

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

SM Merger/Arbitrage, L.P., SM Investors, L.P.
and SM Investors II, L.P., on behalf of
themselves and all others similarly situated,

Plaintiffs,

vs.

BRISTOL-MYERS SQUIBB COMPANY,
GIOVANNI CAFORIO, VICKI L. SATO,
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,

Defendants.

Case No. 21-cv-8255

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

TABLE OF CONTENTS

I. PRELIMINARY STATEMENT 2

A. The Merger Was Consummated Based on a Materially False and Misleading Joint Proxy 3

B. Bristol Assumes Control of Celgene and Files a Materially Deficient Chemistry, Manufacturing and Controls Portion of Liso-cel’s BLA 6

C. Bristol’s Actions Were Contrary to Industry Standards and Its Own Prior Practices 8

1. Bristol Submitted 96 Amendments to Liso-cel’s BLA Application – 50% More Than Those Submitted by Direct Competitors 9

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..... 10

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 10

D. Bristol’s Actions Demonstrate It Intended Never to Meet the Liso-cel Milestone..... 11

II. JURISDICTION AND VENUE 13

III. PARTIES 13

A. Plaintiffs 13

B. Corporate Defendant 14

C. Individual Defendants 14

IV. FACTUAL BACKGROUND..... 15

A. Celgene Acquires Juno Therapeutics in 2018 to Develop its Flagship CAR-T Therapy Liso-cel 15

B. Celgene Assures Investors FDA Approval of Liso-cel is On Track and Expected in 2020..... 19

C. Celgene Accedes to Bristol’s Demand to Issue CVRs to Celgene Shareholders in Exchange for Less Cash Consideration 23

D. Bristol Myers and Celgene Issue The Materially False and Misleading Joint Proxy 25

E. Bristol Assumes Control of the Liso-cel Approval Process and Takes Actions With No Legitimate Business Purpose Other Than to Delay FDA Approval: Bristol Sabotages the Process 27

 1. Bristol Files a BLA for Liso-cel Lacking Basic Information to Enable the FDA to Assess Bristol’s Control Over Analytical Procedures and Validation Reports..... 27

 2. Bristol Further Delays FDA Approval By Failing To Prepare The Liso-cel Manufacturing Facilities 30

F. Bristol Myers Misses the Liso-cel Milestone Approval Date By Thirty-Six Days – Illustrating The Falsity of Its Joint Proxy Disclosure that It Would Make Diligent Efforts to Reach the Milestones..... 33

V. THE MATERIALLY FALSE AND MISLEADING STATEMENTS IN THE JOINT PROXY 34

VI. LOSS CAUSATION..... 37

VII. CLASS ACTION ALLEGATIONS 37

VIII. INAPPLICABILITY OF STATUTORY SAFE HARBOR 38

IX. STATUTE OF LIMITATIONS 39

COUNT I On Behalf of Plaintiffs and the Class Against All Defendants for Violations of Section 14(a) of the Exchange Act and Rule 14a-9 Promulgated Thereunder 39

COUNT II On Behalf of Plaintiffs and the Class Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act 40

PRAYER FOR RELIEF 42

JURY DEMAND 42

Plaintiffs SM Merger/Arbitrage, L.P., SM Investors, L.P. and SM Investors II, L.P. (“Plaintiffs”) allege the following based upon personal knowledge as to themselves and their own acts and upon information and belief as to all other matters. Plaintiffs’ information and belief is based on, *inter alia*, the independent investigation of their undersigned counsel. This investigation included a review and analysis of: (i) public filings submitted by Celgene Corporation (“Celgene”) and Bristol-Myers Squibb Company (“Bristol” or “Bristol Myers”) to the U.S. Securities and Exchange Commission (the “SEC”); (ii) research reports by securities and financial analysts concerning the merger (the “Merger”) of Celgene and Bristol Myers; (iii) transcripts of Celgene and Bristol Myers investor conference calls; (iv) publicly available presentations by Celgene and Bristol Myers; (v) press releases and media reports; (vi) economic analyses of securities movement and pricing data; (vii) publicly available filings in other legal actions brought against Bristol Myers; (viii) publicly available analyses and data concerning the U.S. Food and Drug Administration (“FDA”) Biologic License Application (“BLA”) approval process; (ix) information provided by relevant experts; and (x) other publicly available material and data identified herein. Counsel’s investigation into the factual allegations contained herein is continuing, and many of the relevant facts are known only by Defendants (defined below) or are exclusively within their custody or control. Plaintiffs believe substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

The basis of Plaintiffs’ claims is that the joint definitive proxy statement filed by the Defendants on February 22, 2019 with the SEC on Schedule 14A (“Joint Proxy”) to solicit shareholder approval of the Merger of Celgene and Bristol contained materially false and misleading statements and/or omitted material facts.

