerosis (RMS) and ulcerative colitis." In a user comment responding to the article in which Hasnain was quoted, Frohna stated: "***Thanks for setting the record straight Faheem! You beat me to it*** . . . ."

365. FE 21 and his colleagues were not surprised by what they called the "bullshit blame game" that followed the RTF. FE 21 further stated that the idea that the final NDA submission could be made without the approval of Celgene's leadership was nonsensical. Likewise, FE 22 explained that the NDA would not have been submitted without the approval of Celgene

headquarters, as it was too important a decision to be made at the Receptos executive level. FE 2 also rejected Celgene's attempt to cast blame on Receptos.

366. FE 20 further confirmed that Celgene's statements attempting to shift blame to Receptos for the RTF were empirically false, stating that "they [Celgene] were in charge. Receptos was not." FE 20 added that when Celgene acquired Receptos, Celgene moved in and took over, installed a new head of Receptos, had control over Receptos' budget, took Receptos out of the decision-making loop, placed Receptos under the control of Celgene's New Jersey headquarters, and decisions were made by Celgene in New Jersey or Celgene personnel located onsite at Receptos.

367. Given the sheer number of senior officers and personnel within Celgene aware of the Metabolite, the delays caused by the additional testing required to characterize the Metabolite, and the deficiencies with the NDA submission, Defendants' misstatements and omissions constituted a pervasive fraud on the Company's shareholders.

### D. Celgene's Process for Corporate Disclosures Regarding Clinical Development and Financial Performance During the Class Period

368. As a U.S.-listed public company, Celgene released earnings and other corporate information on a quarterly basis during the Class Period. The Company did so through public filings on SEC Forms 10-Q and 10-K, and also through quarterly earnings calls, press releases, and investor slide presentations Celgene posted on its website in conjunction with its quarterly earnings calls. The Company also published press releases upon important corporate events at other times throughout the year.

369. From at least 2016 through April 2, 2018, Celgene's quarterly disclosures in press releases, earnings calls, related investor slide presentations, and SEC Forms 10-Q and 10-K were prepared and finalized through an internal corporate process involving the Company's senior

executives (the "Quarterly Disclosure Process"). The chief participants in the Quarterly Disclosure Process included the Company's CEO, its CFO, its President and COO, the President of the Hematology and Oncology franchise, and the President of the I&I franchise. Thus, Smith personally participated in Celgene's Quarterly Disclosure Process at all relevant times, with responsibilities first as the President of I&I (through March 31, 2017) and then as President and COO of the Company (from April 1, 2017 through April 2, 2018). Defendant Curran personally participated in the Quarterly Disclosure Process as the President of I&I from April 1, 2017 through the end of the Class Period. Representatives from Celgene's legal and investor relations departments also participated.

370. Celgene's Quarterly Disclosure Process entailed a joint drafting and review undertaking by Celgene's executives that followed a typical cadence in each quarter. The script for the prepared remarks for the given quarter's earnings call was drafted by the executives with speaking roles on the call. The draft earnings call script would then be reviewed and edited by other participants. This collaborative review process typically occurred over several days just prior to the given earnings call, with edits and revisions normally provided in meetings and in emails containing draft documents showing proposed edits and comments in "redline."

371. To the extent information in an earnings call script related to a particular franchise, specifically including clinical development matters regarding products within that franchise, such information was provided to the Quarterly Disclosure Process by the head of the franchise. Thus, for example, if an earnings call script discussed the clinical development of an I&I product, the information regarding that topic was provided by the President of I&I. According to Smith, the President of I&I, in turn, typically obtained such information from the relevant clinical

development project leader within I&I, including Defendant Martin, who headed the Ozanimod NDA project.

372. In the Quarterly Disclosure Process, investor slide presentations that accompanied quarterly earnings calls and their attendant scripts were drafted, reviewed, revised and finalized concurrently and in a similar manner as earning call scripts. Members of Celgene's investor relations department typically drafted initial proposed slides and talking points. The executives in the Quarterly Disclosure Process then revised and finalized them through a joint, iterative process in the days leading up to the day of the earnings call, reviewing drafts in meetings and emails and providing edits and comments, often in redline form. Here again, language regarding clinical development issues in a particular franchise was handled by the head of the relevant franchise.

373. Smith and Curran and the other participants in the Quarterly Disclosure Process reviewed drafts of the press releases that Celgene published in conjunction with its earnings calls. From at least April 1, 2017 through April 2, 2018, Smith and Curran reviewed drafts of the press releases, provided input and comments, and participated in finalizing them. As with Celgene's other public disclosures, if a press release contained information concerning a clinical development matter within the I&I franchise, that information would be provided for purposes of the press releases by the project leaders within I&I, including Defendant Martin, who headed the Ozanimod NDA project.

374. Celgene's senior management, including between April 1, 2017 and April 2, 2018, provided review and input to draft Celgene press releases, whether quarterly or released at other times, through an iterative process, reviewing drafts (often via emails) and providing edits and comments, often in redline form.

375. Information was similarly provided by I&I for purposes of Celgene's Forms 10-Q and 10-K. In the Quarterly Disclosure Process, the head of I&I would review sections of the 10-Q or 10-K that related to the I&I franchise and provide comment and input. After the franchise presidents had completed their review, the draft 10-Q or 10-K would go to the President and COO as well as the CEO and CFO, for their review, and for finalization.

## V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

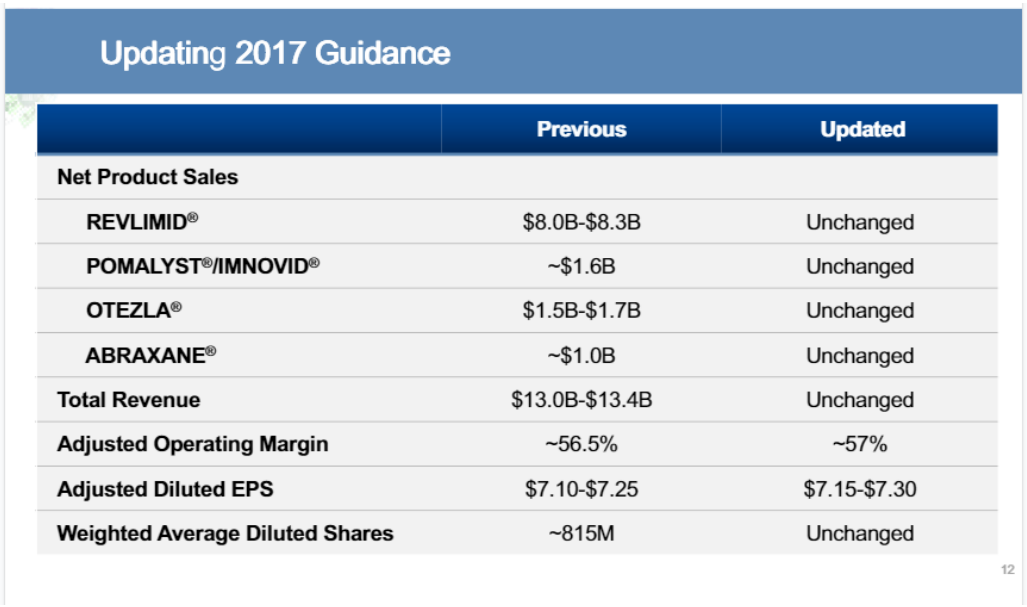
376. During the Class Period, Defendants made a series of materially false and misleading statements and omitted material facts regarding: (i) the current state of the market for Otezla, Otezla's purported success to date, and Otezla's ability to gain market acceptance and market share; and (ii) the completeness of the Ozanimod NDA for MS, the sufficiency of the underlying testing data, and the undisclosed discovery of a key, active metabolite that required further testing.

### A. Otezla

377. On April 27, 2017, Celgene hosted a conference call to discuss the Company's financial results for the first quarter of 2017. During this call, when explaining the first quarter Otezla net product sales miss, Kellogg omitted any reference to the myriad issues impacting Otezla sales evidenced by internal Celgene documents and communications, and recounted by Celgene former employees and falsely suggested that the new large payer contracts would improve Otezla's market share and, by extension, revenues, stating:

> As a reminder, the sequential performance from Q4 to Q1 is always impacted by several items . . . OTEZLA is impacted by managed care dynamics that drive lower total marketplace prescriptions for psoriasis therapies in Q1. In addition, a new dynamic for OTEZLA this quarter was a higher gross-to-net adjustment related to new contracts with several large payers that were implemented in January. These new contracts approximately doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy, which has already improved OTEZLA's market share in these accounts.

378. In connection with this conference call, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, reiterated that the previously issued 2017 guidance for Otezla remained "Unchanged."



Updating 2017 Guidance

| | Previous | Updated |
|---|---|---|
| **Net Product Sales** | | |
| REVLIMID® | $8.0B-$8.3B | Unchanged |
| POMALYST®/IMNOVID® | ~$1.6B | Unchanged |
| OTEZLA® | $1.5B-$1.7B | Unchanged |
| ABRAXANE® | ~$1.0B | Unchanged |
| **Total Revenue** | $13.0B-$13.4B | Unchanged |
| **Adjusted Operating Margin** | ~56.5% | ~57% |
| **Adjusted Diluted EPS** | $7.10-$7.25 | $7.15-$7.30 |
| **Weighted Average Diluted Shares** | ~815M | Unchanged |

12

379. Smith added with respect to Otezla: "The momentum we see in Q2 across a number of fronts gives us confidence that we will deliver on our full year 2017 guidance of $1.5 billion to $1.7 billion."

380. In responding to a request from a UBS analyst that the Company "walk through what gives you confidence [that Otezla] growth will bounce back," Curran also omitted any reference to the myriad issues impacting Otezla sales evidenced by internal Celgene documents and communications, and recounted by Celgene former employees, and falsely stated:

> I think there was really 3 key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased [gross to net] as a result of the contracting. But importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw a minimal drawdown in inventory. Importantly, if we look at the underlying dynamics of the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients. And these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter 1 and into

quarter 2, we do see the net sales rebounding and on track to deliver our 2017 guidance.

381. Analysts seized on Defendants' reaffirmation of the 2017 Otezla guidance notwithstanding the first quarter miss and emphasis on claimed market share growth. For example, BMO Capital Markets noted in an April 27, 2017 report that: "Management reiterated FY2017 Otezla sales of $1.5-1.7bn." UBS stated in an report issued the same day that "Celgene reiterated confidence in achieving 2017 guidance and the longer term outlook for Otezla, citing consistent market share growth (>40% of new patients), narrowing its position behind Stelara in the psoriasis market, and new contracts that increase market access and share" and an April 28, 2017 JMP Securities report observed: "We note that previous guidance of $1.5bil to $1.7bil in net Otezla sales for 2017 remains intact despite this soft quarter."

382. The statements set forth in ¶ 380 above, including Defendants' statements reaffirming the 2017 Otezla sales guidance, stating that there was a minimal drawdown of inventory, that Otezla continued to grow market share, that exit run rates out of quarter 1 and into quarter 2 supported a rebound in net sales and placed Otezla on track to deliver the 2017 Otezla sales guidance, and attributing the slow-down in first quarter 2017 Otezla sales to a "contraction in the overall market volume of prescriptions filled," "increasing gross-to-net adjustments" and "managed care dynamics," were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 94-184 above, at the time Defendants issued these statements, Defendants knowingly or recklessly misrepresented, concealed and/or failed to disclose that:

(i) Defendants' Otezla pricing strategy ensured that Celgene would never attain the growth in sales and revenues necessary to meet the 2017 guidance;

(ii) Celgene sales representatives from across the country were reporting flat Otezla sales growth from the date of the drug's March 2014 launch;

(iii) Otezla's total sales units, gross revenue, and net revenue far underperformed the 2017 Budget forecast for the first quarter of 2017, and April sales, which were flat as against the 2017 Budget forecast, did not make up any ground from the unexpected sales miss in the first quarter;

(iv) Curran and other Celgene executives received and discussed a presentation on April 26, 2017, which stated that Otezla sales were only at 83% of the 2017 Budget to date;

(v) During the third and fourth quarters of 2016, Smith, Curran, and other members of the IIEC and CPMAC were explicitly warned by both Celgene's Senior Vice President of I&I and a senior executive in the U.S. Market Access group that Celgene could not meet the 2017 Otezla guidance and that these numbers should be lowered;

(vi) Tessarolo, Senior Vice President of I&I, U.S., had again warned Defendants in early 2017 that the Company needed to downgrade its 2017 Otezla revenue forecast;

(vii) FE 17 recounted that the Forecasting team was "told to change" the numbers (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth;

(viii) FE 18 confirmed that when Defendants were assessing the 2017 Otezla market access and setting the 2017 targets, the market did not support even close to 57% growth;

(ix) Otezla was plagued by issues including step-edits, poor insurance coverage, and inferior efficacy compared to competitors that impaired its sales and attendant revenues;

(x) Defendants, including Curran, also knew, or were reckless in not knowing, of governmental and independent non-profit reports categorizing Otezla as the least effective drug among its competitors in the PsO and PsA market baskets, including the CDEC and NICE reports, in October 2016 and February 2017, which Curran personally received;

(xi) Defendants' decision to allow wholesalers to buy Otezla in excess of their demand in the fourth quarter of 2016 negatively impacted the first quarter 2017 Otezla sales;

(xii) Otezla's inventory exceeded 20 DOH at year-end 2016, which was well-above normal levels; Curran and other executives learned and discussed that "inventory adjustment" was one of the key factors "driving Q1 weaknesses;" and Otezla's NRx demand metric was also negative and trending downward;

(xiii) The overall PsO and PsA markets contracted in the first quarter of 2017, and internal assessments, internally shared with and discussed by Curran and other Celgene executives, but not revealed to the public, assumed the material risk that

the PsO and PsA markets would continue to contract well-below 2017 Budget forecast assumptions and through year-end.

