EXHIBIT 2

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HOWARD BERNSTEIN, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB CO.; MARK J. ALLES; GIOVANNI CAFORIO, M.D.; SANDRA LEUNG, ESQ.; CHARLES BANCROFT; KAREN M. SANTIAGO; VICKI L. SATO, PH.D.; PETER J. ARDUINI; ROBERT BERTOLINI; MATTHEW W. EMMENS; MICHAEL GROBSTEIN; ALAN J. LACY; DINESH C. PALIWAL; THEODORE R. SAMUELS; GERALD L. STORCH; and KAREN H. VOUSDEN, PH.D,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: UNION COUNTY

Docket No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE SECURITIES ACT OF 1933

DEMAND FOR JURY TRIAL

INTRODUCTION

1. Plaintiff Howard Bernstein ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings by Bristol-Myers Squibb Company ("Bristol-Myers" or the "Company") and Celgene Corporation ("Celgene"), as well as media and analyst reports about and press releases from Bristol-Myers and Celgene. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein.

SUMMARY OF THE ACTION

2. Plaintiff brings this securities class action on behalf of all persons who acquired Bristol-Myers common stock and/or Contingent Value Rights ("CVRs") pursuant or traceable to the S-4 registration statement and prospectus (collectively, the "Registration Statement") issued in connection with Bristol-Myers' November 2019 acquisition of and merger with Celgene (the "Merger" or "Acquisition").

3. This action asserts strict liability claims under §§11, 12(a)(2), and 15 of the Securities Act of 1933 ("1933 Act" or "Securities Act") against Bristol-Myers and certain current and former officers and directors of Bristol-Myers (collectively, Defendants) and Celgene.

4. Ahead of the Acquisition, Celgene was a pharmaceutical company headquartered in Summit, New Jersey, engaged primarily in the discovery, development, and commercialization of therapies for the treatment of cancer and inflammatory disease, one of which was a blockbuster cancer therapy – JCAR017 a/k/a lisocabtagene maraleucel ("Liso-cel"). Celgene common stock traded on the NASDAQ under the ticker symbol "CELG."

5. Defendant Bristol-Myers is a pharmaceutical company headquartered in New York, New York. Bristol-Myers' common stock trades on the New York Stock Exchange ("NYSE") under the ticker symbol "BMY."

6. In November 2019, in connection with the Acquisition, Bristol-Myers issued approximately 714.9 million new shares of BMY common stock and 714.9 CVRs directly to former shareholders of Celgene as follows: Each former share of Celgene common stock issued and outstanding before the Acquisition was automatically converted into the right to receive (1) $50.00 in cash, without interest; (2) one share of BMS common stock; and (3) one CVR. Each of these new shares of Bristol-Myers common stock and CVRs were issued pursuant to the Registration Statement.

7. The Registration Statement contained untrue statements of material fact and omitted to state material facts both required by governing regulations and necessary to make the statements made not misleading. Foremost, it failed to disclose that Bristol-Myers was already implementing operational irregularities and drafting aberrant regulatory filings that diverged from industry practice, contravened ongoing FDA guidance, and that would slow-roll the FDA approval process for a Liso-cel and thereby avoid a $6.4 billion payment promised to CVR holders. By Bristol-Myers' own design, the CVR payout required approval of three therapies, including Liso-cel, by specified dates (the "Milestones"). A single therapy of the three missing its Milestone, even by a single day, was all Bristol-Myers needed to avoid payment to CVR holders. To ensure that miss, Bristol-Myers blatantly strayed both from industry standards and its own long-standing practices in a multitude of prior FDA filings – including, for example, crafting and submitting FDA filings that omitted volumes of basic information concerning Liso-cel and allowing operational lapses at planned manufacturing facilities – all to subvert the FDA regulatory approval process for Liso-cel and thereby miss the Milestone for the CVR payout. Bristol-Myers knew that

each defective submission and each operational stumbling block would delay FDA review, inspection, and approval of Liso-cel, and that by gumming up the approval process, the Liso-cel Milestone (and ultimate payment to CVR holders) would be missed.

8. The plan Bristol-Myers implemented was inconsistent with its own and industry practices. For example, the Biologic License Application ("BLA") portion that Bristol-Myers was drafting before the Merger and would submit to the FDA for review and approval just weeks after the Merger Close was designed to omit critical data, the omission of which, once the FDA predictably demanded it in the form of an amendment, would trigger ***an automatic three-month delay*** to achieving the Liso-cel Milestone. At the same time, Bristol-Myers was allowing its purportedly launch-ready production facilities to lapse basic FDA and industry standards. Again, upon inspection, the FDA predictably found the facilities riddled with "significant" issues risking adulteration, contamination, and harm to patients. This was not Bristol-Myers' first rodeo. These basic self-inflicted wounds were inexcusable and no mistake. Bristol-Myers implemented (and failed to disclose) an egregiously aberrant approval plan that would, *inter alia*:

(i) fail to implement laboratory controls with appropriate specifications and procedures to ensure Liso-cel conformed to appropriate standards of identity, strength, quality and purity;

(ii) fail to document or correct discrepancies between batches of Liso-cel;

(iii) fail to monitor the manufacturing environment to prevent the contamination of sterile drug products;

(iv) fail to ensure the reliability of third-party vendors' Certificates of Analysis, which certify compliance with product specifications;

(v) fail to establish appropriate follow-up procedures, *e.g.*, if a Liso-cel batch did not meet specifications, Bristol-Myers did not take appropriate steps to understand why that batch had failed; and

(vi) fail to timely address FDA concerns.

9. Any one of these obvious deficiencies could severely gum up the FDA approval process and thereby torpedo any prospect of meeting Liso-cel's CVR Milestone. Together, they leave no doubt.

10. Defendants were required to disclose this material information in the Registration Statement for at least three independent reasons. First, SEC Regulation S K, 17 C.F.R. §229.303 ("Item 303"), required disclosure of any known events or uncertainties that had caused or were reasonably likely to cause Bristol-Myers' disclosed financial information not to be indicative of future operating results. The deficient plan Bristol-Myers had in place, and the Company's consequent failure to exercise diligent efforts consistent with industry standards to achieve the Liso-cel Milestone, were all likely to (and in fact, did) materially and adversely affect Bristol-Myers' future results and prospects.

11. Second, SEC Regulation S K, 17 C.F.R. §229.503 ("Item 503"), required, in the "Risk Factor" section of the Registration Statement, a discussion of the most significant factors that make the offering risky or speculative, and that each risk factor adequately describe the risk. Bristol-Myers' discussions of risk factors did not even mention, much less adequately describe the risk posed by, Bristol-Myers' plan to slow-roll the FDA approval process and thereby miss the Liso-cel Milestone, nor the likely and consequent material adverse effects on the Company's future results and prospects.

12. Third, Defendants' failure to disclose rendered false and misleading the Registration Statement's many references to known risks that "***if***" occurring "***may***" or "***could***"

affect the Company. For example, the Registration Statement made a series of risk disclosures regarding the potential diminished value of the CVRs, *e.g.*, that "Your right to receive any future payment on the CVRs will be contingent upon the achievement of certain agreed upon U.S. regulatory milestones within the time periods specified in the CVR agreement . . . . Accordingly, the value, if any, of the CVRs is speculative, and the CVRs may ultimately have no value." The Registration Statement also referenced purported "uncertainty regarding the fair market value of the CVRs and whether any payment will ultimately be realized on the CVRs." These representations and purported risk disclosures were materially misleading because, in truth, the CVRs were worth nothing since Bristol-Myers had no intention of meeting the Milestone dates, much less employing "diligent efforts" to achieve them, or paying anything for the CVRs. In other words, these "risks" were already materializing at the time of the Acquisition.

13. With these misrepresentations and omissions in the Registration Statement, Defendants were able to complete the Acquisition. But as the truth began to emerge, the price of Bristol-Myers common stock and CVRs shares suffered sharp declines, Bristol-Myers unjustly profited by avoiding approximately $6.4 billion in payouts owed to CVRs investors, and as a result Plaintiff and other former Celgene shareholders suffered severe losses.

JURISDICTION AND VENUE

14. This Court has original subject matter jurisdiction under the New Jersey Constitution. Removal is barred by Section 22 of the 1933 Act.

15. This Court has personal jurisdiction and venue is properly laid in this Court because certain defendants reside in or, at relevant times, were headquartered in the State of New Jersey, County of Union, Defendants and their agents affirmatively solicited and sold the subject securities and Registration Statement to Plaintiff and other investors in New Jersey and this county, and the drafting and dissemination of the alleged false and misleading offering documents, the special

meeting of Celgene shareholders, and other central events and contacts give rise to the claims alleged herein, all occurred in this county.

PARTIES

16. Plaintiff owned Celgene shares at the time of the Acquisition, and, via the Acquisition, received newly issued Bristol-Myers common stock and CVRs in exchange directly from Defendant Bristol-Myers pursuant to the Registration Statement and was damaged thereby. After the truth began to emerge, Plaintiff sold Bristol-Myers common stock shares at a price per share below the offering price and thereby suffered a realized loss as a result of Defendants' violation of the Securities Act. After the truth began to emerge, the price per share of Plaintiff's Bristol-Myers CVRs declined precipitously and has never recovered. In December 2020, Bristol-Myers missed the Liso-cel Milestone, terminated the CVR Agreement, delisted the security from NYSE, and to date has failed to make any of the promised payout to Plaintiff or other CVR holders.

17. Non-party Celgene was a pharmaceutical company headquartered in Summit, New Jersey, engaged primarily in the discovery, development, and commercialization of therapies for the treatment of cancer and inflammatory diseases. Celgene common stock traded on the NASDAQ under the ticker symbol "CELG."

18. Defendant Bristol-Myers is a pharmaceutical company incorporated under the laws of Delaware and headquartered in New York, New York. Bristol-Myers' common stock trades on the New York Stock Exchange ("NYSE") under the ticker symbol "BMY." Bristol-Myers, in connection with the Acquisition, issued approximately 714.9 million shares of Bristol-Myers common stock and 714.9 million new CVRs (plus cash consideration) directly to Plaintiff and other former Celgene shareholders in exchange for their Celgene common stock, all pursuant to the Registration Statement.

19. Defendant Mark J. Alles was, at all relevant times, Celgene's Chief Executive Officer ("CEO") and Chairman of the Celgene Board of Directors. Defendant Alles reviewed, contributed to, and signed the Registration Statement. Defendant Alles directly solicited Plaintiff and other former Celgene shareholders to participate in the Acquisition and thereby exchange their Celgene shares for newly issued Bristol-Myers common stock and CVRs.

20. Defendant Giovanni Caforio, M.D., was, at all relevant times, Chief Executive Officer and Chairman of the Board of Bristol-Myers. Defendant Caforio reviewed, contributed to, and signed the Registration Statement. Defendant Caforio directly solicited Plaintiff and other former Celgene shareholders to participate in the Acquisition and thereby exchange their Celgene shares for newly issued Bristol-Myers common stock and CVRs.

21. Defendant Sandra Leung, Esq., was, at all relevant times, Executive Vice President of and General Counsel to Bristol-Myers. Defendant Leung reviewed, contributed to, and signed the Registration Statement.

22. Defendant Charles Bancroft, was, at all relevant times, Chief Financial Officer of Bristol-Myers. Defendant Bancroft reviewed, contributed to, and signed the Registration Statement.

23. Defendant Karen M. Santiago, was, at all relevant times, Senior Vice President, Corporate Controller, and Principal Accounting Officer of Bristol-Myers. Defendant Santiago reviewed, contributed to, and signed the Registration Statement.