I. PRELIMINARY STATEMENT

1. This class action is brought on behalf of all former Celgene shareholders that received Contingent Value Rights (“CVRs”) in exchange for their Celgene shares pursuant to Bristol’s \$74 billion acquisition of Celgene on November 20, 2019, and who were damaged thereby (the “Class”). The claims asserted herein are based upon materially false and misleading statements and omissions of material facts in the Joint Proxy, made in violation of Sections 14(a) and/or 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 14a-9 promulgated thereunder.

2. This action arises from Bristol’s subversion of the FDA approval process for a blockbuster cancer therapy – JCAR017 a/k/a lisocabtagene maraleucel (“Liso-cel”) – for the purpose of avoiding a \$6.4 billion payment to CVR holders. By Bristol’s own design, the CVR payout required approval of three therapies, including Liso-Cel, by specified dates (the “Milestones”). A single therapy missing its Milestone by a single day was all Bristol needed to avoid payment to CVR holders.

3. To assure that miss, Bristol intended to subvert the FDA regulatory approval process. Bristol submitted FDA filings that omitted volumes of basic information concerning Liso-cel in contravention of industry standards and Bristol’s own long-standing practices in a multitude of prior FDA filings. Bristol knew that each defective submission would delay FDA review, inspection and approval of Liso-cel. Bristol plainly exploited the approval process to ensure those delays would cause it to miss the Liso-cel Milestone and evade payment to CVR holders.

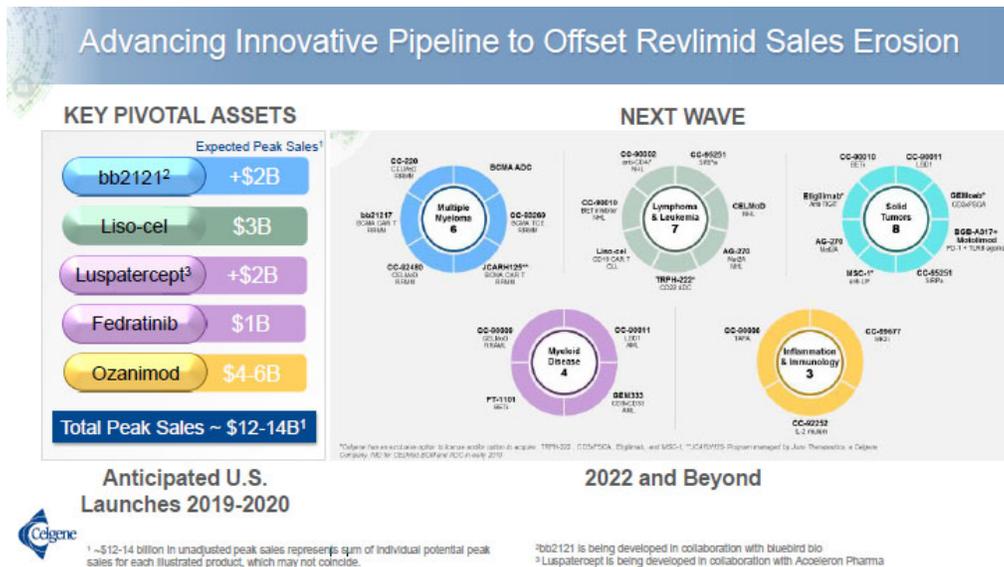
4. The facts demonstrate that from the outset of the Merger, by its own design, Bristol knew it would not take diligent efforts to obtain FDA approval for Liso-cel by the Milestone date of December 31, 2020. Accordingly, the statements in the Joint Proxy concerning the efforts

Bristol would make to meet the Milestones, the likelihood that the Milestones would be met and the purported value of the CVRs were materially false and misleading when made.

A. The Merger Was Consummated Based on a Materially False and Misleading Joint Proxy

5. Critical to Bristol’s decision to pursue an acquisition of Celgene 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’s stated business purpose for the Merger was to acquire Celgene’s pipeline at “an attractive price.”¹

6. 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:



7. 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

¹ <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>

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, to ensure it would enter the market quickly.

8. 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.

9. The valuation of Liso-cel, along with Celgene's other pipeline drugs, was the central point of contention in Merger negotiations between Bristol and Celgene. According to the Joint Proxy, in December 2018, Bristol and Celgene had reached an impasse over the value of Celgene's pipeline. To resolve this disagreement, Bristol suggested at a December 28, 2018 meeting that the parties explore the possibility of issuing CVRs to current Celgene shareholders payable by Bristol, 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.