(xiv) Otezla's market share was flat to declining in both the PsO and PsA segments in the first quarter of 2017;

(xv) Internal Otezla market share assessments, internally shared with and discussed by Curran and other Celgene executives, but not revealed to the public, assumed the material risk that Otezla's share of the PsO market would decline by over 1.5% from 2017 Budget forecast assumptions and through year-end;

(xvi) The market size and market share risk assumptions alone equaled approximately $140 million in net revenue risks, as reflected in internal presentations and assessments received and discussed by Curran and other Celgene executives throughout the first quarter of 2017 and not disclosed to the public;

(xvii) The newly-entered PBM contracts Defendants claimed "doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy" were dependent on forecasted Otezla market share increases but Otezla was not achieving those increases;

(xviii) Those newly-entered PBM contracts had each underperformed Celgene's 2017 Budget forecast in terms of prescription volume for the first quarters of 2017, and ESI and Prime underperformed the 2017 Budget forecast for total market share in the first quarter of 2017;

(xvix) FE 18 recounted that it was clear from the beginning of 2017, based on the models that his team was running monthly, that the PBM contracts were not meeting revenue expectations and Celgene eventually lowered the expectations on many of these PBM contracts internally;

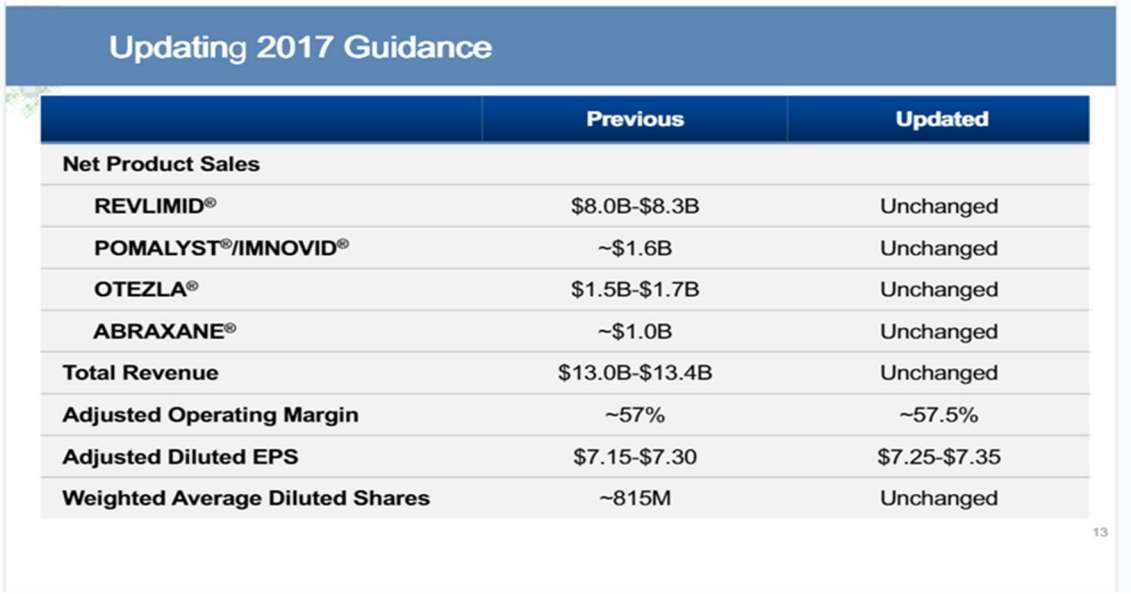
(xx) In discussing the "exit run rates out of quarter 1 and into quarter 2," Curran did not disclose that Otezla's unit forecast for the second quarter of 2017 had already been downgraded by approximately 12,000 units from the 2017 Budget in the March 2017 LE, nor that Celgene executives chose the "exit run rate" based solely upon the amount of unit sales necessary to achieve that revised forecast and in contrast to the Company's standard forecasting methodologies; and

(xxi) Curran did not explain that she and other Celgene executives had decided, absent any reasonable basis, to add over 15,000 units of sales onto the forecast for the fourth quarter of 2017, after Otezla sales fell short by 27,000 units in the first quarter of 2017; that Celgene downgraded the second quarter of 2017 unit forecast; and that, absent the change in the forecasted additional unit sales in the fourth quarter of 2017 (which were not part of the original 2017 U.S. Budget and unsupported by any reasonable sales metrics), Celgene could not achieve the 2017 U.S. Budget forecast or the public guidance.

By electing to speak publicly about Celgene's 2017 Otezla sales guidance and related sales, inventory demand, market share, and other metrics—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding those specific metrics, and that there was no reasonable basis to misrepresent that Otezla sales would meet the public guidance given the numerous issues impacting Otezla net revenue.

383. On July 27, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC announcing certain operating and financial results for second quarter 2017. In the press release attached to this Form 8-K, Celgene stated that the 2017 net sales projections for Otezla remained "Unchanged" at between $1.5 billion and $1.7 billion.

384. On July 27, 2017, Celgene hosted a conference call to discuss the Company's second quarter financial results. In connection with this conference call, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, again stated that the 2017 financial guidance for Otezla remained "Unchanged."



Updating 2017 Guidance

| | Previous | Updated |
|---|---|---|
| **Net Product Sales** | | |
| REVLIMID® | $8.0B-$8.3B | Unchanged |
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| OTEZLA® | $1.5B-$1.7B | Unchanged |
| ABRAXANE® | ~$1.0B | Unchanged |
| **Total Revenue** | $13.0B-$13.4B | Unchanged |
| **Adjusted Operating Margin** | ~57% | ~57.5% |
| **Adjusted Diluted EPS** | $7.15-$7.30 | $7.25-$7.35 |
| **Weighted Average Diluted Shares** | ~815M | Unchanged |

13

385. Curran also spoke during the July 27, 2017 conference call, in which she made the following materially false and misleading statement: "Q2 was an outstanding quarter for Celgene

I&I, highlighted by significant sequential growth for OTEZLA. Key OTEZLA performance indicators continue to strengthen, and market share and prescriber adoption increased significantly in both U.S. and internationally."

386. Analysts once again reiterated Defendants' reaffirmation of the 2017 Otezla guidance. For example, Morgan Stanley stated in a July 28, 2017 report that: "Mgt. reaffirmed prior 2017 net product sales guidance, with . . . Otezla of $1.5B-$1.7B." Analysts also referenced statements relating to increased Otezla market share and prescriber adoption. For example, SunTrust stated in a July 27, 2017 report that: "Otezla is already benefiting from expanded coverage and showed a substantial rebound in growth (Street was expecting a miss) . . . . In 2Q17, U.S. sales growth was driven by increased prescriber adoption and market share gains (benefiting from expanded coverage) . . . ."

387. The statements set forth in ¶ 385 above, including Defendants' statements stating that "Key OTEZLA performance indicators continued to strengthen," and misrepresenting that Otezla "market share and prescriber adoption increased significantly in both U.S. and internationally," were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 94-207 above, at the time Defendants issued these statements, Defendants knowingly or recklessly misrepresented, concealed and/or failed to disclose that:

(i) Otezla's market share was "flat," and that Otezla's market share in the second quarter of 2017 actually declined rather than "increased significantly," which was shown by multiple internal Celgene presentations provided to Curran and other Celgene executives, as well as data showing that Otezla's market share did not increase over the quarter;

(ii) Curran personally recognized in multiple emails that Otezla's market share was "flat" in the second quarter of 2017;

(iii) Curran personally received presentations, information, and other data demonstrating that a decline in Otezla's market share constituted one of the key "risks" that could impact the 2017 Budget assumptions and the Company's public guidance;

(iv) Curran, knew, or was reckless in not knowing, that "prescriber adoption" did not increase significantly in the second quarter of 2017; instead, new patient growth declined on average, and Otezla's share of new-to-brand prescriptions remained relatively flat throughout the second quarter of 2017;

(v) Celgene had adjusted its internal forecast assumptions downward in the first quarter of 2017 regarding both the overall PsO and PsA markets and Otezla's market shares therein; and, all told, these adjustments should have reflected a substantial forecast reduction from Celgene's 2017 Budget and Celgene's March forecast LE based on the contracting market basket and Otezla's declining market share, even before Otezla's market share declined further in both the PsO and PsA markets in the second quarter of 2017;

(vi) Internal reports, received by Curran and other Celgene executives, also depicted a decline in Otezla's new patient growth following the entry of new drugs into the market, including a 12% decrease in New to Product Prescriptions between December 31, 2016, and April 7, 2017 (in contrast to a significant increase in growth regarding the new drugs);

(vii) Curran knew, or was reckless in not knowing, that the PBM contracts had each underperformed Celgene's 2017 Budget forecast in terms of total within-plan market share (and total unit sales) for the second quarter of 2017; and

(viii) At the time of the July 27, 2017 statements, Otezla sales had underperformed the 2017 Budget in terms of total unit prescriptions and net revenue for the first half of 2017; that Otezla's dismal July 2017 sales were far below Celgene's 2017 Budget forecast and the June forecast LE; and that DOH inventory levels rose to high levels existing in the second quarter of 2017, which would further drive sales weakness in the third quarter of 2017 given the state of Otezla's market share and weaknesses in other key performance indicators.

By electing to speak publicly about Celgene's market share and prescriber adoption—and thereby putting those subjects into play—Curran had a duty to fully, completely, and truthfully disclose all material facts regarding Otezla performance metrics and the fact that Otezla's market share and prescriber adoption did not "increase significantly" in the second quarter of 2017. As a result of the foregoing undisclosed material facts, as well as Curran's affirmative false and fraudulent misrepresentations, Curran's public statements lacked a reasonable basis and were materially false and misleading at all relevant times.

**B. Ozanimod**

388. As detailed above in ¶¶ 254-56, by no later than April 2017, Defendants possessed data from the Mass Balance Study evidencing the existence of a new Ozanimod metabolite. Former employees referred to the metabolite finding as a great concern, which required the collection of additional data, including time-consuming Phase I testing, which would prevent the filing of a complete NDA in 2017. The former employees also stated that the submission of the NDA for Ozanimod without the testing and data would lead the FDA to reject the NDA and issue an RTF (which the FDA did). In the face of these and other undisclosed material facts, Defendants issued the following material misrepresentations and omissions during the Class Period.