24. Defendant Vicki L. Sato, Ph.D., was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Sato reviewed, contributed to, and signed the Registration Statement.

25. Defendant Peter J. Arduini was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Arduini reviewed, contributed to, and signed the Registration Statement.

26. Defendant Robert Bertolini was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Bertolini reviewed, contributed to, and signed the Registration Statement.

27. Defendant Matthew W. Emmens was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Emmens reviewed, contributed to, and signed the Registration Statement.

28. Defendant Michael Grobstein was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Grobstein reviewed, contributed to, and signed the Registration Statement.

29. Defendant Alan J. Lacy was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Lacy reviewed, contributed to, and signed the Registration Statement.

30. Defendant Dinesh C. Paliwal was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Paliwal reviewed, contributed to, and signed the Registration Statement.

31. Defendant Theodore R. Samuels was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Samuels reviewed, contributed to, and signed the Registration Statement.

32. Defendant Gerald L. Storch was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Storch reviewed, contributed to, and signed the Registration Statement.

33. Defendant Karen H. Vousden, Ph.D, was, at all relevant times, a Director on the Board of Bristol-Myers. Defendant Vousden reviewed, contributed to, and signed the Registration Statement.

34. The defendants named in ¶¶19-33 are referred to herein as the "Individual Defendants." The Individual Defendants each signed the Registration Statement, solicited the purchase securities issued pursuant thereto, planned and contributed to the Acquisition and

Registration Statement, and attended promotions to meet with and present favorable information to Bristol-Myers and Celgene investors, all motivated by their own and the Company's financial interests.

FACTUAL BACKGROUND

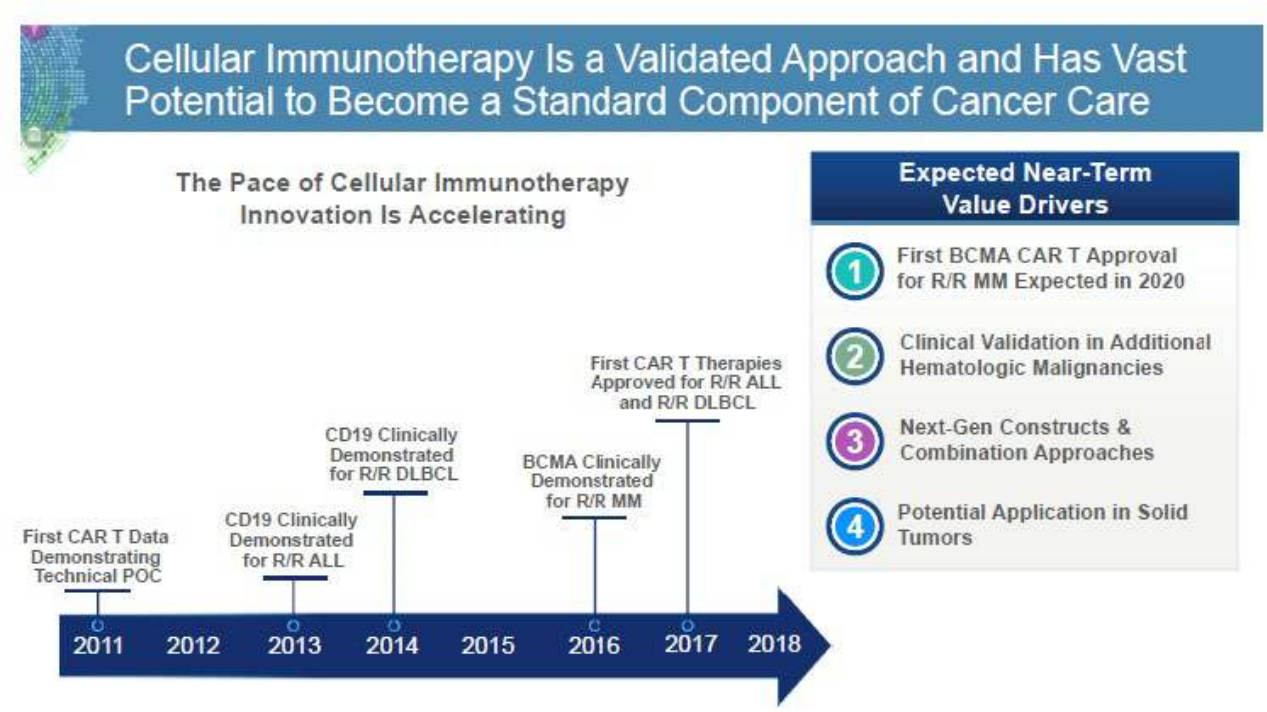
A. Celgene Acquires Juno Therapeutics in 2018 to Develop Its Flagship Car-T Therapy Liso-cel

35. Prior to the Acquisition by Bristol-Myers, Celgene was a global biopharmaceutical company engaged primarily in the discovery, development, and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases. Celgene pursued next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuroinflammation. Celgene invested substantially in research and development in support of multiple ongoing clinical development programs and, in the first through third quarters of 2018, Celgene spent $2.203 billion, $1.251 billion, and $1.081 billion, respectively, on research and development. By the time of the Acquisition, Celgene had ongoing clinical trials in the disease areas of hematology, solid tumors, inflammation, and immunology, with more than 300 clinical trials at major medical centers using compounds from Celgene.

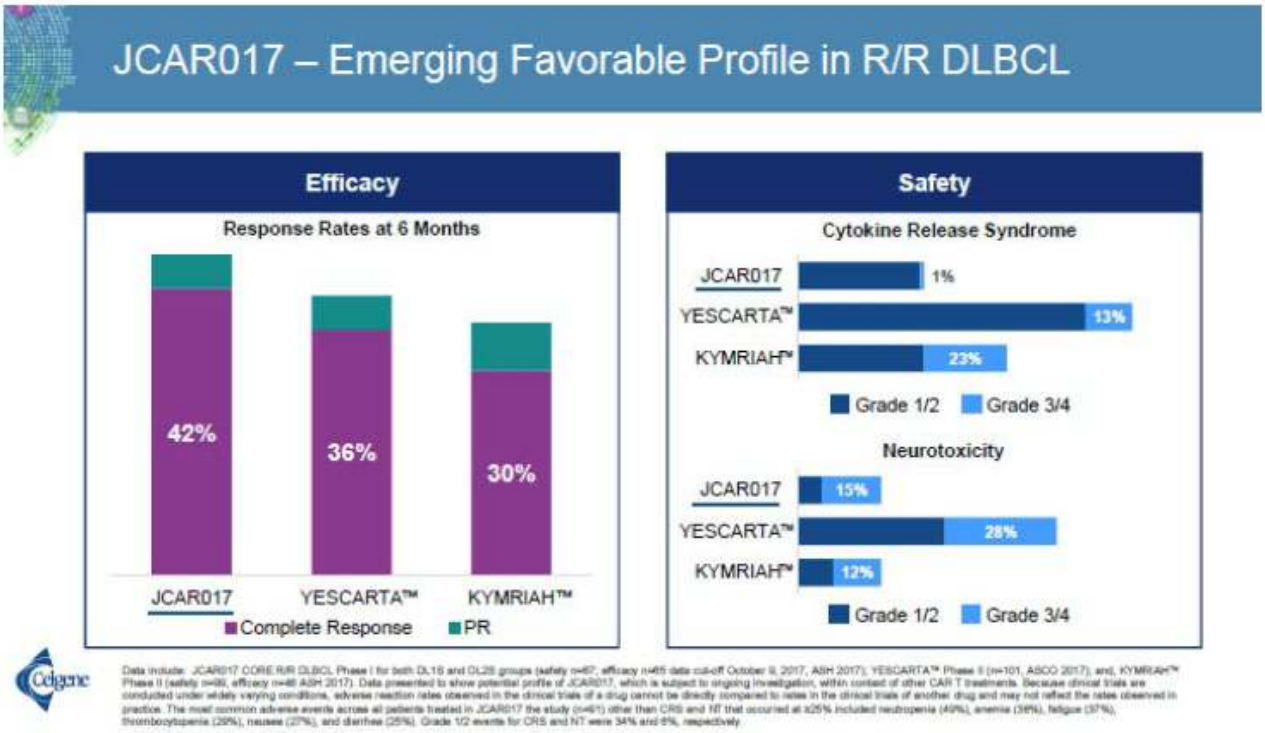
36. In 2018, Celgene sought to expand its immunology division by acquiring a business engaged in the development of products using novel CAR-T therapy. CAR-T is a revolutionary immunotherapy that programs a patient's immune system to recognize and fight cancer. During the treatment process, T-cells are removed from a patient's blood and genetically modified to recognize the patient's cancer cells. The T-cells are then reinfused into the patient for the purpose of recognizing and destroying cancer cells.

37. To that end, in January 2018, Celgene announced it had agreed to acquire Juno Therapeutics, a specialty biopharmaceutical company on the forefront of CAR-T immunotherapy.

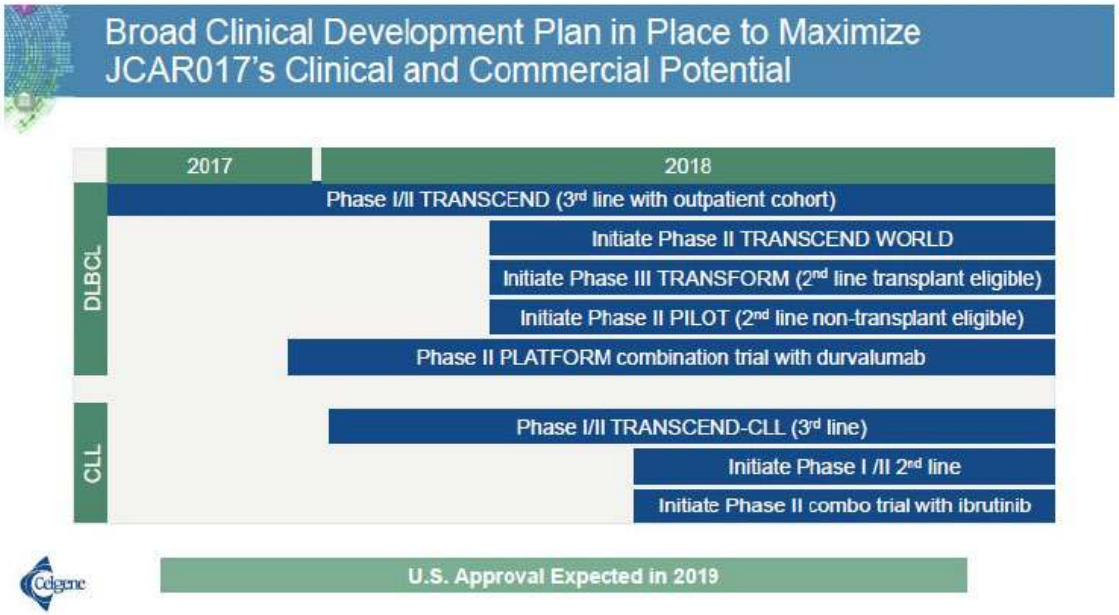
In the presentation discussing the acquisition, Celgene set forth the expected timeline for FDA approval of Juno's CAR-T candidates as follows:



38. In the same presentation, Celgene highlighted the efficacy of Liso-cel relative to other CAR-T therapies developed by competitor biopharmaceutical companies. Liso-cel had a remarkable "Complete Response" rate of 42% versus rivals YESCARTA, with an efficacy rate of 36% and KYMRIAH with an efficacy rate of 30%. The presentation also highlighted Liso-cel's safety profile, including that just 1% of trial participants experienced Cytokine Release Syndrome (a common but occasionally serious side effect), more than 10 times less than the rival CAR-T therapies:



39. Celgene's management also set forth a timeline for comprehensive and exhaustive efficacy and response trials for Liso-cel:



B. Prior to the Acquisition, Expedited FDA Approval of Liso-cel Was on Track

40. Before the Acquisition, Celgene touted the timeline for FDA approval of Liso-cel. For example, during a June 6, 2018 earnings call, Celgene's President of Global Hematology & Oncology, Nadim Ahmed, stated:

> So the approval for JCAR017 liso-cel is 2019, that's still the plan. We're kind of – with the TRANSCEND U.S. study, we are protecting that cohort. That's the pivotal study. So as we see continued updates, we'll continue to update the core study. But we want to make sure that we need to get that study, which is now fully accrued, get all the follow-up data, sit down with the regulatory agencies to make sure we've got a good package and then we'll start thinking about when we present those data publicly.