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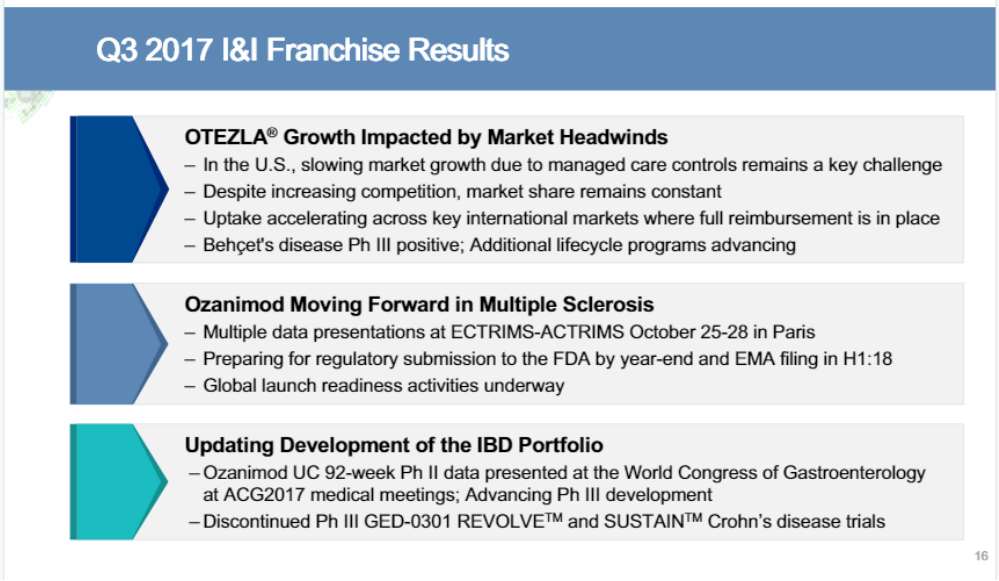
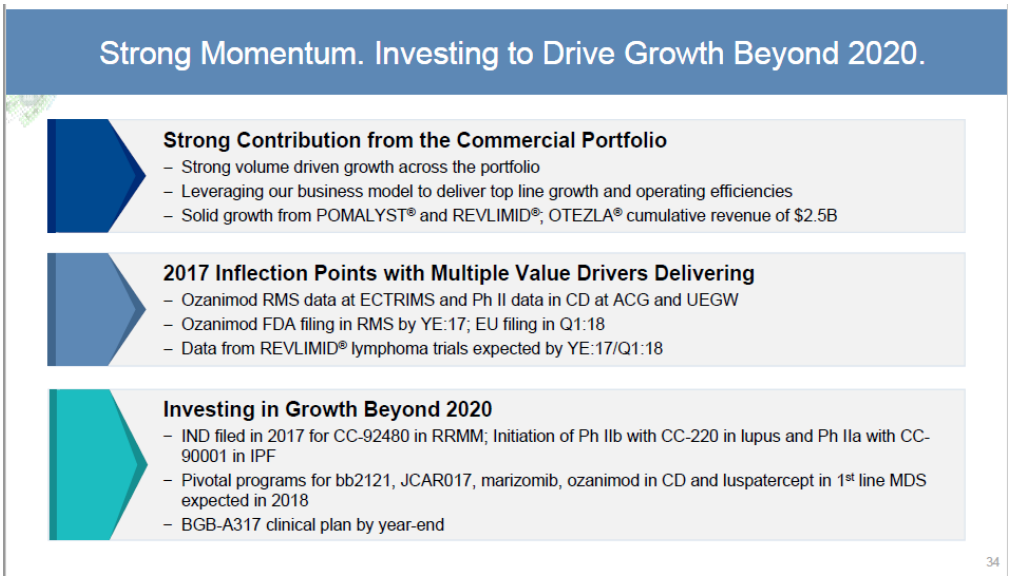
406. On October 26, 2017 Celgene filed a Form 10-Q, signed by Alles and Kellogg, with the SEC. This Form 10-Q represented: "[W]e have phase III trials underway for ozanimod in relapsing multiple sclerosis." Consistent with Celgene's standard Quarterly Disclosure Process, information was furnished for this statement by the I&I franchise, including the Ozanimod NDA team, which was fully aware of the Metabolite. Smith, Curran, and Martin also had known about the Metabolite for months, as of October 26, 2017. Smith, as President and COO of Celgene, reviewed this statement in a draft of the Form 10-Q after I&I franchise leadership had reviewed it.

407. On October 26, 2017, Celgene also hosted a conference call to discuss the Company's third quarter 2017 financial results. In connection with the October 26, 2017 conference call, Celgene issued and published a series of slides on its corporate website. One of the slides, which was presented by Curran, stated that Ozanimod was "***moving forward in Multiple Sclerosis***" and Celgene was "***[p]reparing for regulatory submission [of the Ozanimod NDA] to the FDA by year-end***."




408. Curran presented an additional slide that stated that Celgene would "***[s]ubmit ozanimod U.S. NDA in RMS by YE:17***."


409. Another slide, presented by Smith, characterized Celgene's "***[o]zanimod FDA filing in RMS by YE:17***" as an inflection point in 2017 that would drive growth for Celgene.




410. Paragraph intentionally left blank.

411. On October 26, 2017, Celgene issued a press release, which announced certain of the Company's financial and operating results for the quarter ended September 30, 2017. This press release included "Product and Pipeline Updates" for the I&I franchise and stated, "***Celgene plans to submit a New Drug Application (NDA) to the FDA for Ozanimod in RMS by year-end.***" Consistent with Celgene's standard Quarterly Disclosure Process, information was furnished for this statement by the I&I franchise, including the Ozanimod NDA team, which was fully aware of the Metabolite. Smith, Curran, and Martin also had known about the Metabolite for months, as of October 26, 2017.

412. Following Defendants' October 26, 2017 statements, analysts and other media outlets again reiterated Defendants' representations regarding Celgene's timeline for submission of the Ozanimod NDA. For example, BTIG Equity Research stated in an October 26, 2017 report: "We expect ozanimod to be ***approved*** for MS during 2H2018 (US NDA sub for [R]MS YE2017)." The Dow Jones Institutional News reported in an October 26, 2017 article: "Celgene plans to submit a New Drug Application (NDA) to the FDA for ozanimod in RMS by year-end."

413. Two days later, on October 28, 2017, Celgene held an Investor Event at the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis. During this event, Martin issued misrepresentations concerning Ozanimod.

414. In discussing the Ozanimod "development program" during the event on October 28, 2017, Defendant Martin stated:

> [T]he RADIANCE study and the SUNBEAM study will form the basis of our submission to the FDA and to [the] EMA. ***For the FDA, we are working hard as we speak to get ready to file by the end of the year***.

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417. In reporting on Defendants' statements at the MSParis2017 meeting, Oppenheimer focused on Defendants' repeated representations regarding the Phase III trial data and NDA submission timeline, stating: "Celgene has previously announced that further analyses of the RADIANCE trial are ongoing and it plans to submit an NDA to the FDA, based on the combined SUNBEAM and RADIANCE trials for relapsing MS by the end of 2017."

418. The statements set forth in ¶¶ 406-09, 411, and 414 above, including Defendants' statements that the Phase III studies for Ozanimod were positive and complete and that, in light of these study results, Celgene was set to file the Ozanimod NDA by the end of 2017, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 228-95 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants had discovered a disproportionate Metabolite;

(ii) in light of the discovery of the Metabolite, the results from Celgene's nonclinical toxicology studies were deficient and the Company lacked sufficient time to conduct or re-run these studies before the end of 2017;

(iii) Celgene could not generate the LTS data for the newly-discovered Metabolite required to validate the results of many of the Phase I studies before the end of 2017, putting the Company's NDA filing timeline at risk and rendering it unreasonable; and

(iii) if Celgene submitted the NDA without the necessary metabolite testing and data, the FDA was almost certain to issue an RTF.

By electing to speak publicly about the complete status of Celgene's Ozanimod Phase III studies and the Company's professed ability to submit a complete NDA for Ozanimod in 2017 for FDA approval in 2018—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the need for additional Phase I testing and data that jeopardized Celgene's filing of a complete Ozanimod NDA in 2017 and Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

419. As discussed above (*see* ¶¶ 333-39), Celgene submitted the Ozanimod NDA for MS to the FDA in December 2017, notwithstanding that it omitted the Metabolite testing results demanded by the FDA.

420. On January 8, 2018, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to the Form 8-K, Celgene hyped their December 2017 submission of the Ozanimod NDA for MS, identifying as one of its "2018 Expected Operational Milestones" the "***FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)***." Consistent with Celgene's corporate process for public disclosures, information regarding this clinical and product development matter was furnished by the I&I franchise, and reviewed by I&I President Defendant Curran.

421. Following the January 8, 2018 press release, J.P. Morgan asserted in a January 8, 2018 report, that the "Key 2018 catalysts" included "potential approval of ozanimod in relapsing multiple sclerosis in 2018" and RBC Capital Markets stated in a report published the same day that "CELG confirmed they submitted an NDA for ozanimod in MS."

422. Approximately two weeks later on January 25, 2018, Celgene filed another Form 8-K, signed by Kellogg, with the SEC again highlighting that "***a New Drug Application (NDA) was submitted with the FDA for Ozanimod in relapsing multiple sclerosis*** (RMS) based on data from the phase III RADIANCE™ Part B and SUNBEAM™ trials for evaluating Ozanimod in patients with RMS." Consistent with his role and responsibilities in Celgene's process surrounding public disclosures, Smith received and reviewed draft and proposed final versions of this Form 8-K and press release in the days immediately prior to its issuance. Smith, as President and COO of Celgene, reviewed this statement. Smith also recklessly disregarded and tolerated the misrepresentation and omission of material facts in the statement after its issuance.

423. Following Defendants' repeated reference to its NDA submission, SunTrust Robinson Humphrey stated in a January 25, 2018 report that "Other Late Stage Assets Also Progressing Swiftly," and specifically noted with respect to Ozanimod that "U.S. approval and launch in relapsing multiple sclerosis (RMS) expected in 4Q18 (following NDA filing in December 2017 . . . )."

424. On February 7, 2018, Celgene filed an Annual Report on a Form 10-K signed by Alles and Kellogg, with the SEC ("2017 10-K"), again representing that "***a New Drug Application (NDA) was submitted with the FDA for ozanimod in RMS*** based on data from the phase III trials evaluating ozanimod in patients with RMS." The 2017 10-K also included a chart representing that the "Status" of Ozanimod for RMS was "Regulatory submission" and that Celgene "Entered

current status" in the fourth quarter of 2017. Consistent with his role in Celgene's Quarterly Disclosure Process, Smith received and reviewed at least one draft version of this Form 10-K as it was prepared and finalized in the days before its publication to the market. Smith, as President and COO of Celgene, reviewed this statement. Smith also recklessly disregarded and tolerated the misrepresentation and omission of material facts in the statement after its issuance.

425. The statements set forth in ¶¶ 420, 422, and 424 above, including Defendants' statements discussing the submission of the Ozanimod NDA, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 228-339 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants had discovered a disproportionate Metabolite;

(ii) the results from Celgene's nonclinical toxicology studies were deficient; and

(iii) the necessary testing and studies regarding the Metabolite, including the data required to validate the results of the Phase I studies, were not complete at the time Celgene submitted the NDA, and Celgene's failure to include the results from these studies in the NDA rendered it facially deficient.

By electing to speak publicly about the complete status of Celgene's Ozanimod Phase III studies and the Company's submission of the NDA for FDA approval in 2018—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the incompleteness of the required data from the Phase I testing at the time Celgene filed the Ozanimod NDA in December 2017 which jeopardized Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

## VI. THE RELEVANT TRUTH EMERGES: ALLEGATIONS OF LOSS CAUSATION

426. Defendants' material misstatements and omissions complained of herein artificially inflated the market price of Celgene's publicly traded common stock. The artificial inflation in Celgene's stock price was removed when the facts and risks misstated and omitted by Defendants were revealed to the market. Such corrective information was disseminated to investors through public disclosures on October 26, 2017, February 27, 2018, and April 29, 2018. Each such disclosure partially revealed relevant facts regarding the false and misleading nature of Defendants' material misstatements concerning Otezla and Ozanimod. Each disclosure, more particularly described below, removed artificial inflation in the price of Celgene's publicly traded stock, causing economic injury to Lead Plaintiff and other members of the Class.

### A. October 26, 2017: Celgene Discloses Sharply Negative Financial Results for Otezla

427. On October 26, 2017, the Company released its third quarter 2017 financial results. Celgene reported total Otezla sales of only $308 million, a 14% decline from second quarter 2017 Otezla sales, and blamed "an increase in gross-to-net adjustments from contracts implemented in January and a slowing in overall category growth due to a more challenging market access environment." Curran stated that Otezla experienced "lower-than-expected revenue due to market deceleration, increase in gross-to-net discounts to drive biologic step free access and inventory fluctuation." In addition, Curran referenced Otezla's depressed market share, which "has been somewhat impacted in patients previously exposed to biologics." Curran also stated that "declined script volume became more prominent" in the third quarter of 2017. According to Curran, declining script volume, combined with "the market's softening, increased competition, as well as the impact from GTN" led to disappointing third quarter of 2017 results.

428. Celgene also announced that it no longer expected 2017 Otezla net product sales to be between $1.5 billion and $1.7 billion as it had previously stated, but rather expected 2017 sales to be only approximately $1.25 billion. Celgene also stated that it was lowering its fiscal 2020 guidance as a result of the poor Otezla results.

429. In response to Defendants' disclosures on October 26, 2017, the price of Celgene common stock fell by $19.57 per share—more than 16%—from a close of $119.56 on October 25, 2017 to close at $99.99 on October 26, 2017 on abnormally high trading volume of 24.1 million shares. This wiped out more than $14 billion in Celgene market capitalization.

430. Analysts commented negatively not only on Celgene's missed and lowered guidance, but also on management's credibility. For instance, J.P. Morgan reported on October 26, 2017 that Celgene "management faces a major credibility issue." That day, Cowen and Company similarly reported that the shortfall on Otezla sales "is likely to impact the company's credibility." On October 26, 2017, *SeekingAlpha* also reported that "the Street has suddenly lost trust in Celgene's pipeline as well as the credibility of management's guidance." Raymond James downgraded Celgene stock from Strong Buy to Market Perform, and reported:

> ***[T]oday's update substantially alters our outlook and confidence in the company's ability to execute***. We previously viewed Celgene's immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-0301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a 'show me' story[.]

431. PiperJaffray also reported on October 26, 2017 that "despite an attractive valuation, we think management will need to start executing better commercially, clinically and strategically before this stock begins to work again." PiperJaffray further reported that:

> While some expected management to revisit 2020 guidance, given the GED-0301 failure from last week, we think ***the magnitude of the reset has clearly shaken investors***. Indeed, in one fell swoop, 2020 revenue guidance was shaved by $1.5B, with hematology accounting for >80% of revenue up from 70% of revenue. . . . With this new outlook, we can't imagine angst on this front will go away any time soon.