41. Thereafter, during a July 26, 2018 conference call, Celgene's Chief Medical Officer Jay Backstrom stated: "***In keeping with our goal to be a global leader in cellular immunotherapy, both bb2121 and liso-cel continue to advance and remain top priorities***." Mr. Backstrom further stated that Liso-cel "***BLA preparations are underway, and the program remains on track for an expected 2019 approval***." During an October 26, 2018 conference call, Celgene's CEO Mark J. Alles stated "we are making meaningful progress advancing our late-stage pipeline to high-value inflection." [Emphasis added.]

42. Celgene's statements regarding the likelihood of Liso-cel approval continued following the announcement of the acquisition by Bristol-Myers. In this regard, during a January 7, 2019 investor call, Nadim Ahmed (Celgene's President of Global Hematology & Oncology) stated: "***I think everything is on track from a manufacturing process, actually across all of our CAR T programs, both from the clinical trial perspective and the commercial perspective***."[1] [Emphasis added.]

[1] Chimeric Antigen Receptor ("CAR") immunotherapy designed to train T-cells ("CAR-T" or "CAR T").

43. On the same call, Celgene's EVP of Global Pharmaceutical Development, Joanne T. Beck, stated:

> Now we just wait. You know the data set. You know the safety profile. This is the point about being derisked ***liso-cel, we've had the pivotal data for about 6, 8 months. Our focus is on the BLA, not updating the world about follow-up data, but on the regulatory submission for liso-cel***. So when we think about the CVR and the 3 products that we've agreed are perhaps a little bit more idiosyncratic or unique, they make up the CVR, but there are 5 products here that are expected to launch, as Giovanni says, with derisked data in the next 18 to 24 months. All have the kind of upside opportunity in the short term in advance of any IP scenario that we see happening to Revlimid and its erosion, and that's on top of the life cycle for OPDIVO and other products that mechanically drive the cash flows and the upside for the company.

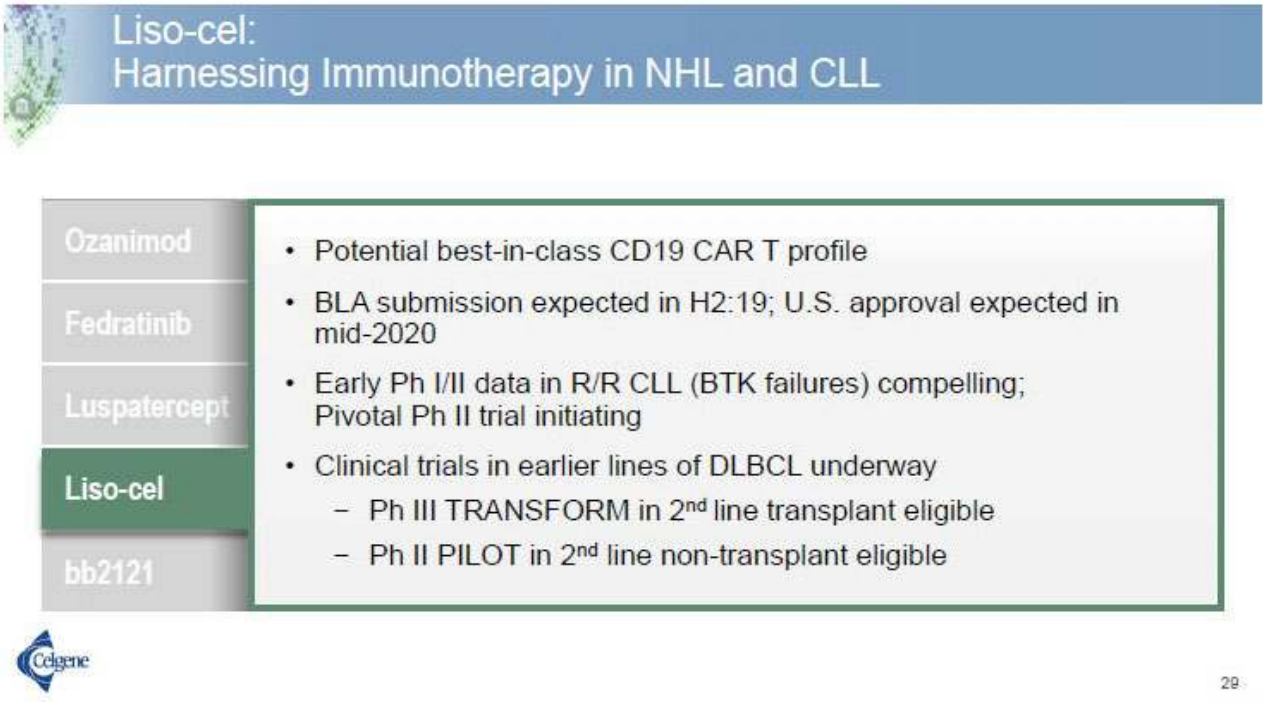
[Emphasis added.]

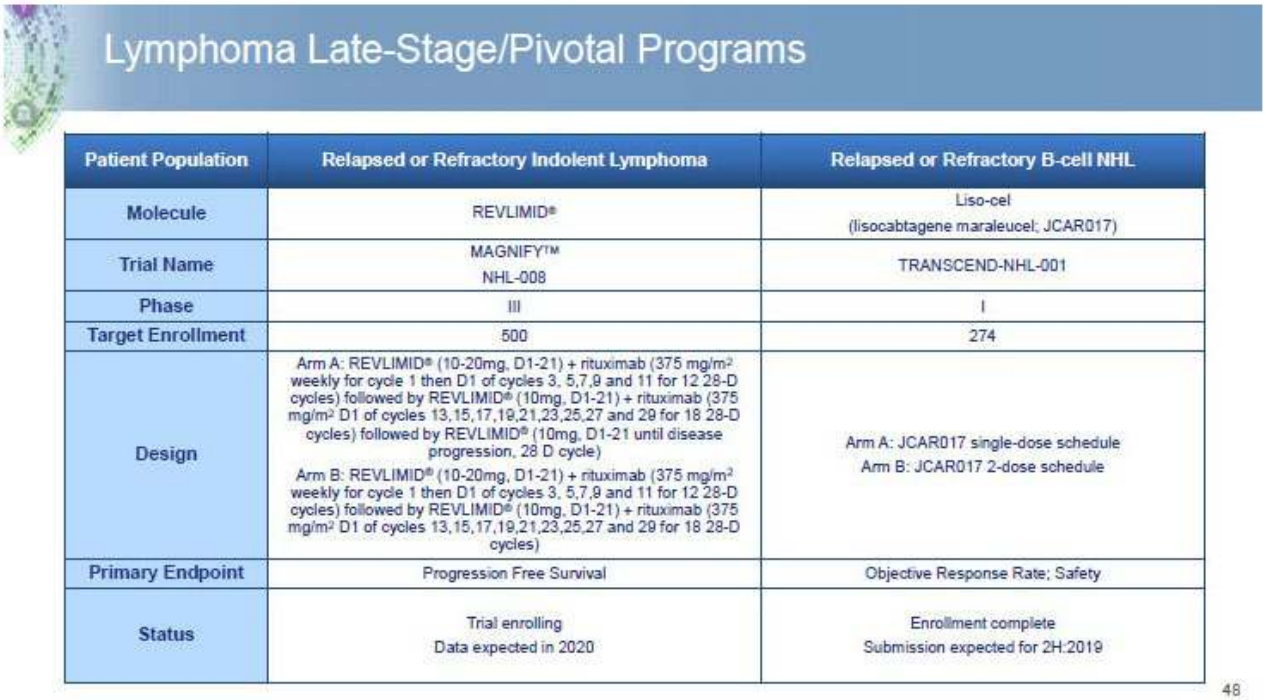
44. On January 31, 2019, during Celgene's call to discuss Fourth Quarter and full year financial results, Mr. Ahmed stated:

> Now turning to our CAR T programs. ***Both liso-cel and bb2121 remain on target for expected 2020 approvals. For liso-cel, on Slide 29, we remain on track for submitting the BLA in the second half of 2019 with an expected U.S. approval in mid-2020. As we've previously mentioned, the BLA will include a robust data package containing substantial follow-up on the relapsed/refractory diffuse large B-cell lymphoma cohort, allowing further characterization of the duration of response and will include a safety database that will be approaching 300 treated patients by the time of our submission, a safety database that will be 2x to 3x that included in the initial submissions for the 2 approved CD19-directed CAR Ts***. In addition, we are advancing liso-cel to earlier lines of treatment, with the secondline studies TRANSFORM and PILOT in diffuse large B-cell lymphoma patients who are transplant eligible or nontransplant eligible, respectively.

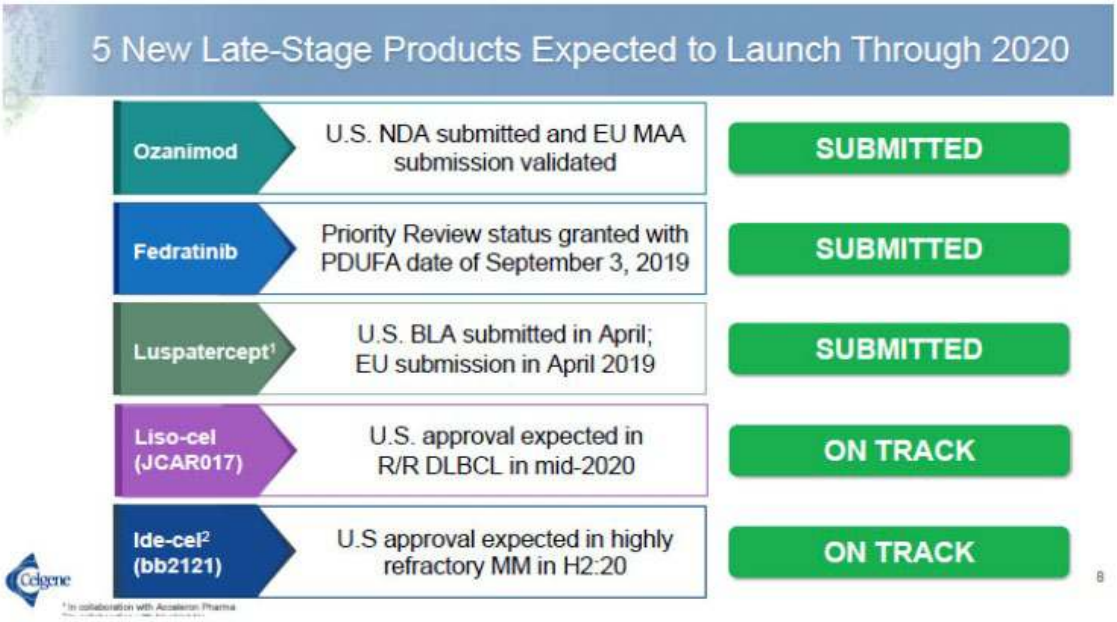
[Emphasis added.]