432. Similarly, BTIG Equity Research reported on October 26, 2017 that Celgene's third quarter results "***severely disappointed relative to expectations on Otezla***, and mgmt significantly lowered 2020 guidance due to several product forecast revisions." Jefferies Group LLC also reported that day that "***CELG put up an unusual notable revenue miss (it's been a few years since that happened by this much)*** and notably lowered 2017 revenue guidance and 2020 revenue and EPS guidance," and that "it will take some time to re-engage in credibility to hit targets and get quarters back on track and reset the situation."

433. Analysts also discussed the factors that drove Celgene's lower Otezla revenues. For example, in an October 26, 2017 report, BMO Capital Markets attributed the Otezla miss in part to discounting and competition from other PsO treatments, stating that "[a]lthough Otezla script growth was apparent (+4% Q/Q), it just wasn't enough to offset the aggressive discounting and slowing growth of psoriatic arthritis and ***greater competition*** in psoriasis markets."

434. Analysts reported that the magnitude of Celgene's miss was a surprise to the market. On October 26, 2017, J.P. Morgan reported that:

> In a word, CELG's print this morning was ugly. The company reported a top-line miss (total revenue of $3.28B vs. cons of $3.42B) with a bottom-line beat (non-GAAP EPS of $1.91 vs. cons of $1.87). . . . Otezla, in particular, was the standout for the wrong reasons with a bad miss ($380M vs. $411M). We believe a weak quarter was expected based on lackluster Rx trends, but not to this extent.

435. UBS similarly reported the same day that:

> While some shift in the makeup of 2020 guidance was expected (though not today), lowered guidance is a ***surprise*** – leaving the company even more dependent on Revlimid just as the focus on that[] drug['s] IP (rightly or wrongly) intensifies.

436. Also on October 26, 2017, Leerink Partners reported:

> This morning ***Celgene reported alarming Q3 2017*** with revenues 4% below consensus and pro forma EPS 2% above consensus, and the company lowered their long-term 2020 revenue targets by 5-10% after recent pipeline failures and negative market trends for Otezla. ***Investors are likely to ask whether the company's good fortune has run out, with disappointments (mongersen) and negative revisions (Otezla) left and right.*** Recently installed new management are likely to face tough questions from investors about the company's direction and leadership after the operational and guidance disappointments this quarter.

437. Even those analysts initially bullish on Celgene ultimately downgraded their ratings of Celgene shares. For example, Cantor Fitzgerald downgraded Celgene from Overweight to Neutral on October 26, 2017, and reported that:

> [T]he upside is now considerably less, given the lower visibility on the longer term. We had believed that pipeline execution would see CELG shares through the loss of REVLIMID, but the company's revisitation of guidance in the wake of GED-0301's failure creates an overhang and perhaps places greater pressure to execute on a strategic/business development option.

438. Despite Celgene's disclosures concerning Otezla results and related stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to misrepresent and conceal material information from investors concerning Ozanimod. For example, during the October 26, 2017 conference call, Alles tried to shift the focus from GED-0301 (a failed developmental drug) to Ozanimod and falsely and misleadingly claimed to investors that the "immediate shift from GED-0301 to ozanimod in Crohn's disease is a great example of the pipeline optionality and opportunity we have built and continue to build into our research model for hematology, oncology and inflammation and immunology."

### B. February 27, 2018 and April 29, 2018: Celgene Receives a Refusal-to-File Letter for Ozanimod Based on Its Lack of Metabolite Testing

#### (a) February 27, 2018: Celgene discloses the refusal-to-file letter for Ozanimod

439. After market close on February 27, 2018, just three weeks after Celgene's Form 2017 10-K touted the fact that "a New Drug Application (NDA) was submitted with the FDA for Ozanimod in RMS based on data from the phase III trials," Celgene issued a press release revealing that it had received an RTF from the FDA regarding its recently submitted NDA for Ozanimod. Celgene's press release stated:

> [U]pon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review. Celgene intends to seek immediate guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA.

440. In response to the Company's disclosure on February 27, 2018, the price of Celgene common stock fell by $8.66 per share—more than 9%—from a close of $95.78 on February 27, 2018 to a close of $87.12 on February 28, 2018, on abnormally heavy trading volume of 27.9 million shares. This disclosure wiped out more than $6.5 billion in market capitalization.

441. Analysts responded immediately and negatively to this news, expressing shock and disappointment, particularly given management's recent positive commentary on Ozanimod. On February 27, 2018, for example, Raymond James reported that the market "didn't see this one coming," and called the RTF news an "unexpected development." *SeekingAlpha* reported the same day that the news of Celgene's RTF was "hard to accept as a reality" because receiving such a refusal to file letter from the FDA is "almost unheard of for a major company." Credit Suisse similarly reported that "we are disappointed by the timing delay related to the filing, and we think that this will continue to further concerns associated with management execution."

442. Reflecting on the critical implications the RTF would have for Celgene, RBC Capital Markets reported on February 27, 2018 that "given that [Celgene] will be requesting a Type A meeting with the FDA, it may be some time before there is additional clarity on the potential path forward. We view ozanimod as one of the most, if not the most, important pipeline programs for CELG[.]"

443. Other analyst firms also reported on February 27, 2018 that the RTF raised questions about Celgene's ability to diversify away from Revlimid. For example, PiperJaffray reported that:

> It's been a rough couple of months [for Celgene]. GED0301 failure notwithstanding, this isn't the first execution-related hurdle that I&I franchise has faced, with Otezla routinely falling short of expectations and the timeline for ozanimod in UC also recently delayed [], only raising more questions regarding CELG's efforts to diversify away from Revlimid.

444. Despite Celgene's disclosure of the RTF and the related stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to conceal material information from investors concerning the testing required to address the Metabolite and how that testing would affect the timeline for submitting the revised NDA.

**(b) April 29, 2018: Investors learn that the resubmission of the NDA will be delayed up to three years**

445. After almost two months of speculation surrounding the RTF, on April 25, 2018, in a presentation of Phase III Ozanimod Multiple Sclerosis data at an AAN meeting, a Celgene investigator disclosed new information about a "major active metabolite" of Ozanimod (CC112273), which, in fact, is behind the vast majority of Ozanimod's efficacy. Specifically, the investigator disclosed that Celgene first identified the Metabolite in a human mass balance study conducted in parallel with the Phase III Ozanimod trials, that the Metabolite levels were much lower in the animal species used in the non-clinical studies than in humans, and that the Metabolite is responsible for approximately 90% of Ozanimod's clinical activity.

446. Despite Celgene's disclosure of the Metabolite on April 25, 2018, the price of Celgene common stock remained artificially inflated as Defendants continued to conceal material information from investors concerning the testing required to address the Metabolite and how that testing would affect the timeline for submitting the revised NDA.

447. The market's initial response to this news was mixed, as analysts tried to digest what it meant for Celgene and investors. For example, Morgan Stanley issued an analyst report after the close of trading on April 25, 2018 that concluded that the "Disclosure of active metabolite for Ozanimod is a ***net positive*** as it suggests the FDA RTF is due to lack of characterization of the metabolite." The analyst added that "[w]ith mgt. indicating it will provide an update with earnings and highlighting this disclosure at AAN, ***we suspect many investors will view this positively*** . . . ." As a result, Morgan Stanley wrote that it "would expect to see CELG ***up*** in the low-to-mid single digit % on the news."

448. The next day, April 26, 2018, RBC Capital Markets reported that "[t]hough we still do not know the exact reasons CELG received an RTF, the fact pattern suggested by yesterday's new details strongly indicates [the RTF] likely relates to ***some FDA discomfort*** around the characterization of this metabolite []" but that "[w]hether this can be quickly rectified, perhaps with add'l clinical characterization remains the key question and ***the key unknown***."

449. The ambivalence came to an end on Sunday, April 29, 2018, after Morgan Stanley issued a strongly negative report based on its detailed review of certain obscure data related to Ozanimod's other metabolites. Morgan Stanley's April 29, 2018 report entitled, "More Bread Crumbs Yield Less Confidence in Ozanimod," stated that its "analysis of prior ozanimod pre-clinical studies suggest [that] CC112273 concentrations in prior pre-clinical work is unlikely to

approximate human clinical doses" and, "[t]herefore we believe it is increasingly likely mgt. will need to complete new preclinical work on CC112273 ***setting up a 1 to 3 year delay***."

450. The Morgan Stanley analysts explained that their analysis was only made possible after they "were able to locate copies of [] posters over the weekend [April 28 and 29]" containing the "previously published ozanimod preclinical toxicology results and studies of [the two] known metabolites," i.e., other than CC112273. The posters established that the two previously identified metabolites produced levels in the animal studies that were just above the human therapeutic dose and therefore approximated the human dose. The analysts further explained that, based on their review of FDA guidance on metabolites, "the only way for mgt. to avoid synthesizing CC112273 and re-running preclinical [i.e., Phase I] toxicology [i.e., engaging in protracted testing] was by having exposure of CC112273 in animals equivalent to the human therapeutic dose" so that Celgene could simply recycle the prior testing used on the known metabolites. However, as Morgan Stanley explained, a "1 to 3 year delay" in completing the requisite testing was unavoidable given the significantly higher levels of the Metabolite in humans compared to animals. Morgan Stanley referred to its "prior review of FDA guidance on metabolites" and stressed that:

> However, given that mgt. indicated 'CC112273 levels were ***much lower*** . . . in the animal species used in the non-clinical studies than the amount produced by humans' and that ***our calculations suggest the prior set of identified (and thus studied metabolites) produced levels barely above the human therapeutic dose, we believe it is increasingly unlikely CC112273 produced levels near the human therapeutic dose in the prior preclinical work. Thus, mgt. will likely need to re-run preclinical toxicology which could take 6 months (rats) to 2 years (another carcinogenicity study). Given the timeline to start the study, produce the study reports and refile, we believe the delay is at a minimum 1 year and up to 3 years if mgt. must redo all animal work.***

The bolding and italics above appeared in the original Morgan Stanley April 29, 2018 report, to emphasize the importance of this text to its readers.

451. Celgene's stock price fell on the news of the significant additional testing required from Celgene and the significant delay for Ozanimod approval as a result of the Company's premature submission of the NDA. Specifically, Celgene's common stock dropped from a close of $91.18 on April 27, 2018 to close at $87.10 on April 30, 2018, a 4.5% decline that wiped out approximately $3 billion in market capitalization.

452. Analysts attributed this decline to the revelations that resulted from Morgan Stanley's detailed, specialized analysis and digestion of Celgene's informationally-complex AAN disclosure. For example, *The Motley Fool* wrote on April 30, 2018 that: "[S]hares of Celgene lost 4.5%. The biotech giant got negative comments from analysts at Morgan Stanley, who predicted that it could take several years for Celgene to move forward with plans to file for approval from the U.S. Food and Drug Administration for its multiple sclerosis candidate drug ozanimod." Similarly, *Citywire* reported on the same day that "Celgene shares fell 4.5% after Morgan Stanley said it expects a delay of up to three years for Celgene's key multiple sclerosis drug, ozanimod." Likewise, *Marketwatch* reported on this date that "Celgene Corp. . . . fell 4.5% after a Morgan Stanley report predicted a one- to three-year delay on any new attempt to file for U.S. approval of the company's highly anticipated drug ozanimod, which is designed to treat multiple sclerosis."

453. As a result of Defendants' misstatements and omissions, which were corrected by the disclosures discussed above, in total, the price of Celgene common stock ended the Class Period at $87.10, more than 40% below its Class Period high of $146.52 on October 4, 2017.

## VII. ADDITIONAL ALLEGATIONS OF SCIENTER

454. Celgene and the Individual Defendants were active and culpable participants in the fraud, as evidenced by their knowing or reckless issuance of and/or control over Celgene's and the Individual Defendants' materially false and misleading statements and omissions. Celgene, through its management and other senior level employees, and the Individual Defendants acted

with scienter in that they knew or recklessly disregarded that the public statements set forth in Section V above were materially false and misleading when made, and knowingly or recklessly participated or acquiesced in the issuance or dissemination of such statements as primary violators of the federal securities laws. In addition to the facts alleged in Section IV above, regarding Celgene's and the Individual Defendants' personal knowledge and/or reckless disregard of the materially false misrepresentations and omissions, Celgene's and the Individual Defendants' scienter is evidenced by the specific facts discussed below.

### A. Defendants' Knowledge and Reckless Disregard of Misstatements Regarding Otezla and Ozanimod

455. Defendants were directly involved in and participated in both the management and day-to-day operations of the Company at its highest levels. Accordingly, as detailed below, Defendants each had access to detailed information concerning the Company's I&I franchise generally, and Otezla and Ozanimod, specifically. This information was transmitted and learned through meetings, reports and other regular communications, as detailed by numerous confidential witnesses, and by documents and testimony obtained in discovery.