45. The related slides from the accompanying presentation reiterated that Liso-cel's BLA submission was expected in 2019 and FDA approval was expected in mid-2020. Specifically, the presentation highlighted Liso-cel as a "potential best-in-class CD19 CAR T profile," that Phase I/II trial data was "compelling" and that Celgene expected to submit the BLA in mid-2019, which would enable FDA approval of Liso-cel in mid-2020:

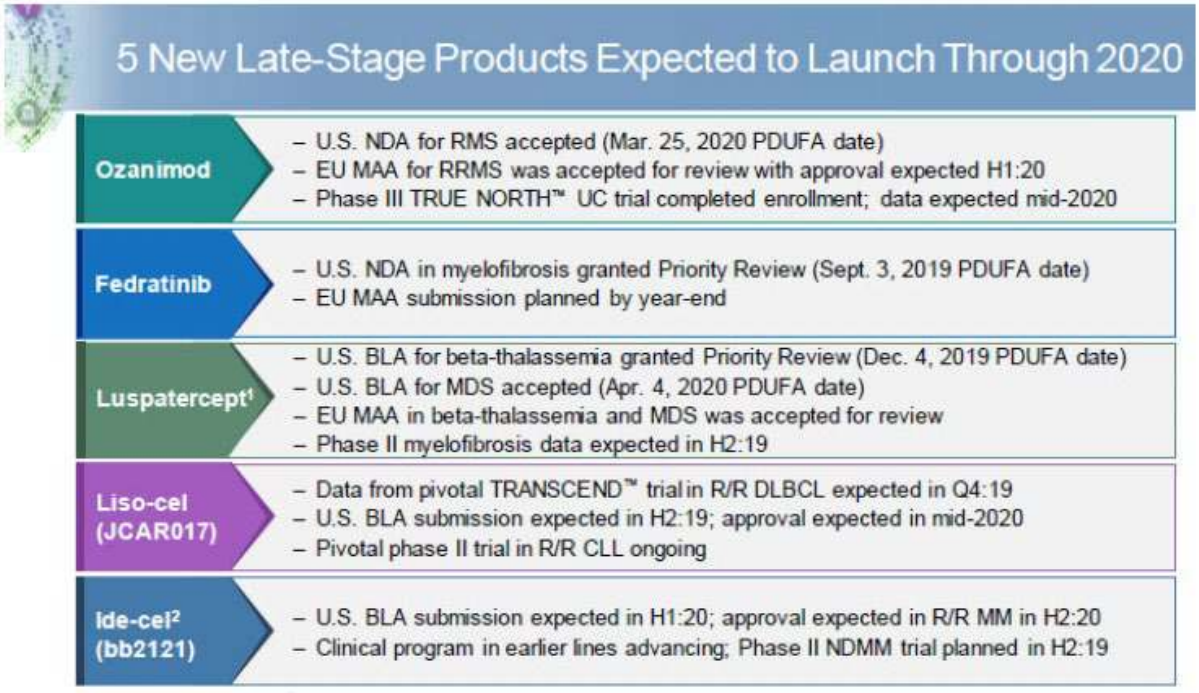




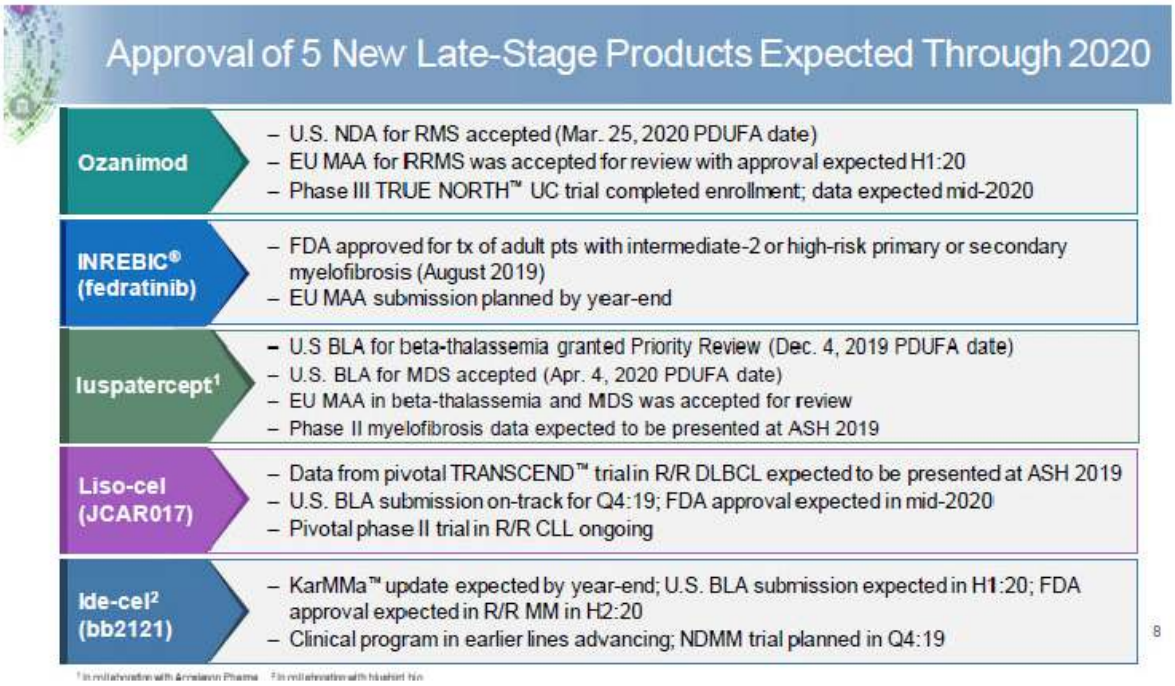
46. Similarly, in Celgene's First Quarter earnings presentation published April 25, 2019, it represented to investors that Liso-cel was "on track" and that U.S. approval was expected in "mid-2020."



47. Celgene's Second Quarter 2019 earnings presentation published on July 30, 2019 again stated that Liso-cel approval was expected in mid-2020. The presentation further explained that the data from the TRANSCEND trial for Liso-cel was expected in the Fourth Quarter of 2019:



48. Celgene's Third Quarter earnings presentation on October 31, 2019, represented that the BLA submission was "on track" in the Fourth Quarter and that "approval was expected in mid-2020."



49. As such, ahead of the Merger, the submission of the BLA for Liso-cel and FDA approval for Liso-cel was on track for mid-2020.

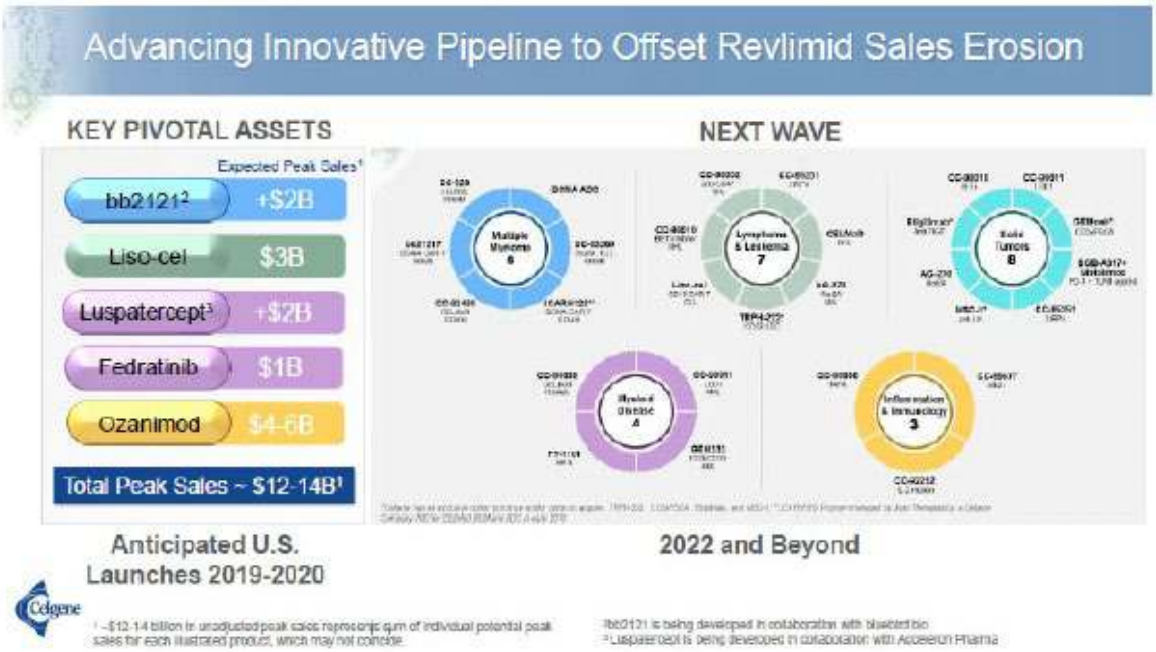
C. In Negotiating the Acquisition, Bristol-Myers Demands Issuing CVRs to Celgene Shareholders in Exchange for Less Cash Consideration

50. In September 2018, Bristol-Myers contacted Celgene to propose a transaction that would result in Celgene becoming a wholly owned subsidiary of Bristol-Myers. The two parties had previously discussed a strategic transaction and Celgene expressed interest in renewing those negotiations. During the ensuing months, the companies began merger negotiations, with Celgene's valuation the main point of contention.

51. Critical to Bristol-Myers' decision to pursue the Acquisition was Celgene's robust pipeline of five late-stage, near-term drugs slated for imminent FDA approval that were expected

to generate upwards of $15 billion in annual revenue. Bristol-Myers' stated business purpose for the Merger was to acquire Celgene's pipeline at "an attractive price."[2]

52. In the months preceding the Merger, Celgene had touted to its investors that the five pipeline drugs were "Key Pivotal Assets" designed to offset its sales erosion from the expiration of patents on earlier drugs:



53. The crown jewel of Celgene's late-stage, near-term pipeline was Liso-cel, a revolutionary Chimeric Antigen Receptor ("CAR") immunotherapy designed to train T-cells ("CAR-T" or "CAR T") to recognize and attack specific proteins on cancer cells for use in patients with relapsed or refractory B-cell Non-Hodgkin's lymphoma. The development of Liso-cel was so crucial to the treatment of such cancer that the FDA designated it as both a "Breakthrough Therapy" and a "Regenerative Medicine Advanced Therapy." Both designations meant that Liso-cel would receive an expedited review process by a dedicated team of senior FDA personnel working with Celgene, and later Bristol-Myers, to ensure it would enter the market quickly.

[2] https://news.bms.com/news/corporate-financial/2019/Bristol-Myers-Squibb-Announces-Filing-of-Definitive-Proxy-Statement-in-Connection-with-Proposed-Merger-with-Celgene/default.aspx

54. Celgene's management repeatedly stated – both prior to and following the announcement of the Merger – that Celgene was "on track for submitting the [Biologic License Application or BLA for Liso-cel] in the second half of 2019 with an expected U.S. approval in mid-2020." Celgene further stated that the Liso-cel BLA would "include a robust data package containing substantial follow-up on the relapsed/refractory diffuse large B-cell lymphoma cohort." Thus, at the time the Merger was announced, Liso-cel was well on its way to securing expedited approval from the FDA.