#### 1. Otezla

456. Celgene's and the Individual Defendants' scienter with respect to the misstatements and omissions regarding multiple Otezla sales, inventory, demand, and market metrics as of the first quarter of 2017; the unreasonableness and unattainability of the Company's 2017 Otezla sales guidance as of April 27, 2017, as a result of those significantly underperforming first quarter of 2017 sales, inventory, demand, and market metrics (and the false and misleading statements that Curran made about them); and the misstatements and omissions regarding Otezla's market share, prescriber adoption, and "Key OTEZLA performance indicators" in the second quarter of 2017, is evidenced by the following facts, among others:

**(a) Smith, Curran and others in senior management were warned that the 2017 Otezla sales guidance could not be met and should be lowered**

(i) FE 7 repeatedly warned Smith that the Company's strategy of offering deep discounts and rebates for Otezla was fatally flawed and rendered it "impossible" for the Company to achieve the 2017 Otezla guidance. As early as the Otezla launch, FE 7 informed Smith—who had the final say with regard to Otezla and Market Access decisions—that he would be destroying the "best price" for the drug by offering large rebates and discounts, thereby setting Otezla up for consistently depressed net revenues going forward;

(ii) FE 7 wrote multiple emails to Celgene's senior executive management, including Smith, documenting his concerns about the discounts and rebates that Celgene was offering for Otezla. FE 7 also told Smith that Celgene should never "pay to play"—i.e., offer rebates and deep discounts in exchange for market access—as that would prevent Celgene from maximizing its profits;

(iii) According to FE 14 and FE 12, Celgene's management had access to Otezla sales data that Celgene received from IMS through Tableau. This data reflected straight volume, volume growth, number of prescriptions by territory, number of prescriptions by provider, and number of prescriptions attributed to each salesperson. Sales representatives from across the country all reported that sales of Otezla, which were reflected in Tableau, were steady to flat from 2014 through 2017;

(iv) No later than the third quarter of 2016, Tessarolo communicated in weekly meetings with the IIEC, which included Smith and Curran, that the 2017 Otezla guidance could not be met;

(v) During presentations in the third and fourth quarters of 2016, FE 17 and his team informed the IIEC that the 2017 Otezla sales guidance could not be met. FE 17 recounted that "***everyone knew that the actual stated forecast was not reasonable***" and could not be met;

(vi) In the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered;

(vii) By the end of 2016, Tessarolo again warned the IIEC of the need to lower the 2017 Otezla sales guidance, but the IIEC insisted that the forecasts would not be changed;

(viii) The forecasting team was "***told to change***" ***the numbers*** (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth;

(ix) According to FE 17, Defendants refused to lower the Otezla guidance per his warnings and instead put pressure on the salespeople to hit the impossible numbers; and

(x) FE 18 indicated that the aggressive Otezla guidance did not account for the introduction of new competition to the PsA and PsO market and that CPMAC knew of, but simply ignored, this factor.

**(b) Multiple former employees confirmed that Defendants knew that 57% year-over-year growth in Otezla net product sales between 2016 and 2017 was unachievable**

(i) FE 19 stated that in late 2016, when Smith was assessing the 2017 Otezla market access information that FE 19's team put together and setting the sales targets, the market did not support anything close to the 57% growth Defendants told the public. According to FE 19, there was no way Smith could have interpreted what his Market Access team was reporting and translated that into 57% sales growth for Otezla in 2017;

(ii) FE 17 stated that as early as April 2016, the rebates due on existing Otezla prescriptions covered by "underwater" PBM contracts were "significant." In light of these outstanding rebates, FE 17 stated that Celgene management should have given a warning to investors in the fourth quarter of 2016 because the IIEC knew about the rebate issue and the impact that it was going to have on the Company's 2017 Otezla revenues;

(iii) In anticipation of a planned 2017 price increase for Otezla, Celgene's management acceded to the requests of many wholesalers to purchase in December 2016 the quantities of Otezla they were slated to purchase in January 2017, in order to take advantage of the lower price. This buy-in negatively and foreseeably impacted Otezla sales in the first quarter of 2017;

(iv) FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that the Company needed to downgrade its 2017 Otezla guidance. However, rather than heed Tessarolo's warning, Smith cut him off, stating that he had heard enough of the negative information; and

(v) FE 7, added that "***there isn't any way to grow [Otezla] revenue by 57%***." FE 7 was very vocal to senior management and specifically told them that Otezla's growth could not continue because of the step-edit hurdles and the saturation of competitor drugs in the market. FE 7's warnings, however, were ignored.

**(c) Defendants lacked a reasonable basis for representing that new PBM contracts and the removal of step-edits would help the Company hit the 2017 Otezla sales guidance**

(i) In November or December of 2016, FE 7 met with Grausso, Curran, Tessarolo, Swartz, Willcox and Owen and again warned these executives that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges;

(ii) Even though the Company entered into new PBM contracts that went into effect in 2017, Celgene did not recognize revenues from prescriptions for many patients covered by these contracts until months later. FE 18 stated that it was clear from the beginning of 2017 that the new PBM contracts were not meeting revenue expectations. FE 18 communicated this fact to his boss, Swartz, and she reported this information to the CPMAC. According to FE 18, notwithstanding the data showing that the contracts were underperforming, Celgene refused to lower expectations for the PBM contracts; and

(iii) FE 18 confirmed that the market for Otezla did not change rapidly in 2017: "***We saw what was happening way before then***. ***We had monthly meetings with the contract and pricing teams . . . very early on in 2017***" and there was "worry" and "concern" at these meetings. As FE 18 further stated: "We were in trouble with our Otezla contracts. You heard that from a lot of the pricing and contract people."

**(d) Curran lacked a reasonable basis for representing that Otezla would achieve its 2017 public guidance, given her misrepresentations regarding Otezla's key sales, inventory, demand, and market metrics, and her recognition (along with other Celgene executives) of material risks to Otezla's net revenue given market contraction and Otezla's underperforming market share**

(i) Curran received, discussed, and presented information that Otezla's total sales units, gross revenue, and net revenue far underperformed the 2017 Budget forecast for the first quarter of 2017, and that April sales, which were flat as against the 2017 Budget forecast, did not make up any ground from the unexpected sales miss in the first quarter;

(ii) Curran received, discussed, and presented information that Otezla wholesalers held excess amounts of inventory, and that "inventory adjustment," which impacted first quarter of 2017 sales, was a key factor driving the first quarter of 2017 underperformance;

(iii) Curran received, discussed, and presented information that the PsO and PsA markets contracted in the first quarter of 2017, and that Otezla's market share was flat or declining;

(iv) Curran received, discussed, and presented information that the I&I franchise had determined that the 2017 Budget assumptions for the growth of the overall PsO and PsA markets were flawed, yet failed to provide complete and accurate information to investors relating to the extent of the market contraction and its material impact on the 2017 Budget and public guidance;

(v) Curran received, discussed, and presented information that the 2017 Budget assumptions for Otezla's shares of the PsO and PsA markets were also flawed, yet

failed to provide complete and accurate information to investors relating to the risk of Otezla's decreasing market share and its impact on the 2017 Budget and public guidance;

(vi) Curran knew, or was reckless in not knowing, that the three PBM contracts, which she touted to investors, had each underperformed forecasted unit sales, and that two of those contracts, ESI and Prime, each underperformed their forecasted within-plan market shares;

(vii) Curran referenced the exit run rate from the first quarter of 2017 into the second quarter of 2017, but she knew, or was reckless in not knowing, and failed to provide full and accurate information regarding the run rate so as not to render her statement false and misleading, including (a) that total unit sales underperformed by 27,000 units in the first quarter of 2017; and (b) that the March 2017 LE downgraded total unit sales for the second quarter of 2017 from the 2017 Budget; and

(viii) Curran knew, or was reckless in not knowing, and did not otherwise explain to investors, that she and other Celgene executives had decided, absent any reasonable basis, to add over 15,000 units of sales onto the forecast for the fourth quarter of 2017, after Otezla sales fell short by 27,000 units in the first quarter of 2017; that Celgene downgraded the second quarter of 2017 unit forecast; and that, absent the additional unit sales in the fourth quarter of 2017 (which were not part of the original 2017 U.S. Budget and unsupported by any reasonable sales metrics), Celgene could not achieve the 2017 U.S. Budget forecast or the public guidance.

**(e) Curran understood internally, including through internal clarification, that Otezla market share was "flat," yet drafted and delivered remarks to investors falsely stating that Otezla's market share had "increased significantly" in the second quarter of 2017**

(i) Curran received numerous presentations and reports throughout the second quarter of 2017 indicating that Otezla's market share was either flat or declining throughout the second quarter of 2017;

(ii) Curran, also knew, or was reckless in not knowing, that Otezla sales through managed care contracts with each of Aetna, ESI, and Prime had underperformed their forecasted total sales and their within-plan market shares in the second quarter of 2017;

(iii) On July 24, 2017, Curran's assistant emailed "Terrie's slides" in connection with Celgene's upcoming earnings call on July 27, 2017, a graphic of which depicted Otezla's overall PsO market share in the United States. The underlying data for the graphic showed that Otezla's overall market share decreased over the second quarter of 2017;

(iv) Additional presentations received, given, and discussed by Curran, throughout the second quarter of 2017, recognized that Otezla's share of the PsO and PsA markets was declining or flat over the quarter;

(v) On July 25, 2017, Curran recognized in an email that market share was "flat" versus the previous quarter. That same day, a member of Curran's team replied that Otezla's market share was "relatively flat" – which Curran herself repeated in a follow-up email to other Celgene executives;

(vi) Despite her internal recognition that Otezla's market share was "flat," which corresponded with data that Curran had submitted to other Celgene executives, Curran accepted false and misleading changes to a conference call script that she had drafted which stated that Otezla's market share "increased significantly" in the second quarter of 2017;

(vii) Curran thereafter gave materially false and misleading public remarks during the second quarter of 2017 conference call, stating that market share and prescriber adoption "increased significantly" in the second quarter;

(viii) Curran reaffirmed in an internal company email after her public comments that Otezla had not, in fact, grown market share throughout 2017; and

(ix) Given such information in these internal presentations and reports, as well as Curran's internal statements to other Celgene executives, Curran lacked any reasonable basis to make a false statement publicly regarding Otezla's "significant increase" in market share, which differed from information revealed through non-public, internal presentations and reports.

**(f) Curran lacked any reasonable basis for misrepresenting that "prescriber adoption" had increased significantly in the second quarter of 2017**

(i) A May 9, 2017 presentation submitted to Curran and other Celgene executives stated that Otezla's new patient growth—"new patients and not the NRx"—was "down" following the launch of new competitors Taltz and Cosentyx, despite earlier 2017 Budget assumptions that IL 17 inhibitors, such as Taltz and Cosentyx, would have "no impact to Otezla";

(ii) Otezla I&I Performance slides throughout July, including as late as July 19, showed that Otezla's New Patient Growth decreased, in total prescriptions, throughout the second quarter of 2017;

(iii) Otezla's market share of "New-to-Brand" customers also remained relatively stable, with no percentage growth in the larger PsO segment and only slight growth in the PsA segment—which itself paced below Otezla's percentage of the "New-to-Brand"

market entering January 2017; a July 31, 2017 presentation also confirmed a decrease in the "New Patients by Month End" metric through June 30, 2017; and

(iv) Given such information in these internal presentations and reports, Curran lacked any reasonable basis to claim publicly a "significant increase" in prescriber adoption, which differed from information revealed through non-public, internal presentations and reports.

**(g) Curran knew that other Otezla performance metrics had vastly underperformed against Celgene's internal forecasts during the first and second quarters of 2017**

(i) In addition to the market size, market growth, and prescriber adoption information set forth in Sections IV.B.6-9, *supra*, Curran knew, or was reckless in not knowing, that as of July 27, 2017, Otezla had failed to achieve the budgeted forecast for the first and second quarters of 2017;

(ii) Curran also knew, or was reckless in not knowing, that Otezla's net revenues and unit sales in the second quarter of 2017 failed to achieve the 2017 Budget; that Otezla sales to date in July 2017 vastly underperformed the June latest forecast estimate; and that, given that July 4th sales were recognized in the second quarter of 2017, Otezla could not make up the variance between actual sales and the June forecast latest estimate in the third quarter of 2017 and through year-end;

(iii) In addition, Curran knew, or was reckless in not knowing, that wholesaler inventory levels coming out of the second quarter of 2017 had increased, which would, like the first quarter of 2017, lead to lagging sales in the third quarter of 2017 until inventory levels were reduced;

(iv) Curran further received reports, including multiple reports issued by government agencies, independent non-profits, and third-parties commissioned by Celgene, stating that Otezla was viewed as the least effective drug within the overall market basket of competitor drugs; and

(v) Given such negative information, which Curran and other Celgene executives possessed internally, Curran lacked any reasonable basis for claiming that "Key OTEZLA performance indicators continue to strengthen." Having chosen to mischaracterize Otezla's performance as "strong," Curran was required to provide complete and accurate information to investors regarding the host of negative sales metrics that plagued Otezla through the first half of 2017 and in the second quarter of 2017, which she failed to do and omitted from her public statements.