55. The valuation of Liso-cel, along with Celgene's other pipeline drugs, was the central point of contention in Merger negotiations between Bristol-Myers and Celgene.

56. In December 2018, Bristol-Myers proposed introducing a CVR component to the merger consideration for purposes of bridging a reduction in the upfront aggregate value per Celgene share. According to the Registration Statement, in December 2018, Bristol-Myers and Celgene had reached an impasse over the value of Celgene's pipeline. To resolve this disagreement, Bristol-Myers suggested at a December 28, 2018 meeting that the parties explore the possibility of issuing CVRs to current Celgene shareholders payable by Bristol-Myers, in addition to the cash and stock components of the Merger consideration. A CVR is a security payable upon the occurrence of a specified future event (*i.e.*, upon obtaining regulatory approval for a drug candidate), often used by acquiring companies as partial merger consideration to the target company's shareholders.

57. In the course of the negotiations, members of Celgene's management proposed that the CVR provide a payout of up to $10, with $2 payable upon FDA approval of each of Celgene's five near-term, late-stage pipeline drugs. Consistent with industry practice, Celgene proposed structuring the CVR agreement to provide a separate payout to CVR holders upon FDA approval of each of Celgene's five near-term, late-stage pipeline assets. Under this structure, CVR holders

would be entitled to a $2 payout upon FDA approval of each drug, for a total potential payout of $10. The CVRs would not terminate if Bristol-Myers failed to achieve FDA approval for one or more drugs. This proposal would provide a payout to CVR holders even if Bristol-Myers failed to obtain FDA approval for all five drugs. The Celgene board noted that the terms of the CVR should be clear and tied to near-term events.

58. However, Bristol-Myers flatly refused Celgene's proposed CVR structure, stating it was unwilling to pay any amount under a CVR agreement unless multiple milestones were achieved before specified dates. Under this "all-or-nothing" approach, Bristol-Myers countered that it would be agreeable to a payout of $9 under a CVR agreement conditioned on approval of three of Celgene's five near-term, late-stage pipeline assets – (i) Liso-cel, (ii) Ozanimod, and (iii) bb2121 a/k/a Ide-cel – prior to a Milestone date of December 31, 2020.

59. After intense negotiations over the terms of the CVR Agreement, Bristol-Myers and Celgene came to an agreement on the price, catalyst events, and dates for CVR payments. Celgene ultimately agreed to Bristol-Myers' demands after convincing Bristol-Myers to extend the Milestone date for Ide-cel to March 31, 2021 (while keeping the Liso-cel and Ozanimod Milestone dates on December 31, 2020). The parties agreed that each CVR would carry a one-time $9.00 payment, contingent on the FDA approving the marketing applications (BLAs for biologics and NDAs for drugs) for three Celgene products: (i) Liso-cel, which treats diffuse large B-cell Non-Hodgkin's lymphoma; (ii) Ozanimod, which treats relapsing multiple sclerosis; and (iii) Ide-cel, which treats relapsed and refractory multiple myeloma (collectively, the "Milestone Therapies"). The $9.00 per CVR payment was contingent on the Liso-cel and Ozanimod Milestone being achieved by December 31, 2020 for, and the Milestone for Ide-cel being achieved by March 31, 2021. If all three were approved by their respective Milestone dates, Bristol-Myers

would owe the CVR holders a total of $6.4 billion. If any Milestone was missed – even by a single day – Bristol-Myers would owe the CVR holders nothing.

60. A Form CVR Agreement ("CVR Agreement") was appended to the Registration Statement and represented that Bristol would use "***diligent efforts***" to achieve approval of the three Celgene near-term, late-stage assets covered by the CVR – *i.e.*, Liso-cel, Ide-cel and Ozanimod. In this regard, the CVR Agreement stated that Bristol-Myers' "***diligent efforts***" ***would include "such effort and employ[] such resources normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of" these Milestone drugs. The CVR Agreement further represented to investors that Bristol's efforts to achieve the Milestones would be benchmarked objectively against other drugs with "similar market potential at a similar stage in its development or product life."*** [Emphasis added.]

61. With the materially false and misleading statements and omissions in the Registration Statement, Celgene shareholders of record (at the time) overwhelmingly voted to approve the Merger on April 12, 2019. The transaction closed on November 21, 2019, with Celgene shareholders of record (as of that later date) receiving one CVR valued at $9, along with one share of Bristol-Myers common stock and $50 in cash, for each share of Celgene common stock exchanged.

D. While Still Under Celgene's Control, Liso-cel Remained On-Track for Regulatory Approval

62. While Celgene controlled Liso-cel and Ide-cel, they were both on the fast track for approval. The FDA had designated both as Breakthrough Therapies and had designated Liso-cel as a Regenerative Medicine Advanced Therapy. These designations ensured an expedited development and review process. The FDA committed to provide intensive, interactive guidance during both therapies' development — with senior FDA personnel involved in a proactive,

collaborative guidance for and review of the therapies — so that both therapies could enter the market quickly and safely. Before the Merger announcement, all three Milestone Therapies were on the fast track for approval and well ahead of the Milestones, including Liso-cel. The FDA designated Liso-cel as a "Breakthrough Therapy" in 2016.

63. Liso-cel's designation as a "Regenerative Medicine Advanced Therapy" in 2017 expedited the development and review process for Liso-cel. A Regenerative Medicine Advanced Therapy designation provides ways to accelerate the review process further and to satisfy post-approval requirements. The combined result of the Breakthrough Therapy and Regenerative Medicine Advanced Therapy designations is an expedited development and review process designed to allow the therapy to reach the market quickly so that it can start saving lives as soon as possible.

64. Throughout the Merger negotiations, Liso-cel continued to progress through FDA approvals under its designations as a Breakthrough Therapy and a Regenerative Medicine Advanced Therapy. Clinical trials showed strong response rates in patients suffering from diffuse large B-cell Non-Hodgkin's lymphoma, and most patients did not experience the life-threatening side-effects associated with the two other FDA approved therapies for this cancer. The FDA concluded the clinical trials were "well-controlled" and "demonstrated high response rates and durability of [complete response] rate.

E. Bristol-Myers Issues False and Misleading Offering Documents

65. On January 2, 2019, Bristol-Myers and Celgene executed the Merger Agreement. For each outstanding Celgene share, Celgene shareholders would receive one share of Bristol-Myers common stock, $50.00 in cash, and one CVR.

66. On February 1, 2019, Defendants filed with the SEC on Form S-4 a draft Registration Statement, as amended on February 1, 2019 and February 20, 2019, which would

register the Bristol-Myers Common Stock and CVRs to be issued and exchanged in the Acquisition following a series of amendments in response to SEC comments, including comments from the SEC emphasizing the importance of adequately disclosing material trends and risk factors, as required by Items 303 and 503.

67. On February 20, 2019, Defendants filed an amendment to the Registration Statement.

68. On February 22, 2019, the SEC declared the Registration Statement effective.

69. Also on February 22, 2019, Defendants filed a final prospectus on Form 424B3 for the Bristol-Myers shares issued and exchanged in the Acquisition, which prospectus forms part of the Registration Statement.

70. On or about February 22, 2019, Defendants commenced mailing the Registration Statement and prospectus to stockholders of Celgene.

71. The Registration Statement also explained the agreement between Bristol-Myers and Celgene governing the CVRs. Specifically, it stated that "[e]ach holder of a CVR is entitled to receive $9.00 per CVR, which is referred to in this joint proxy statement/prospectus as the milestone payment, if the CVR milestone is achieved." The Registration Statement provided the following completion dates for each of the Milestone Therapies in order for Celgene shareholders to obtain payment on the CVRs: "(i) the [Ide-cel] milestone has occurred on or prior to March 31, 2021; (ii) the [Liso-cel] milestone has occurred on or prior to December 31, 2020; and (iii) the Ozanimod milestone has occurred on or prior to December 31, 2020."

72. Critically, the Registration Statement told Celgene shareholders that Bristol-Myers would engage in "diligent efforts" to achieve the CVR Milestone dates. Specifically, the Registration Statement informed shareholders that:

> Bristol Myers Squibb has agreed to use "***diligent efforts***" to achieve the CVR milestone. "Diligent efforts" means, with respect to [Ide-cel], [Liso-cel] or

> Ozanimod, efforts of a person or entity to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity (including patent coverage, regulatory and other exclusivity), safety and efficacy, product profile (including tolerability and convenience), the competitiveness of alternate products in the marketplace or under development, the launch or sales of one or more generic or biosimilar products, actual or likely pricing/reimbursement [Ide-cel], [Liso-cel] or Ozanimod, the likely timing of such product's entry into the market, the likelihood of regulatory approval of such product and applicable labeling, and the profitability of such product, and other relevant factors, including technical, commercial, legal, scientific, and/or medical factors, based on conditions then prevailing.

[Emphasis added.]

73. The Registration Statement also attached a Form CVR Agreement which discloses the same to Celgene shareholders.

74. On April 12, 2019, Celgene shareholders approved the Merger on April 12, 2019.

75. On November 20, 2019, Defendants completed the Acquisition, issuing approximately 714 million shares of Bristol-Myers common stock directly to former shareholders of Celgene common stock as follows: Each former share of Celgene common stock was automatically converted into the right to receive one share of newly issued Bristol-Myers common stock (plus cash and CVR consideration). Each of these new shares of Bristol-Myers common stock issued pursuant to the Registration Statement.

F. Bristol-Myers Assumes Control of the Liso-cel Approval Process and Takes Actions with No Legitimate Business Purpose Other than to Delay FDA Approval

1 Bristol-Myers Files a BLA for Liso-cel Lacking Basic Information to Enable the FDA to Assess Bristol-Myers' Control over Analytical Procedures and Validation Reports

76. Celgene submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019, before the Merger became effective. A BLA is a request to the FDA to introduce a biologic product into interstate commerce. Its issuance requires a determination that

the product, the manufacturing process, and the manufacturing facilities where the product is produced meet applicable requirements to ensure the continued safety, purity, and potency of the product. The BLA must include, among other things, clinical data demonstrating the safety and efficacy of the therapy, information concerning the manufacturing and controls for production, a detailed description of the manufacturing facility and the proposed product label. The BLA is the last step in the development process before a therapy can be brought to market. To enable the FDA to conduct its review, the BLA must include, among other things, clinical data demonstrating the safety, and efficacy of the therapy, information concerning the manufacturing and controls for production, a detailed description of the manufacturing facility, and the proposed product label. The FDA issues its approval once it has reviewed the BLA, conducted facility inspections and concluded that the therapy is efficacious, safe and appropriately labeled.

77. Soon after Celgene submitted the first component of the Liso-cel BLA, both the Merger and the CVR Agreement became effective on November 20, 2019. The remainder of the approval process for Liso-cel was then controlled by Bristol-Myers. The NDA for Ozanimod, one of the three Milestone Therapies, had been submitted well before the Merger closed, and the FDA granted Ozanimod approval on March 26, 2020, shortly after the Merger closed. Thus, in order for Bristol-Myers to avoid paying CVR holders $6.4 billion under the CVR Agreement, it had to delay the FDA approval process for Liso-cel or Ide-cel, both of which were on the fast-track for approval well before their respective Milestone dates.

78. Immediately after the Merger closed, Bristol-Myers assumed control of the regulatory approval process for the Milestone therapy Liso-cel. On December 18, 2019, Bristol submitted the Chemistry, Manufacturing and Controls ("CMC") portion of the BLA to the FDA.[3]

[3] The CMC section specifies the manufacturing processes, product characteristics, and product testing upon which the manufacturer relies to ensure that its therapy is safe, effective, and consistently manufactured.