**2. Ozanimod**

457. Celgene's and the Individual Defendants' scienter with respect to the misstatements and omissions regarding the submission of the Ozanimod NDA and the status of the Company's Ozanimod clinical development, is evidenced by the following facts, among others:

**(a) Upon acquiring Receptos, Celgene exercised control and decision-making authority over Receptos and Ozanimod**

(i) FE 20 explained that once Celgene agreed to acquire Receptos on July 14, 2015, all decisions were made by Celgene in New Jersey or on-site Celgene personnel;

(ii) FE 21 stated that after the July 14, 2015 acquisition, Celgene did not allow Receptos' leadership to partake in any decisions that could potentially impact Celgene's stock price;

(iii) FE 2 recalled that Martin, who FE 2 described as a "control freak" and Smith's right-hand man, was sent by Celgene to San Diego to serve as the Managing Director for Receptos. FE 2 referred to Martin as the *de facto* chief executive of Receptos;

(iv) FE 5 likewise described Martin as the CEO of Receptos after the acquisition and confirmed that Martin was in charge of the entire Receptos organization and reported directly to Smith. FE 5 also recounted that Smith sent Gary Cline, Head of Strategic Research and Innovation, to San Diego to keep tabs on Ozanimod for him; and

(v) FE 22 further corroborated that Martin reported directly to Smith and Saillot was Martin's second in command.

**(b) Defendants knew that the Metabolite required additional testing prior to submitting the NDA, and that the NDA was deficient upon submission**

(i) Defendants recognized that the belated Mass Balance Study posed significant risks, including the belated discovery of a highly active metabolite, to the publicly-stated timeline for the Ozanimod NDA, which allowed "little time for delays/errors," as stated in a presentation received by Martin. In fact, during a January 12, 2017 meeting, the Ozanimod project team specifically discussed that "[i]f a significant new metabolite is identified, ***then we will not have sufficient toxicology [studies] to support the [NDA] submission***";

(ii) Defendants also knew, based on express instructions from the FDA in a March 2, 2017 letter (sent to Martin, among other Ozanimod project team members), that "***[f]ull Clinical Study Reports are needed for [ongoing Phase I]***

***pharmacology studies at the time of the NDA submission***." As such, Defendants knew that any newly-discovered metabolite would need the full array of necessary testing completed prior to the submission of the NDA in December 2017, as reflected in a March 28, 2017 presentation stating that the "***[c]urrent tox data package would not be sufficient*** if a new metabolite is identified in the [Mass Balance Study]";

(iii) FE 21, who had first-hand knowledge of the Metabolite, discussed the discovery with Martin and noted that it was of great concern. In response, Martin told FE 21 not to tell anyone about the Metabolite discovery and that Martin would tell him who needed to know and would send people to him to work on the Metabolite;

(iv) FE 21 stated that the employees in his role and Martin's role at Celgene knew about the Metabolite discovery. FE 21 also stated that Celgene's senior leadership was briefed on the discovery of the Metabolite and the ongoing characterization efforts "quite some time before the filing" of the NDA;

(v) FE 5 recalled that during an Ozanimod meeting in March or April of 2017, Tran confirmed the need for additional testing and studies of the Metabolite. FE 5 confirmed that Martin, Saillot (who reported to Martin), Frohna (Vice President of Clinical Development and Translational Medicine, Receptos who reported to Martin), Kopicko (Executive Director of Biometrics, Receptos, who reported to Martin), Penenberg (Director, Receptos, who reported to Kopicko), Aranda (Vice President of Clinical Development, Receptos, who reported to Martin), Skolnick (Executive Director of Clinical Development, Receptos, who reported to Aranda), and others attended this March/April 2017 meeting;

(vi) FE 5 further recalled that at this March/April 2017 meeting Tran directed his comments concerning the Metabolite to Martin and Saillot, but that Martin and Saillot quickly shut down the conversation;

(vii) A presentation sent to Martin following a meeting on April 24, 2017 indicated the existence of the Metabolite and the need for further testing per FDA guidance. The presentation acknowledged the possibility that Celgene would need to delay the NDA submission by up to eight months to perform the necessary testing;

(vii) FE 21 stated that he and his colleagues discussed the need to perform additional testing after finding the Metabolite and the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would receive a refusal to file letter. FE 21 confirmed that this was said to his direct management;

(ix) FE 21 and his colleagues agreed that the Company should wait to complete testing on the Metabolite before submitting the NDA as there was no empirical reason to submit without it. He was never provided any reason why Celgene was rushing to submit when it was clear that more work was required. When he

expressed his feelings to his leaders he was told to keep his personal feelings to himself;

(x) On May 16, 2017, Saillot insisted that Martin explain to Smith the risks posed by the Metabolite to the NDA submission, stating that "***[i]n the best case scenario the December timeframe [for filing the NDA] is extremely optimistic***." On May 30, 2017, Tran echoed Saillot's concerns in an email to Saillot, stating that the additional testing that would be required on the Metabolite "***could have a significant negative impact on the NDA deliverables and timeline***";

(xi) By early June 2017, Defendants knew, on the basis of FDA guidance, that Celgene lacked adequate LTS data required to validate the stability of the Metabolite in human plasma, and that the testing required to generate such data would not be completed for well over a year, rendering Celgene's aggressive December 2017 target date for the NDA submission unattainable;

(xii) During a June 1, 2017 meeting of the Receptos Executive Committee, attended by Martin, the committee reviewed slides stating that the lack of sufficient LTS data was a "Primary concern" and that "***Regulatory agencies will not consider data as validated due to lack of long-term stability (LTS) data***." This concern was echoed in a presentation at a June 15, 2017 Ad Hoc Executive Committee meeting, which listed Martin as an invitee, which stated that "***results are not considered validated due to lack of long-term stability data for PK samples at the time of filing [the NDA]***." Martin also received a presentation on July 17, 2017 confirming that Celgene would not have the necessary LTS data at the time of the NDA submission;

(xiii) Defendants also knew that the late discovery of the Metabolite meant that Celgene's non-clinical toxicology testing of the Metabolite would be deficient at the time of the NDA submission;

(xiv) As detailed above, federal regulations and FDA guidance—which Defendants had a duty to monitor, must have known about, and were required to follow: (i) stress the importance of testing for metabolites before filing an NDA; (ii) require additional testing of metabolites where the results between human and animal testing differ; and (iii) mandate that NDAs address drug metabolism. Martin expressly acknowledged this in an email to Curran on July 25, 2017, which was forwarded to Smith, in which Martin stated that "FDA guidance on safety testing of metabolites (2016), metabolites present at disproportionately higher levels in humans than in any of the animal test species should be considered for (non-clinical) [sic] safety assessment," and therefore "***adequate characterization of Clinical Pharmacology properties of RP112273 is required by regulatory agencies***";

(xv) As early as July 2017, Defendants recognized that if "***Unaddressed [the discovery of the Metabolite] would lead to a Refusal to File by FDA***," as reflected in a July 17, 2017 draft Q&A document created for Martin. Accordingly,

Defendants sought to "negotiate [with the FDA] submission of the NDA within the original timeframe, with agreement for additional data to be submitted during the review period [i.e., after the NDS submission date]";

(xvi) Multiple senior Celgene employees working on the NDA, as well as Celgene's external consultants, acknowledged the severe deficiencies in the NDA. In an October 19, 2017 email, Lamb recognized that Celgene's proposal to provide additional data after the submission was not "ready for submission and requires substantial rework." Houn agreed, stating, "I don't see the rationale for the delayed metabolite characterization submission by 4 months with the other late submissions." In another email on this date, Reiss stated: "***It seems like you are going over board to sell a concept that the FDA will not buy anyway***—be careful with your credibility." Similarly, MacDonald advised Saillot on November 16, 2017 that "***[t]he late discovery of RP112273 has had an impact on the non-clinical safety evaluation of ozanimod. A clear acknowledgement of this and the resulting deficiencies in the package will enhance the credibility of the submission***." Jacobson-Kram similarly advised Martin and others on November 15, 2017 that Celgene should expect "***major pushback***" from the FDA;

(xvii) On November 16, 2017, Saillot emailed Martin expressing concerns about the NDA submission, stating that "[t]he current text and positioning is at best confusing and at worse misleading and lacks credibility. ***I am now at a stage where I am very concerned about the approvability of the NDA unless these issues are addressed***";

(xviii) Confirming that Defendants knew that the FDA could reject the Ozanimod NDA if all required testing was not completed before the submission, Curran agreed on November 20, 2017 that Celgene should consider pursuing a PRV if they "***decide to wait until March-April 2018 to submit the NDA***." This proposal was also shared with Martin and Smith;

(xix) According to FE 22, in November 2017, Celgene met with the FDA for a pre-NDA meeting. FE 22 stated that during this pre-NDA meeting, the FDA told the Company: (i) the FDA needed the study results for the Metabolite; (ii) the results were very important; and (iii) the results had to be included in the Ozanimod NDA. This express direction from the FDA is documented in the FDA's Preliminary Meeting Comments, sent on November 21, 2017, which were reviewed by Martin, Smith, and Curran, among other senior Celgene executive and employees;

(xx) Celgene then cancelled the pre-NDA meeting with the FDA. Saillot acknowledged in an email to Martin and Tran on November 22, 2017 that there was "***No need for discussion – Feedback from Agency is clear***." Tran agreed, noting that any further meetings with the FDA could prompt a response prohibiting the filing of the NDA in December 2017;

(xxi) Multiple employees within Celgene recognized that the FDA's Preliminary Meeting Comments meant that an RTF was nearly certain in the event Celgene proceeded with the NDA submission without the required testing of the Metabolite. On November 27, 2017, Houn stated that "***I hope we do NOT submit without all the info as the risk for RTF is real. FDA has warned us.***" Houn shared her views with Backstrom. On November 28, 2017. Lamb documented discussions with Curran regarding "***potential refusal to file concerns***." Similarly, Backstrom confirmed on this date that he had spoken to Smith regarding "***potential RTF issues***." A December 13, 2017 email from Faletto likewise documented "***the frequent discussions on potential for RTF***" among senior members of the Ozanimod team;

(xxii) Celgene's receipt of the RTF is additional evidence of Defendants' scienter because: (i) according to the FDA, "an RTF is based on omissions of clearly necessary information (e.g., information required under the statute or regulations) or omissions or inadequacies so severe as to ***render the application incomplete on its face***"; (ii) only 45 RTFs have been issued between December 31, 2001 and February 28, 2018; and (iii) at least one market analyst noted that companies like Celgene "do not make execution mistakes like the one [involving the Ozanimod NDA]". Significantly, draft FDA guidance regarding RTFs, which was reviewed by senior Celgene employees prior to the NDA submission, expressly stated that "***[u]nless the applicant and the FDA have agreed at the presubmission meeting to delayed submission of certain components of the application, the FDA expects applications to be complete at the time of submission***";

(xxiii) Following Celgene's receipt of the RTF letter, multiple senior Celgene employees, including Lamb and Tran, recognized that the RTF letter was consistent with the FDA's pre-NDA feedback. As aptly summarized by Lamb in a March 15, 2018 email, "***FDA repeatedly stated what they expected, it was ignored and we got a RTF***";

(xxiv) Celgene admitted after the fact (in June 2018) that the NDA was facially deficient upon submission when it blamed Receptos for the NDA filing; and

(xxv) FE 21, FE 22, and FE 2 all rejected the idea that the deficient NDA was submitted without the approval of Celgene's leadership; and Hasnain, the former CEO of Receptos, and Frohna, the former Vice President of Clinical Development and Translational Medicine at Receptos, publicly stated that Celgene was responsible for filing the NDA.

**(c) Defendants were motivated to file the NDA for Ozanimod in late 2017 without the necessary Metabolite testing**

(i) Defendants were motivated to submit the NDA in late 2017, rather than wait to complete the necessary Metabolite testing, because Gilenya was set to lose its patent exclusivity, paving the way for Gilenya generics that would compete with Ozanimod to enter the RMS market by the end of 2019. By submitting the NDA

in late-2017 for early-2018 approval, Celgene sought to gain a year's worth of market share for Ozanimod before having to fend off cheaper competition from generics;

(ii) Defendants also were motivated to hide the results of the Mass Balance Study, as they demonstrated that the Metabolite's half-life was much longer than Gilenya's, thereby wiping out a previously reported advantage of Ozanimod;

(iii) Defendants also were financially motivated to submit the NDA in 2017. ¶ 337. FE 22 stated that both Martin and Saillot received bonuses for submitting the Ozanimod NDA by year-end 2017. FE 20 confirmed that the compensation for the Celgene and Receptos personnel, including Martin, was tied to the Ozanimod NDA filing, and that the higher you went up the corporate chain, the greater the amount of compensation tied to the NDA filing; and

(iv) Celgene's annual proxy statement on Form DEF 14A, filed with the SEC on April 27, 2017, disclosed that Smith was entitled to a performance award based in part on the "filing of a new drug application." Smith received a lucrative performance award for 2017 of $629,125, along with company stock.

**B. The I&I Franchise Was One of Celgene's Core Operations**

458. Celgene's I&I franchise—which consisted of commercial stage Otezla and pipeline drug Ozanimod—was one of the Company's core operations during the Class Period. Celgene devised a plan to develop and market three I&I drugs—GED-0301, Otezla, and Ozanimod—in an attempt to replace the Company's revenue stream from its extremely successful cancer drug, Revlimid.

459. Defendants' own statements confirm that they paid particularly close attention to the status of Otezla and Ozanimod. Throughout the Class Period, Defendants repeatedly acknowledged the importance of Otezla and Ozanimod to Celgene's success. For example, in announcing the Receptos acquisition, Celgene noted that its "I&I pipeline will, upon completion of the [Receptos] transaction, consist of three high-potential commercialized or late-stage assets: OTEZLA, GED-0301 and Ozanimod." Celgene also touted these drugs as being among the Company's "multiple potential blockbuster products in I&I," which were the keys to replacing revenue when Revlimid lost its patent exclusivity. For example, on July 23, 2015, Celgene touted

GED-0301, along with Ozanimod and Otezla, as being among their "multiple potential blockbuster products in I&I" which were expected to lead the company towards "significant growth through 2020 and beyond."

460. The repeated statements made by the Individual Defendants throughout the Class Period reaffirming the strength of Otezla and discussing the progress of Ozanimod toward NDA submission strongly and plausibly suggest that each Defendant had detailed knowledge of or access to material facts and information misrepresented or concealed by Celgene's and the Individual Defendants' statements. In addition, the Individual Defendants' repeated statements regarding these topics demonstrate that these were areas upon which the Individual Defendants were particularly focused, had a duty to monitor, and therefore knew or recklessly disregarded the omitted and misrepresented information.

### C. Defendants Were Financially Motivated to Conceal Material Information From Investors

461. Curran was financially motivated to commit securities fraud and realized substantial financial benefits from her personal sales of Celgene stock at the same time that she and the Company misrepresented and concealed from investors Celgene's material problems with Ozanimod and Otezla. These sales are detailed in the chart below:

| Name | Date | Shares Sold | Price | Proceeds | Cost per Share | Profit | % of Shares Sold |
|---|---|---|---|---|---|---|---|
| Curran | 9/25/2017 | 1,727 | $143.89 | $248,498 | Not publicly disclosed | | 30.56% |

462. Curran's sales of Celgene stock were suspicious in timing and amount. Curran, Celgene's President of Inflammation & Immunology, sold 1,727 shares of Celgene stock on or about September 25, 2017, at a price of $143.89, for proceeds of $248,498. Curran's sale was

suspiciously timed because it occurred after Curran: (i) received multiple presentations throughout the first and second quarters and into September 2017 that described multiple underperforming Otezla sales, market, inventory, and demand metrics; (ii) personally recognized the existence of a "flat" Otezla market share on July 25, 2017; (iii) received a presentation on September 8, 2017, listing the "Latest Assumptive Scenario" for U.S. Otezla sales as tracking between $150 million - $215 million below the U.S. Budget; and (iii) personally recognized, in an email dated September 11, 2017, that there were multiple factors contributing to Otezla's flat growth in 2017 which had not been adequately forecast or expected. It also occurred after Curran and other senior executives had been warned that the 2017 Otezla sales guidance could not be met and should be lowered, but right before Celgene publicly disclosed the lowered guidance. Indeed, just weeks after Curran's September 25, 2017 stock sale, on October 26, 2017, Celgene disclosed sharply disappointing financial results for Otezla and lowered its financial guidance as a result. In response to that news, the price of Celgene stock fell to $99.99 on October 26, 2017. Curran's sale was suspicious in amount because it represented 30.56% of her currently-held shares of Celgene common stock at that time. A comparison of these sales to Curran's annual salary and bonus compensation is not possible at this time because her salary and bonus compensation is not publicly reported in Celgene Proxy Statements. In addition, a comparison of Curran's Class Period sales to her pre-Class Period sales is not possible at this time because her pre-Class Period sales are not publicly disclosed.

463. Celgene Form 4 filings with the SEC indicate that Curran's sales of Celgene common stock on September 25, 2017 were made pursuant to a Rule 10b5-1 trading plan. However, public filings do not specify when Curran entered into the plan. Accordingly, based on the currently-available record, it is quite likely that Curran entered into the Rule 10b5-1 plan governing these

sales at times when she was already in possession of material adverse non-public information, thus negating the ability of such plans to immunize the trades from securities liability.

**D. Terminations of High-Ranking Personnel Are Probative of Scienter**

464. The terminations and resignations of high-ranking executives, including certain of the Individual Defendants, during or shortly after the revelation of the alleged fraud, are further indicia of scienter.

465. In June 2017—while Celgene employees internally acknowledged that the Company was likely to receive an RTF in light of its decision to push ahead with the Ozanimod NDA submission without including the results from the additional Metabolite studies—Fouse, who made repeated statements regarding the timeline for Celgene's submission of the NDA, abruptly left Celgene. Fouse's departure came just a year after she was promoted to President and COO of Celgene.

466. Swartz, the Vice President of U.S. Market Access, was terminated in November 2017, one month after Celgene announced Otezla's failure to meet its 2017 guidance. As discussed above (*see* ¶ 128), Swartz was forced out due to her pushback regarding the unachievable 2017 Otezla guidance and Defendants' repeated fraudulent statements reaffirming this guidance.

467. Smith, who was promoted from President of I&I to COO in April 2017, abruptly resigned one year later, in April 2018. Smith's unexpected exit came just months after Celgene terminated its Phase III clinical trials for GED-0301, slashed its Otezla sales guidance, and disclosed that the FDA rejected Ozanimod's NDA for failing to provide the required data regarding the Metabolite.

468. Within a few weeks of Smith's resignation, George Golumbeski, Executive Vice President of Business Development, quietly resigned from his position on April 16, 2018. Notably,

Golumbeski played a leading role in several of Celgene's acquisitions, including the acquisitions of Receptos (and Ozanimod) and GED-0301.

**E. The Scienter of Curran, Martin and Smith Is Imputed to Celgene**

469. The scienter of Curran, Martin and Smith is imputed to Celgene given that they were high managerial agents of Celgene who reviewed, prepared, approved, furnished information for, ratified, and/or tolerated the misrepresentations and omissions regarding Otezla and Ozanimod, as described at ¶¶ 43-45, 368-75, and 376-425 *supra*.

470. In their roles as President and COO, President of Celgene's Global I&I franchise, and Corporate Vice President and Managing Director at Celgene-Receptos, Smith, Curran and Martin, respectively, were responsible for issuing statements regarding the Ozanimod NDA and were authorized to act as an agent of Celgene to discuss the Ozanimod NDA.

471. Furthermore, as set forth above in ¶¶ 368-75, both Smith and Curran directly participated in Celgene's Quarterly Disclosure Process, which included preparing, drafting, reviewing, revising and finalizing Celgene's public statements in press releases and SEC filings. In this capacity, Smith directly participated in the review, preparation, and approval of several statements concerning the Ozanimod NDA which were directly belied and rendered materially false or misleading by information known to him as of the date of these statements. *See* ¶¶ 397, 402, 403, 406, 410, 411, 422, and 424. In making such statements, Smith received information about the status of the Ozanimod NDA from Martin, Curran, and others within I&I leadership. *See* ¶¶ 371-73, 402, 404, 410, 411, 416.

472. The scienter of Defendant Celgene may also be independently inferred given the sheer number of high-ranking officials within Celgene who were aware of the Metabolite, the need for additional testing of the Metabolite, and the inability to complete the testing before the planned NDA submission date in December 2017. As alleged above, no fewer than 15 senior Celgene

employees—in addition to Smith, Martin and Curran, who directly participated in the review and approval of Celgene's corporate statements and/or provided information for the inclusion in these statements—were responsible for drafting, reviewing, and approving portions of the Ozanimod NDA. These senior Celgene employees, among others, were intimately involved in all aspects of the Ozanimod NDA and had knowledge of undisclosed material facts rendering Celgene's public statements regarding the Ozanimod NDA materially false or misleading, including the existence of the Metabolite and the need for further testing before submission of the NDA. The extensive involvement of these senior employees in the Ozanimod NDA, in addition to the involvement of the Individual Defendants—who were aware of or participated in the preparation of Celgene's public statements—demonstrates that Defendants' fraud was sufficiently widespread and pervasive to infer Celgene's scienter irrespective of the scienter of the Individual Defendants, which is also imputed to Celgene.

## VIII. CLASS ACTION ALLEGATIONS

473. Lead Plaintiff brings this action on its own behalf and as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all persons and entities who purchased the common stock of Celgene from April 27, 2017 through and including April 27, 2018, and were damaged thereby. Excluded from the Class are: (i) Defendants; (ii) members of the immediate families of the Individual Defendants; (iii) the Company's subsidiaries and affiliates; (iv) any person who is or was an officer or director of the Company or any of the Company's subsidiaries or affiliates during the Class Period; (v) any entity in which any Defendant has a controlling interest; and (vi) the legal representatives, heirs, successors, and assigns of any such excluded person or entity.

474. As the Court has already found, the members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Celgene had more than 800

million shares of common stock outstanding and actively trading on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that the proposed Class numbers in the thousands and is geographically widely dispersed. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

475. As the Court has already found, Lead Plaintiff's claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' alleged conduct in violation of the Exchange Act as complained of herein.

476. As the Court has already found, Lead Plaintiff will fairly and adequately protect the interests of the members of the Class. Lead Plaintiff has retained counsel competent and experienced in class and securities litigation.

477. As the Court has already found, common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include:

- whether Defendants violated the federal securities laws by their acts and omissions as alleged herein;
- whether Defendants made statements to the investing public during the Class Period that contained material misrepresentations or omitted material facts;
- whether and to what extent the market price of Celgene's common stock was artificially inflated during the Class Period because of the material misstatements and omissions alleged herein;
- whether Celgene and the Individual Defendants acted with the requisite level of scienter;
- whether reliance may be presumed; and

- whether the members of the Class have sustained damages as a result of the conduct complained of herein and, if so, the proper measure of damages.

478. As the Court has already found, a class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## IX. THE FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

479. At all relevant times, the market for Celgene's common stock was efficient for the following reasons, among others:

(i) Celgene's common stock met the requirements for listing, and was listed and actively traded on the NASDAQ Global Select Market, a highly efficient and automated market;

(ii) As a regulated issuer, Celgene filed periodic public reports with the SEC and the NASDAQ Global Select Market;

(iii) Celgene regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(iv) Celgene was followed by multiple securities analysts employed by major brokerage firms who wrote reports, which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace. Indeed, more than nine hundred analyst reports on Celgene were published during the Class Period.

480. As a result of the foregoing, the market for Celgene's common stock promptly digested current information regarding Celgene from all publicly available sources and reflected such information in the price of Celgene's stock. Under these circumstances, all purchasers of

Celgene's common stock during the Class Period suffered similar injury through their purchase of Celgene's stock at artificially inflated prices and a presumption of reliance applies.

481. Further, at all relevant times, Lead Plaintiff and other members of the putative Class reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Lead Plaintiff and the other members of the Class would not have purchased or otherwise acquired Celgene common stock at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent that Defendants concealed or improperly failed to disclose material facts with regard to the Company and its business, Lead Plaintiff and other members of the Class are entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

## X. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE ARE INAPPLICABLE

482. The Private Securities Litigation Reform Act's statutory safe harbor and/or the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances do not apply to any of the materially false or misleading statements alleged herein.

483. None of the statements complained of herein was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time each statement was made.

484. To the extent that any materially false or misleading statement alleged herein, or any portion thereof, can be construed as forward-looking, such statement was a mixed statement of present and/or historical facts and future intent, and is not entitled to safe harbor protection with respect to the part of the statement that refers to the present and/or past.

485. To the extent that any materially false or misleading statement alleged herein, or any portions thereof, may be construed as forward-looking, such statement was not accompanied by

meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement or portion thereof. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

486. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged herein, or a portion thereof, Defendants are liable for any such false or misleading statement because at the time such statement was made, the speaker knew the statement was false or misleading, or the statement was authorized and approved by an executive officer of Celgene who knew that such statement was false or misleading.

## XI. CAUSES OF ACTION

### COUNT I
### For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against Celgene and the Individual Defendants

487. Lead Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.

488. This Count is asserted pursuant to Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder on behalf of Lead Plaintiff and all other members of the Class, against Celgene and the Individual Defendants.

489. As alleged herein, throughout the Class Period, Celgene and the Individual Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of national securities exchanges, made materially untrue statements of material fact and/or omitted to state material facts necessary to make their statements not misleading and carried out a plan, scheme, and course of conduct, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated

thereunder. Celgene and the Individual Defendants intended to and did, as alleged herein: (i) deceive the investing public, including Lead Plaintiff and members of the Class; (ii) artificially inflate and maintain the prices of Celgene's common stock; and (iii) cause Lead Plaintiff and members of the Class to purchase the Company's common stock at artificially inflated prices.