Celgene had submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019, before the Merger.[4]

79. After Bristol-Myers failed to submit Liso-cel's Chemistry, Manufacturing and Controls data, the most important section of the BLA, on December 18, 2019, the FDA had only 60 days to conduct an initial review to determine whether the application was complete and whether to grant "Priority Review" for Liso-cel.

80. The FDA reserves Priority Review for therapies that are significant improvements to the safety or efficacy of the treatment, diagnosis or prevention of a serious condition. A "Priority Review" designation provides a substantial benefit to the manufacturer as it reduces the time of the review process. The FDA commits to try to render a decision on all BLAs by a set date. For drugs with Priority Review, that date is six months after the initial review – four months shorter than its typical review time. The FDA strives to approve or deny BLAs and NDAs by its stated date at least 90% of the time. In reality, the FDA does even better. For the 155 BLAs and New Molecular Entity Drug Applications (which are reviewed under the same program) that were granted Priority Review in fiscal years 2014 through 2018, the FDA made a decision by its goal date in all but three instances, which is 98% of the time. For fiscal years 2016 to 2018, the FDA approved those applications by its goal date 100% of the time.

81. The FDA completed its initial review of the Liso-cel BLA on February 13, 2020, and granted it Priority Review. This meant that, despite Bristol-Myers' delay in submitting the most important part of the BLA (*i.e.*, Liso-cel's CMA data), the FDA aimed to review Liso-cel by August 17, 2020 – four and a half months before the December 31, 2020 Liso-cel Milestone date.

[4] Bristol was unable to exercise meaningful control over the Milestone therapy for Ozanimod because the FDA had already accepted the New Drug Application ("NDA") for that therapy.

82. However, soon after completing its initial review of the Liso-cel BLA, the FDA found significant additional omissions in the application. In the CMC section of the Liso-cel BLA submitted on December 18, 2019, Bristol-Myers made the extremely atypical decision to omit basic data detailing (i) the tests used to ensure that Liso-cel is safe and efficacious, referred to as assays, and (ii) the studies that assess whether those assays worked as they were supposed to, referred to as validation. These data are rigorously compiled over the course of developing a biologic and are routinely included in BLAs. As Bristol-Myers knew or should have known, they are fundamental components of a BLA, without which the FDA cannot make an informed decision, or any decision, on approval. FDA provisions governing the CMC portion of BLAs obligate applicants to "include a full description of the manufacturing process, including analytical procedures that demonstrate the manufactured product meets prescribed standards of identity, quality, safety, purity, and potency" and provide that the substantiating data "must be available to establish that the analytical procedures used in testing meet proper standards of accuracy, sensitivity, specificity, and reproducibility and are suitable for their intended purpose."[5] In fact, as subsequently revealed in regulatory documentation released by the FDA, in direct contravention of these guidelines, the CMC portion of the Liso-cel BLA submitted by Bristol-Myers in December 2019 only included "summaries" of assays (*i.e.*, tests used to ensure the drug is safe and efficacious) and platform validations performed at contract testing organizations that the FDA later deemed "inadequate to understand and assess control of the analytical procedures and respective validations." These and other failures were detailed in the final CMC BLA Review Memorandum from the FDA's Center for Biologics Evaluation and Research:

[5] https://www.fda.gov/files/drugs/published/Analytical-Procedures-and-Methods Validation-for-Drugsand-Biologics.pdf.

> Juno received a Major Amendment Acknowledgement letter from the FDA on 05/05/2020 due to information submitted for review in Amendment 31 (received on 04/15/2020). Amendment 31 included analytical procedures and validation reports for all (b) (4) tests performed at (b) (4) , with the exception of 2 validation reports provided in Amendment 51 (received on 04/29/2020). The original BLA submission contained, in most cases, summaries of assays and platform validations performed at contract testing organizations, which was inadequate to understand and assess control of the (b) (4) analytical procedures and respective validations.

83. On March 23, 2020, the FDA submitted an information request to Bristol-Myers seeking the missing data on assays and validation.

84. On April 15, 2020, Bristol-Myers submitted Amendment 31 to the Liso-cel BLA by amending the CMC section of the BLA to provide the missing information. The additional information contained in Bristol's Amendment 31 was so significant that it prompted the FDA to issue a Major Amendment Acknowledgment on May 5, 2020. The FDA typically tries to avoid issuing a Major Amendment Acknowledgment such as this. It only does so if there is a "substantial amount" of new data or new manufacturing or facility information, or if there is a new analysis of clinical studies not previously submitted to the FDA. The FDA is largely successful in avoiding this designation and does so only in the rarest of situations. This is because a major amendment automatically extends the review of the therapy by three months. A major amendment for a cancer therapy designated as both a Breakthrough Therapy and a Regenerative Medicine Advanced Therapy and selected for Priority Review is exceptionally rare, since the purpose of such designations is to ensure the FDA is deeply involved in the therapy's development.

85. The Major Amendment Acknowledgement had two substantive results that effectively foreclosed FDA approval of Liso-cel by the Milestone date of December 31, 2020. First, the Major Amendment Acknowledgment automatically extended the FDA's target approval deadline from August 17, 2020, to November 16, 2020 – within weeks of the Liso-cel Milestone deadline. Second, the Major Amendment Acknowledgement prompted the FDA to reschedule its planned Pre-License inspection of Liso-cel's two manufacturing facilities – the Juno facility in

Bothell, Washington (the "Juno Facility") and the Lonza Group AG facility in Houston, Texas (the "Lonza Facility") – from June 2020 to October and December 2020, respectively.

86. Following Bristol-Myers' announcement of the Major Amendment, the price of the CVRs fell substantially.

87. Had Bristol-Myers satisfied its stated contractual obligation to exercise "diligent efforts" to achieve the Liso-cel Milestone, there would not have been a major amendment or the accompanying delay in FDA approval.

2 Bristol-Myers Further Delays FDA Approval by Failing to Prepare the Liso-cel Manufacturing Facilities

88. Bristol-Myers also caused critical delays during the next step of the FDA's review of Liso-cel's BLA – the Pre-License Inspection of the Liso-cel manufacturing facilities. A Pre-License Inspection aims to ensure that the facilities used to manufacture a therapy comply with basic FDA safety regulations and requirements. The two facilities to be inspected were the Juno Facility in Bothell, Washington, and the Lonza Facility in Houston, Texas. Bristol-Myers is responsible for ensuring that both facilities comply with FDA regulations, including through monitoring and instructing its contract vendor at the Lonza Facility concerning FDA compliance.

89. Bristol-Myers knew that (i) the Pre-License Inspections were critical to timely FDA approval of the Liso-cel BLA; (ii) the FDA had already rescheduled the June 2020 Pre-License Inspections for Liso-cel's manufacturing facilities after the major amendment pushed the Liso-cel review back three months; and (iii) the FDA announced that, in response to the COVID-19 pandemic, it would selectively deploy its resources to inspect manufacturing facilities for BLAs and NDAs. Thus, the rescheduled inspections had the possibility of creating a major delay in Liso-cel's approval.

90. However, because the FDA understood the life-saving importance of Liso-cel, it rescheduled the Pre-License Inspection for later in 2020. The FDA provides advance notice to

manufacturers prior to conducting Pre-License Inspections to give manufacturers the opportunity to fix problems before the inspection and to streamline the Pre-License Inspection process. Thus, Bristol-Myers was well aware of the upcoming Pre-License Inspections and had ample time to prepare both the Juno and Lonza Facilities. Shortly after Bristol-Myers acquired Celgene, it described Liso-cel's manufacturing facilities in public presentations as "launch ready." But after a year of Bristol-Myers' control, those facilities fell far short on basic safety and regulatory requirements. Despite the FDA's inspection notice and Bristol-Myers' opportunity to get ready and address any deficiencies, both facilities were left woefully unprepared.

91. The inspection of the Juno Facility (in Bothell, Washington, where Bristol-Myers produces Liso-cel) occurred from October 7, 2020, to October 16, 2020. Even though Bristol-Myers had advance notice of the inspection, it inadequately prepared the Juno Facility, and the FDA inspectors found numerous, substantial deviations from known or readily determinable FDA regulations and guidelines. Following that inspection, the FDA issued a Form 483, which documents "significant" issues identified during an inspection that may violate FDA regulations because they pose a risk that therapies could be adulterated and harm patients. These observations must be addressed to the FDA's satisfaction before approval is granted.

92. The FDA identified numerous, easily avoidable deficiencies in the Form 483 for the Juno Facility, for example:

- Bristol-Myers failed to enforce procedures at the Juno Facility designed to prevent contamination of sterile drug products.
- Bristol-Myers had failed to implement laboratory controls with appropriate specifications and procedures to ensure drugs conformed to appropriate standards of identity, strength, quality and purity.
- Bristol-Myers had, on numerous occasions, failed to review discrepancies between batches of Liso-cel — discrepancies that were not properly documented and not properly corrected.

- Bristol-Myers failed to ensure the reliability of third-party vendors' Certificates of Analysis, which certify compliance with product specifications.

- Bristol-Myers failed to establish appropriate follow-up procedures; for instance, if a Liso-cel batch did not meet specifications, Bristol-Myers did not take appropriate steps to understand why that batch had failed.

93. As Bristol-Myers is one of the world's largest pharmaceutical companies and has brought numerous therapies to market, it knew or should have known these deficiencies were unacceptable in advance of the FDA's inspection and fixed the issues. Yet, Bristol-Myers' overt failure to comport with basic FDA standards for safe and reliable manufacturing further delayed the FDA's approval of Liso-cel.

94. Remarkably, Bristol-Myers repeated many of the same issues during the inspection of the Lonza Facility where a critical component of Liso-cel is manufactured. Following the FDA's inspection of the Lonza Facility from December 3, 2020 to December 10, 2020, it issued a Form 483 that identified a "litany of errors." Many of these errors overlapped with similar problems identified during the Juno Facility inspection. For example, during both inspections, the FDA identified insufficient controls to check for microbiological contamination of sterile materials and deficient procedures for inspecting raw materials. Following the Juno Facility inspection, Bristol-Myers could have no reasonable doubt concerning what systems the FDA would be scrutinizing. Bristol-Myers could have — and should have — ensured that it corrected these issues before the Lonza Facility inspection. It simply chose not to.

95. The other issues the FDA observed at the Lonza Facility, while different from those at the Juno Facility, reflected the opposite of "diligent efforts" to ensure Liso-cel's timely approval. For example:

- The FDA observed that materials intended for use within the United States were stored in the same bin within the same freezer that stored materials intended for foreign markets, as well as ***materials that had been rejected by quality control***.

- Freezer bins containing materials were "poorly maintained and organized." For example, the FDA noted "the bottom of the freezer was filled" with "overturned" bottles and "substantial frost" had built up on certain bottles.

- Materials were labeled in a manner that made mix-ups likely. For example, "[b]ottles of both accepted and rejected material [we]re designated by a 'RELEASED' label that has green background and black text with identical font." Thus, material that had failed quality control easily could have been confused for material that had passed.

- The FDA also observed conduct in direct contravention of express written procedures, including procedures that required freezers containing quarantined materials to be kept locked and that required expired batches of drug materials to be discarded. Batches that had expired on April 30, 2020 — more than seven months earlier — were still at the facility at the time of the FDA's inspection.

96. On November 5, 2020, nearly a month after the FDA began its inspection, Bristol-Myers responded to the Juno Facility's Form 483 and acknowledged many of the failures the FDA identified. Bristol-Myers stated it would take actions "to further enhance" its "processes and controls and improve the overall effectiveness of [its] operations and quality system." But the FDA pointed to "***unclear and questionable points***" in Bristol-Myers' response and required it to supplement the response further. Bristol-Myers did not complete its Juno Facility Form 483 response until December 18, 2020, over two months after the FDA inspection, a month after the FDA's target review date, and a matter of days before the Liso-cel Milestone date. Indeed, the FDA subsequently stated that "***there were outstanding concerns from the [Juno] facility inspection prior to the action due date***." The FDA could not complete its review of the Liso-cel BLA until this response was complete. Had Bristol-Myers' efforts been truly diligent as represented in the Registration Statement, such further delay would have been avoided. [Emphasis added.]

97. Bristol-Myers first responded to the Form 483 for the Lonza Facility on December 18, 2020, the same day it submitted its supplemental response to the Juno Facility Form 483. This response, like the first response to the Juno Facility Form 483, was woefully deficient and required

Bristol-Myers to submit additional information. Bristol-Myers did so on December 23, 2020 – again, just days before the Liso-cel Milestone and in the middle of the winter holidays.

G. Bristol-Myers Misses the Liso-cel Milestone Approval Date by 36 Days – Illustrating the Falsity of Its Registration Statement Commitments

98. Following the three-month delay caused by Bristol-Myers filing a major amendment to the Liso-cel BLA, the two facility inspections resulting in FDA Forms 483 identifying violations, and the inadequate response to at least one of those Forms 483, the Liso-cel Milestone date passed on December 31, 2020 without FDA approval.

99. Bristol-Myers wasted no time in trumpeting that it no longer owed $6.4 billion to CVR holders. The very next day, January 1, 2021, Bristol-Myers stated that "[b]ecause the milestone of approval of [L]iso-cel by December 31, 2020 was not met, the CVR Agreement has automatically terminated in accordance with its terms, the security will no longer trade on the NYSE, and the CVRs are no longer eligible for payment."

100. 36 days later, the FDA approved the Liso-cel BLA. Despite its repeated delinquency in timely responding to FDA requests for further information both in its BLA submission and in response to FDA Form 483s identifying significant issues at the Juno and Lonza facilities, Bristol-Myers disingenuously placed the blame solely on COVID-related plant inspection delays.

101. For these reasons, Bristol-Myers issued a false and misleading Registration Statement which stated that it would make "diligent efforts" to ensure that Liso-cel was approved before its Milestone date. It never intended to do so. Had Bristol-Myers actually used diligent efforts to achieve the Liso-cel Milestone, it would have met the deadline. Instead, as it always intended, Bristol-Myers was able to avoid a $6.4 billion payment to CVR holders under the CVR Agreement by necessitating a major amendment to Liso-cel's BLA that caused at least a three-month delay and two Forms 483 that caused several more months of delay.

H. Bristol-Myers' Conduct Was Contrary to Industry Standards and Its Own Prior Practices

102. Myriad facts demonstrate that Bristol-Myers' representations regarding its "diligent efforts" to obtain FDA approval for Liso-cel as represented in the Registration Statement were materially false and misleading, and that its actions were commercially unreasonable when compared to its prior practices and industry peers.

103. Indeed, Mizuho analyst, Salim Syed, who followed the Bristol-Myers BLA approval process, reviewed the primary source FDA documents and performed an empirical study on Bristol-Myers' Liso-cel timeline versus that of its competitors. Mr. Syed remarked that Bristol-Myers "may not have been entirely thorough" during the application and review process and that "[a]pplications are either complete or not – this is a very binary concept." Mr. Syed similarly challenged Bristol-Myers' contention that the failure to obtain approval for Liso-cel was solely due to COVID related inspection delays, stating its "not the whole story" because the inadequate BLA information was submitted months prior to the pandemic.

1 Bristol-Myers Submitted 96 Amendments to Liso-cel's BLA Application – 50% More than Those Submitted by Direct Competitors

104. FDA regulatory filings demonstrate that Bristol-Myers made a total of 96 amendments to the Liso-cel BLA application, 50% more than the average made by competitor companies seeking FDA approval of similarly situated CAR-T rival therapeutics:

CAR-T Therapy	Manufacturer	BLA Amendments Submitted
Liso-cel	***BRISTOL-MYERS***	***96***
Kymriah	NOVARTIS	70
Yescarta	GILEAD (KITE)	61

105. The fact that Bristol-Myers submitted 50% more amendments than those submitted by its competitors for the same type of therapy demonstrates that the delayed approval was intentional or due to a grossly negligent application.

2. Liso-cel Was Approved 415 Days After Celgene's BLA Submission, More than Twice the 194-Day Average for Similarly Situated CAR-T Therapies

106. In addition to submitting an excessive quantity of BLA amendments relative to peer therapies with less efficacy, Bristol-Myers also obtained FDA approval for Liso-cel 415 days after its initial BLA filing – more than twice the 194-day average time for FDA approval of similar and less effective therapies:

CAR-T Therapy	Manufacturer	BLA Submission Date	FDA Approval Date	Days from BLA Submission Date to FDA Approval
Liso-cel	***BRISTOL-MYERS***	***12/19/2019***	***2/5/2021***	***415***
Tecartus	Gilead (Kite)	12/11/2019	7/24/2020	226
Kymriah	Novartis	3/28/2017	8/30/2017	155
Yescarta	Gilead (Kite)	3/31/2017	10/19/2017	202

107. As set forth in the above table, Bristol-Myers' direct competitor, Gilead, submitted a BLA for its rival CAR-T therapy, Tecartus, on December 11, 2019, just eight days prior to the submission of the BLA for Liso-cel. The FDA approved Tecartus on July 24, 2020 – over half a year before the approval of Liso-cel.

108. Notably, Gilead obtained FDA approval for Tecartus during the height of the COVID-19 pandemic. At the same time, Bristol-Myers falsely represented to investors that FDA approval for Liso-cel would be delayed due to pandemic-induced issues impacting FDA Pre-License inspections of Liso-cel's manufacturing facilities.

3 The 415-Day Approval Time Was Nearly Twice that of Every Other Original BLA/NDA Submitted by Both Celgene and Bristol from 2014-2020

109. Bristol and Celgene submitted nine therapies for FDA approval between July 2014 and 2020. As set forth in the chart below, the average time for FDA approval of these therapies was 239.6 days:

Original NDA and Original BLA Approvals Filed by Bristol-Myers and Celgene 2014-2020				
Applicant	**Proprietary Name**	**FDA Received Date**	**Approval Date**	**Days from FDA Received Date to Approval Date**
Bristol-Myers	Opdivo	7/30/2014	12/22/2014	145
Bristol-Myers	Evotaz	4/4/2014	1/29/2015	300
Bristol-Myers	Daklinza	3/31/2014	3/4/2015	338
Bristol-Myers	Empliciti	6/29/2015	11/30/2015	154
Celgene	Idhifa	12/30/2016	8/1/2017	214
Celgene	Reblozyl	4/4/2019	11/8/2019	218
Celgene	Zeposia	3/25/2019	3/25/2020	366
Celgene	Onureg	3/3/2020	9/1/2020	182
			Shortest Days to Approval	145
			Average Days to Approval	239.6

4 Bristol-Myers' Actions Demonstrate It Could Not Meet the Liso-cel Milestone

110. As set forth above, Bristol-Myers' BLA submission for Liso-cel negligently and inexcusably omitted volumes of basic information required by the FDA. No one, much less an experienced drug company like Bristol-Myers, would ever have omitted such key information they represented using "diligent efforts" to obtain FDA approval of Liso-cel by the Milestone date. This is particularly true where, as here, the omitted data was so incredibly favorable to Liso-cel as an effective therapeutic. The Company failed to disclose the risks stemming from its derelict and

dilatory FDA approval process, which implementation undercut the promised payment on the CVR.

111. By Bristol-Myers' own design, the CVR payout required approval of all three therapies within the Milestone periods. A single miss by a single day was all Bristol-Myers needed to avoid billions of dollars in payments under the CVR Agreement. Throughout, Bristol-Myers subverted the process, from its first BLA submission within weeks of the Merger closing to its intentional delays in the Juno and Lonza Facility inspections.

112. Bristol-Myers' dereliction and delay are demonstrated by its success in subverting the process with the resulting near 36-day miss and 415 days from the date of the BLA submission to final approval. These facts demonstrate that, from the outset, Bristol-Myers' plan assured that it would not obtain FDA approval for Liso-cel by the stated Milestone date, and the value of the CVRs received by Celgene investors at the time of the Merger was $0.

113. Accordingly, the statements in the Registration Statement concerning the CVRs were based on the false premise that they had value as partial consideration in the Merger and were misleading when made. Moreover, the Registration Statement's representations concerning the valuation of the CVRs, the probability of success in reaching the Milestones, Bristol's promise to use diligent efforts to achieve the Milestones and the related risk factors in the Registration Statement were materially false and misleading when made because, given Bristol-Myers slow-rolled exploitation of the FDA approval process, the CVRs were already likely worthless.

114. As a result of these material misrepresentations and omissions, Celgene shareholders were misled into accepting consideration from the Merger that was significantly lower than represented.

I. Bristol-Myers Conceals Information on Its Efforts to Meet the Milestones by Improperly Rejecting a Proper Books and Records Demand

115. On December 29, 2020, the Trustee under the CVR Agreement — seeking to investigate whether Bristol-Myers was satisfying its obligation under the CVR Agreement to pursue the Milestones for Liso-cel and Ide-cel diligently, or whether there was evidence that Bristol-Myers had failed to do so purposefully or ineptly — demanded to review Bristol-Myers' relevant books and records. Bristol-Myers refused to comply.

116. The CVR Agreement requires Bristol-Myers and its subsidiaries "to use commercially reasonable efforts to keep[] true, complete and accurate records in reasonably sufficient detail to enable the [CVR] Holders to determine if [Bristol-Myers] has complied with its obligations under this CVR Agreement." And the CVR Agreement states that the Trustee "shall be entitled to examine the pertinent books and records of [Bristol-Myers]" to investigate "the facts or matters stated in any . . . statement, opinion, report, notice . . . or other paper or document."

DEFENDANTS' FALSE AND MISLEADING REGISTRATION STATEMENT AND PROSPECTUS

117. Defendants conducted the Acquisition with the Registration Statement containing untrue statements of material fact and omitting material facts both required by governing regulations and necessary to make the statements concerning the CVRs and the development and approval of Liso-cel made not misleading.

118. The Registration Statement falsely and misleadingly stated there was a strong possibility that the Milestones would be met, and that Bristol-Myers would in use diligent efforts to meet them. Specifically, the Registration Statement informed Celgene shareholders that "***Celgene's key late-stage product candidates, which are expected to launch in 2019 and 2020, are ozanimod, fedratinib, luspatercept, [Liso-cel], and [Ide-cel]***." The Registration Statement falsely and misleadingly stated that "***Bristol-Myers Squibb management provided an estimate of***

the probability of achieving the three FDA approvals required to trigger the $9 payment under the CVR agreement to the BMS Board in connection with its evaluation of the merger, and to each of Morgan Stanley, Dyal Co. and Evercore for purposes of their respective financial analyses and opinions. This estimate [] was 45%." In truth, these representations were false and misleading because, among other things, (i) Bristol-Myers planned to submit a materially deficient BLA for Liso-cel that would require supplemental information in the form of an amendment; and (ii) Bristol-Myers never intended to meet the Milestone. [Emphasis added.]