490. The Individual Defendants were individually and collectively responsible for making the materially false and misleading statements and omissions alleged herein and having engaged in a plan, scheme, and course of conduct designed to deceive Lead Plaintiff and members of the Class, by virtue of having made public statements and prepared, approved, signed, and/or disseminated documents that contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading.

491. As set forth above, Celgene and the Individual Defendants made the materially false and misleading statements and omissions and engaged in the fraudulent activity described herein knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful deceit and fraud upon Lead Plaintiff and the other members of the Class who purchased the Company's common stock during the Class Period.

492. In ignorance of the materially false and misleading nature of Celgene's and the Individual Defendants' statements and omissions, and relying directly or indirectly on those statements or upon the integrity of the market price for Celgene's common stock, Lead Plaintiff and other members of the Class purchased the Company's common stock at artificially inflated prices during the Class Period. But for the fraud, Lead Plaintiff and members of the Class would not have purchased the Company's common stock at such artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of Celgene's common stock declined precipitously, and Lead Plaintiff and members of the Class were harmed and damaged as

a direct and proximate result of their purchases of the Company's common stock at artificially inflated prices and the subsequent decline in the price of that stock when the truth was disclosed.

## XII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff respectfully prays for judgment as follows:

493. Determining that this action is a proper class action maintained under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, certifying Lead Plaintiff as class representative, and appointing Kessler Topaz Meltzer & Check, LLP as class counsel pursuant to Rule 23(g);

494. Declaring and determining that Defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

495. Awarding Lead Plaintiff and the Class compensatory damages against all Defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

496. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

497. Granting such other and further relief as the Court deems just and proper.

## JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury.

Dated: August 29, 2025

Respectfully submitted,

**CARELLA, BYRNE, CECCHI, BRODY & AGNELLO P.C.**

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# EXHIBIT A

**CERTIFICATION**

AMF Tjänstepension AB ("AMF") declares, as to the claims asserted under the federal securities laws, that:

1. AMF did not purchase the securities that are the subject of this action at the direction of AMF's counsel or in order to participate in any private action.

2. AMF has been serving and will continue to serve as a representative party on behalf of the certified Class, including providing testimony at trial, if necessary.

3. AMF's Class Period purchase and sale transactions in the Celgene Corporation securities that are the subject of this action are attached in Schedule A.

4. AMF has full power and authority to bring suit to recover for its investment losses.[1]

5. AMF has reviewed the Fourth Amended Consolidated Class Action Complaint and authorizes its filing.

6. I, Anders Grefberg, Legal Counsel, am authorized to make legal decisions, and execute this certification, on AMF's behalf.

7. AMF will continue to actively monitor and vigorously pursue this action for the benefit of the Class.

8. AMF will endeavor to provide fair and adequate representation and work directly with the efforts of Class Counsel to ensure that the largest recovery for the Class consistent with good faith and meritorious judgment is obtained.

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1 AMF has received an assignment of claims from AMF Fonder AB with respect to all rights, titles, and interests in the claims, demands, or causes of action against any defendant relating to transactions by AMF Fonder and its mutual funds, AMF Aktiefond Global, AMF Aktiefond Världen, AMF Balansfond and AMF Aktiefond Nordamerika, in any security issued by Celgene Corporation.

9. AMF has sought to serve as a representative party in a class action filed under the federal securities laws during the three years prior to the date of this Certification in *Cronin v. Merck & Co., Inc.*, No. 25-cv-1208 (D.N.J.) (motion pending).

10. AMF has not otherwise sought to serve as a representative party for a class action filed under the federal securities laws during the three years prior to the date of the Certification.

11. AMF will not accept any payment for serving as a representative party on behalf of the Class beyond AMF's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the Class as ordered or approved by the Court.

I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct.

Executed this 28th day of August 2025.

AMF Tjänstepension AB

By: DocuSigned by: Anders Grefberg C2FE10844E264C6...

Anders Grefberg
Legal Counsel

# SCHEDULE A

## AMF Tjänstepension AB

| Security | Buy/Sell | Date | Quantity | Price |
|---|---|---|---|---|
| Common Stock | BUY | 4/28/2017 | 24,385 | $123.87 |
| Common Stock | BUY | 7/5/2017 | 61,723 | $132.39 |
| Common Stock | BUY | 10/12/2017 | 39,602 | $138.50 |
| Common Stock | SELL | 1/10/2018 | 17,101 | $105.46 |
| Common Stock | SELL | 3/8/2018 | 29,367 | $91.19 |
| Common Stock | SELL | 4/17/2018 | 26,704 | $91.10 |

## AMF Aktiefond Nordamerika

| Security | Buy/Sell | Date | Quantity | Price |
|---|---|---|---|---|
| Common Stock | BUY | 6/22/2017 | 156 | $134.00 |
| Common Stock | BUY | 10/30/2017 | 300 | $100.70 |
| Common Stock | BUY | 10/31/2017 | 700 | $100.74 |
| Common Stock | BUY | 11/7/2017 | 300 | $102.15 |
| Common Stock | BUY | 12/18/2017 | 300 | $108.97 |
| Common Stock | BUY | 1/26/2018 | 400 | $106.13 |
| Common Stock | BUY | 1/29/2018 | 946 | $105.49 |
| Common Stock | BUY | 3/6/2018 | 454 | $88.97 |
| Common Stock | BUY | 4/13/2018 | 800 | $90.25 |
| Common Stock | SELL | 6/15/2017 | 1,506 | $119.56 |
| Common Stock | SELL | 7/26/2017 | 1,300 | $136.88 |
| Common Stock | SELL | 10/5/2017 | 300 | $140.10 |
| Common Stock | SELL | 10/20/2017 | 900 | $122.23 |
| Common Stock | SELL | 10/26/2017 | 300 | $97.53 |
| Common Stock | SELL | 1/4/2018 | 400 | $106.81 |
| Common Stock | SELL | 1/5/2018 | 400 | $105.93 |

## AMF Aktiefond Världen

| Security | Buy/Sell | Date | Quantity | Price |
|---|---|---|---|---|
| Common Stock | BUY | 6/21/2017 | 2,530 | $130.44 |
| Common Stock | BUY | 6/22/2017 | 400 | $134.00 |
| Common Stock | BUY | 10/30/2017 | 1,300 | $100.70 |
| Common Stock | BUY | 10/31/2017 | 2,700 | $100.74 |
| Common Stock | BUY | 11/7/2017 | 1,300 | $102.15 |
| Common Stock | BUY | 11/10/2017 | 2,420 | $101.73 |
| Common Stock | BUY | 11/24/2017 | 1,500 | $104.94 |
| Common Stock | BUY | 12/18/2017 | 600 | $108.97 |

| | | | | |
|---|---|---|---|---|
| Common Stock | BUY | 12/19/2017 | 1,200 | $107.76 |
| Common Stock | BUY | 1/26/2018 | 750 | $106.13 |
| Common Stock | BUY | 1/29/2018 | 3,780 | $105.49 |
| Common Stock | BUY | 3/6/2018 | 3,000 | $88.97 |
| Common Stock | BUY | 4/16/2018 | 3,080 | $91.00 |
| Common Stock | SELL | 6/15/2017 | 5,622 | $119.56 |
| Common Stock | SELL | 7/26/2017 | 5,200 | $136.88 |
| Common Stock | SELL | 10/5/2017 | 2,300 | $140.10 |
| Common Stock | SELL | 10/20/2017 | 3,600 | $122.23 |
| Common Stock | SELL | 10/26/2017 | 1,100 | $97.53 |
| Common Stock | SELL | 1/4/2018 | 2,700 | $106.81 |
| Common Stock | SELL | 1/5/2018 | 1,600 | $105.93 |

**AMF Aktiefond Global**

| Security | Buy/Sell | Date | Quantity | Price |
|---|---|---|---|---|
| Common Stock | BUY | 6/21/2017 | 1,180 | $130.44 |
| Common Stock | BUY | 6/22/2017 | 90 | $133.00 |
| Common Stock | BUY | 8/17/2017 | 570 | $129.35 |
| Common Stock | BUY | 10/30/2017 | 400 | $100.70 |
| Common Stock | BUY | 10/31/2017 | 800 | $100.74 |
| Common Stock | BUY | 11/7/2017 | 300 | $102.15 |
| Common Stock | BUY | 11/10/2017 | 910 | $101.73 |
| Common Stock | BUY | 12/18/2017 | 100 | $108.97 |
| Common Stock | BUY | 12/19/2017 | 600 | $107.76 |
| Common Stock | BUY | 1/26/2018 | 400 | $106.13 |
| Common Stock | BUY | 1/29/2018 | 1,039 | $105.49 |
| Common Stock | BUY | 3/6/2018 | 600 | $88.97 |
| Common Stock | BUY | 4/13/2018 | 900 | $90.25 |
| Common Stock | SELL | 6/15/2017 | 1,438 | $119.56 |
| Common Stock | SELL | 6/22/2017 | 200 | $133.99 |
| Common Stock | SELL | 7/26/2017 | 1,400 | $136.88 |
| Common Stock | SELL | 10/5/2017 | 600 | $140.10 |
| Common Stock | SELL | 10/20/2017 | 1,000 | $122.23 |
| Common Stock | SELL | 10/26/2017 | 400 | $97.53 |
| Common Stock | SELL | 1/4/2018 | 700 | $106.81 |
| Common Stock | SELL | 1/5/2018 | 400 | $105.93 |

**AMF Aktiefond Mix ***

| Security | Buy/Sell | Date | Quantity | Price |
|---|---|---|---|---|
| Common Stock | BUY | 6/21/2017 | 1,900 | $130.44 |
| Common Stock | BUY | 8/17/2017 | 570 | $129.35 |

| | | | | |
|---|---|---|---|---|
| Common Stock | BUY | 9/1/2017 | 530 | $138.50 |
| Common Stock | BUY | 10/2/2017 | 1,020 | $146.81 |
| Common Stock | BUY | 10/30/2017 | 700 | $100.70 |
| Common Stock | BUY | 10/31/2017 | 1,600 | $100.74 |
| Common Stock | BUY | 11/7/2017 | 600 | $102.15 |
| Common Stock | BUY | 11/10/2017 | 1,210 | $101.73 |
| Common Stock | BUY | 11/24/2017 | 1,200 | $104.94 |
| Common Stock | BUY | 12/18/2017 | 400 | $108.97 |
| Common Stock | BUY | 12/19/2017 | 900 | $107.76 |
| Common Stock | BUY | 1/26/2018 | 400 | $106.13 |
| Common Stock | BUY | 1/29/2018 | 2,129 | $105.49 |
| Common Stock | BUY | 2/22/2018 | 1,060 | $95.24 |
| Common Stock | SELL | 6/15/2017 | 2,867 | $119.56 |
| Common Stock | SELL | 6/22/2017 | 700 | $133.99 |
| Common Stock | SELL | 7/26/2017 | 2,700 | $136.88 |
| Common Stock | SELL | 10/5/2017 | 1,300 | $140.10 |
| Common Stock | SELL | 10/20/2017 | 2,000 | $122.23 |
| Common Stock | SELL | 10/26/2017 | 700 | $97.53 |
| Common Stock | SELL | 1/4/2018 | 1,500 | $106.81 |
| Common Stock | SELL | 1/5/2018 | 900 | $105.93 |

**AMF Balansfond**

| Security | Buy/Sell | Date | Quantity | Price |
|---|---|---|---|---|
| Common Stock | BUY | 9/6/2017 | 114 | $139.85 |
| Common Stock | BUY | 9/6/2017 | 285 | $139.66 |
| Common Stock | BUY | 9/6/2017 | 171 | $139.99 |
| Common Stock | BUY | 10/30/2017 | 400 | $100.70 |
| Common Stock | BUY | 10/31/2017 | 1,000 | $100.74 |
| Common Stock | BUY | 11/7/2017 | 400 | $102.15 |
| Common Stock | BUY | 11/10/2017 | 910 | $101.73 |
| Common Stock | BUY | 12/18/2017 | 200 | $108.97 |
| Common Stock | BUY | 1/26/2018 | 500 | $106.13 |
| Common Stock | BUY | 1/29/2018 | 1,260 | $105.49 |
| Common Stock | BUY | 3/6/2018 | 700 | $88.97 |
| Common Stock | SELL | 6/15/2017 | 1,973 | $119.56 |
| Common Stock | SELL | 6/22/2017 | 300 | $133.99 |
| Common Stock | SELL | 7/26/2017 | 1,800 | $136.88 |
| Common Stock | SELL | 10/5/2017 | 900 | $140.10 |
| Common Stock | SELL | 10/20/2017 | 1,300 | $122.23 |
| Common Stock | SELL | 10/26/2017 | 400 | $97.53 |
| Common Stock | SELL | 1/4/2018 | 800 | $106.81 |

| | | | | |
|---|---|---|---|---|
| Common Stock | SELL | 1/5/2018 | 500 | $105.93 |

*** AMF Aktiefond Mix merged with AMF Aktiefond Global in June 2019.**