119. The Registration Statement also made a series of false and misleading statements regarding the value of the CVRs. The Registration Statement stated that "***The CVRs are contingent value rights to be issued by Bristol-Myers Squibb as part of the merger consideration to Celgene stockholders and certain holders of Celgene equity awards. Each CVR represents the right to receive a one-time cash payment of $9.00 if the [] FDA, approves, by the [Milestones]***." In truth, Defendants knew that the CVRs were worthless as Bristol-Myers had no intention of meeting the Milestones and paying any value for the CVRs. [Emphasis added.]

120. The Registration Statement falsely and misleadingly claimed that Bristol-Myers would use "diligent efforts" to achieve approval of the three Celgene near-term, late-stage assets on track for regulatory approval – *i.e.*, JCAR017 a/k/a lisocabtagene maraleucel ("Liso-cel"), bb2121 ("Ide-cel") and Ozanimod – by the CVR Milestone dates set in the CVR Agreement. The CVR Agreement stated that Bristol-Myers' "diligent efforts" included "such effort and employ[] such resources normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of" these Milestone drugs. The CVR Agreement further represented to investors that Bristol-Myers' efforts to achieve the Milestones would be benchmarked objectively against other drugs with "similar market potential at a similar stage in its development or product life." In the words of the Registration Statement:

> Bristol Myers Squibb has agreed to use "diligent efforts" to achieve the CVR milestone. "Diligent efforts" means, with respect to [Ide-cel], [Liso-cel] or Ozanimod, efforts of a person or entity to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity (including patent coverage, regulatory and other exclusivity), safety and efficacy, product profile (including tolerability and convenience), the competitiveness of alternate products in the marketplace or under development, the launch or sales of one or more generic or biosimilar products, actual or likely pricing/reimbursement [Ide-cel], [Liso-cel] or Ozanimod, the likely timing of such product's entry into the market, the likelihood of regulatory approval of such product and applicable labeling, and the profitability of such product, and other relevant factors, including technical, commercial, legal, scientific, and/or medical factors, based on conditions then prevailing.

121. In truth, Bristol-Myers: did not plan and did not use diligent efforts to achieve the Liso-cel Milestone. Further, Bristol-Myers' actions were inconsistent with industry standards and the Company's prior practices. For example, the BLA Bristol-Myers submitted to the Food and Drug Administration for review and approval omitted critical data the FDA demanded in the form of an amendment that would trigger an automatic three-month delay thereby imposing a roadblock to achieving the Liso-cel Milestone. Additionally, Bristol-Myers failed to disclose that its purportedly launch-ready facilities for the production of Liso-cel failed to meet basic FDA and industry standards and were riddled with "significant" issues posed a risk that therapies could be adulterated and harm patient. For example, Bristol-Myers (i) failed to implement laboratory controls with appropriate specifications and procedures to ensure Liso-cel conformed to appropriate standards of identity, strength, quality and purity; (ii) failed to document or correct discrepancies between batches of Liso-cel; (iii) failed to monitor the manufacturing environment to prevent the contamination of sterile drug products; (iv) failed to ensure the reliability of third-party vendors' Certificates of Analysis, which certify compliance with product specifications; (v) failed to establish appropriate follow-up procedures, *e.g.*, if a Liso-cel batch did not meet

specifications, Bristol-Myers did not take appropriate steps to understand why that batch had failed; and (vi) failed to timely address FDA concerns.

122. Defendants were required to disclose this material information in the Registration Statement for at least three independent reasons. First, SEC Regulation S K, 17 C.F.R. §229.303 ("Item 303"), required disclosure of any known events or uncertainties that had caused or were reasonably likely to cause Bristol-Myers' disclosed financial information not to be indicative of future operating results. The deficient plan Bristol-Myers had in place, and the Company's consequent failure to exercise diligent efforts consistent with industry standards to achieve the Liso-cel Milestone, were all likely to (and in fact, did) materially and adversely affect Bristol-Myers' future results and prospects.

123. Second, SEC Regulation S K, 17 C.F.R. §229.503 ("Item 503"), required, in the "Risk Factor" section of the Registration Statement, a discussion of the most significant factors that make the offering risky or speculative, and that each risk factor adequately describe the risk. Bristol-Myers' discussions of risk factors did not even mention, much less adequately describe the risk posed by, Bristol-Myers' plan to slow roll the FDA approval process and thereby miss the Liso-cel Milestone, were likely to (and in fact did) materially and adversely affect Bristol-Myers' future results and prospects, nor the likely and consequent material adverse effects on the Company's future results and prospects.

124. Third, Defendants' failure to disclose rendered false and misleading the Registration Statement's many references to known risks that "***if***" occurring "***may***" or "***could***" affect the Company. For example, the Registration Statement also purported to warn of numerous risks that "***if***" occurring "***may***" or "***could***" adversely affect the Company while failing to disclose that these very "risks" had already materialized at the time of the Acquisition. For example, the Registration Statement made a series of risk disclosures regarding the potential diminished value

of the CVRs. Specifically, the Registration Statement stated, "Your right to receive any future payment on the CVRs will be contingent upon the achievement of certain agreed upon U.S. regulatory milestones within the time periods specified in the CVR agreement . . . Accordingly, the value, if any, of the CVRs is speculative, and the CVRs may ultimately have no value." The Registration Statement also stated that:

> There is also uncertainty regarding the fair market value of the CVRs and whether any payment will ultimately be realized on the CVRs. Accordingly, at the time of the Celgene special meeting, Celgene stockholders will not know or be able to determine the market value of the merger consideration they would be entitled to receive upon completion of the merger.

125. These representations, reported trends, and purported risk disclosures, were false and misleading because as detailed above, in truth, Defendants knew, or should have known, that the CVRs were worth nothing since Bristol-Myers had no intention of meeting the Milestone dates, much less employing "diligent efforts" to achieve them, or paying anything for the CVRs. In other words, these "risks" were already materializing at the time of the Acquisition.

126. With the foregoing misrepresentations and omissions in the Registration Statement, defendants were able to complete the Acquisition. But as the truth emerged, the price of Bristol-Myers common stock and CVRs shares suffered sharp declines, Bristol-Myers unjustly profited by avoiding approximately $6.4 billion in payouts owed to CVRs investors, and as a result, Plaintiff and other former Celgene shareholders suffered severe losses.

CLASS ACTION ALLEGATIONS

127. Plaintiff brings this action as a class action on behalf of two classes (the "Classes"):

Common Stock Class: All persons who acquired Bristol-Myers common stock in exchange for Celgene securities pursuant to the Acquisition.

CVR Class: All person who acquired Bristol-Myers CVRs pursuant or traceable to the Registration Statement.

Excluded from both Classes are Defendants and their families, the officers and directors and affiliates of Defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

128. The members of the Classes are so numerous that joinder of all members is impracticable. While the exact number of class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds of members in the proposed Classes. Record owners and other members of the Classes may be identified from records maintained by Bristol-Myers or their transfer agents and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

129. Plaintiff's claims are typical of the claims of the members of both Classes, as all members of the Classes are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

130. Plaintiff will fairly and adequately protect the interests of the members of the Classes and has retained counsel competent and experienced in class and securities litigation.

131. Common questions of law and fact exist as to all members of the Classes and predominate over any questions solely affecting individual members of the Classes. Among the questions of law and fact common to the Classes are:

(a) whether Defendants violated the Securities Act;

(b) whether the Registration Statement was negligently prepared and contained inaccurate statements of material fact and omitted material information required to be stated therein; and

(c) to what extent the members of the Classes have sustained damages and the proper measure of damages.

132. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as 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 Classes to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CAUSE OF ACTION

For Violation of §11 of the Securities Act
Against All Defendants

133. Plaintiff incorporates all of the foregoing paragraphs by reference.

134. This Cause of Action is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Classes, against all Defendants.

135. The Registration Statement contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

136. Defendants are strictly liable to Plaintiff and the Classes for the misstatements and omissions.

137. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

138. By reason of the conduct herein alleged, each Defendant violated, or controlled an agent, employee, or other representative who violated, §11 of the Securities Act.

139. Plaintiff acquired Bristol-Myers common stock and CVR shares pursuant to the Registration Statement.

140. Plaintiff and the Classes have sustained damages. The value of Bristol-Myers common stock and CVR shares has declined substantially subsequent and due to Defendants' violations.

141. At the time of their acquisition of Bristol-Myers shares, Plaintiff and other members of the Classes were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that Plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that Plaintiff commenced this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time plaintiff commenced this action.

SECOND CAUSE OF ACTION

For Violation of §12(a)(2) of the Securities Act Against All Defendants

142. Plaintiff incorporates all of the foregoing paragraphs by reference.

143. By means of the defective Prospectus, Defendants and their agents promoted and sold Bristol-Myers common stock and CVRs directly to Plaintiff and other members of the Classes.

144. The prospectus contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. Defendants owed Plaintiff and the other members of the Classes who purchased Bristol-Myers common stock and CVRs pursuant to the prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the prospectus as set forth above.

145. Plaintiff did not know, nor in the exercise of reasonable diligence could have known, of the untruths and omissions contained in the prospectus at the time Plaintiff acquired Bristol-Myers common stock and CVRs pursuant to the Acquisition.

146. By reason of the conduct alleged herein, Defendants violated §12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiff and the other members of the Classes who purchased Bristol-Myers common stock and CVRs pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, Plaintiff and the other members of the Classes who hold the common stock and CVRs issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby constructively tender their shares to defendants sued herein. Class members who have sold their common stock and CVRs seek damages, disgorgement of unjust profits, and other remedies to the extent permitted by law and equity.

THIRD CAUSE OF ACTION

For Violation of §15 of the Securities Act Against All Defendants

147. Plaintiff incorporates all of the foregoing paragraphs by reference.

148. This Cause of Action is brought pursuant to §15 of the Securities Act against the Defendants.

149. The Individual Defendants were controlling persons of Bristol-Myers by virtue of their positions as directors or senior officers of Bristol-Myers and Celgene. The Individual Defendants each had a series of direct or indirect business or personal relationships with other directors or officers or major shareholders of Bristol-Myers. The Company controlled the Individual Defendants and all of Bristol-Myers' employees.

150. Bristol-Myers and the Individual Defendants were each a culpable participant in the violations of §§11 and 12(a)(2) of the Securities Act alleged in the First and Second Causes of

Action above, based on their having signed or authorized the signing of the Registration Statement, having participated in the solicitation of purchases pursuant to the Prospectus, and having otherwise participated in the process which allowed the Acquisition to be successfully completed.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Certifying this class action, appointing Plaintiff as Class representative and appointing Plaintiff's counsel as Class Counsel on behalf of the Classes;

B. Awarding damages in favor of Plaintiff and the Classes against all Defendants, jointly and severally, in an amount to be proven at trial, including interest thereon;

C. Ordering an accounting and disgorgement of Defendants' unjust profits;

D. Awarding Plaintiff and the Classes the right to rescind and recover the full consideration paid for the Bristol-Myers common stock and CVRs they acquired;

E. Awarding Plaintiff and the Classes their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

F. Awarding such other equitable or injunctive relief as deemed appropriate by the Court.

CERTIFICATION PURSUANT TO RULE 4:5-1

I hereby certify that, to the best of my knowledge and belief, the transactional facts in the matter in controversy are the subject of the following two pending actions: *SM Merger/Arbitrage, L.P., et al. v. Bristol-Myers Squibb, et al.*, Case No. 21-cv-8255 (S.D.N.Y filed Oct. 6, 2021) and *UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, Case No. 21-cv-4897 (S.D.N.Y filed June 3, 2021). To the best of my knowledge and belief, there are no additional parties known to Plaintiffs who should be joined in this action.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: November 12, 2021

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