10. 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 failed to achieve FDA approval for one or more drugs.

11. However, Bristol 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 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) JCAR017 a/k/a Liso-cel, (ii) Ozanimod and (iii) bb2121 a/k/a Ide-cel – prior to a Milestone date of December 31, 2020. Celgene ultimately agreed to Bristol's demands after convincing Bristol 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).

12. A Form CVR Agreement ("CVR Agreement") was appended to the Joint Proxy and notably 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's "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."

13. In reliance on these and other false and misleading representations in the Joint Proxy, Celgene shareholders overwhelmingly voted to approve the Merger on April 12, 2019. The transaction closed on November 21, 2019, with existing Celgene shareholders receiving one CVR

valued at \$9, along with one share of Bristol common stock and \$50 in cash, for each share of Celgene common stock owned.

B. Bristol Assumes Control of Celgene and Files a Materially Deficient Chemistry, Manufacturing and Controls Portion of Liso-cel’s BLA

14. Immediately after the Merger closed, Bristol 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. Celgene had submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019, before the Merger became effective.²

15. 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.”³

16. 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 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*

² 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.

³ <https://www.fda.gov/files/drugs/published/Analytical-Procedures-and-Methods-Validation-for-Drugs-and-Biologics.pdf>

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:

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.

17. Bristol caused one inexcusable delay after another. On April 15, 2020, Bristol submitted Amendment 31 to the Liso-cel BLA remedying the CMC defects observed by the FDA. 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. Such a step is rarely taken by the FDA, particularly where, as here, a therapy has received a “Breakthrough” designation. The Major Amendment Acknowledgement had two substantive results that effectively foreclosed FDA approval of Liso-cel by the Milestone date of December 31, 2020.

18. 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.

19. 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.***

20. The rescheduling of the outside approval date and the inspection of Liso-cel's manufacturing facilities all but ensured the CVRs would not become payable, particularly when considering the pandemic-induced FDA inspection and approval backlog. Moreover, documents released by the FDA in connection with Liso-cel also indicate that Bristol wholly failed to prepare the facilities for Pre-License inspection. Indeed, FDA documents reveal that when the inspections of Liso-cel's manufacturing facilities were conducted, the FDA identified myriad basic manufacturing and quality control problems – which the FDA characterized as a “*litany of errors*” – requiring a response and remediation plan by Bristol.

21. Regulatory documents released in connection with Liso-cel further reveal that the FDA found Bristol's responses to the FDA “*unclear*” with “*questionable points identified,*” and that Bristol failed to supplement these responses until December 18, 2020 – only two weeks before the outside date on the Liso-cel Milestone. Indeed, the FDA subsequently stated that “*there were outstanding concerns from the [Juno] facility inspection prior to the action due date.*”

22. On December 31, 2020, the Milestone date for Liso-cel lapsed and the CVRs were terminated, destroying billions of dollars in potential value for CVR holders. The FDA approved Bristol's BLA for Liso-cel just 36 days later. 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 disingenuously placed the blame solely on COVID-related plant inspection delays.

C. Bristol's Actions Were Contrary to Industry Standards and Its Own Prior Practices

23. As set forth above, Bristol's deficient CMC submission set in motion a chain of events – extending the FDA approval deadline and delaying FDA inspections of manufacturing facilities – that doomed the approval of Liso-cel by the Milestone date and, therefore, the CVRs.

24. Myriad facts demonstrate that Bristol never intended to employ “diligent efforts” to obtain FDA approval for Liso-cel as represented in the Joint Proxy, and that its actions were commercially unreasonable when compared to its prior practices and industry peers.

25. Indeed, Mizuho analyst Salim Syed, who followed the Bristol BLA approval process, reviewed the primary source FDA documents and performed an empirical study on Bristol’s Liso-cel timeline versus that of its competitors. Mr. Syed remarked that Bristol “*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’s 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 Submitted 96 Amendments to Liso-cel’s BLA Application – 50% More Than Those Submitted by Direct Competitors

26. FDA regulatory filings demonstrate that Bristol 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
<i>Liso-cel</i>	<i>Bristol</i>	96
Kymriah	Novartis	70
Yescarta	Gilead (Kite)	61

27. The fact that Bristol submitted 50% more amendments than those submitted by its competitors for the same type of therapy demonstrates that the delayed approval was due to a grossly deficient 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

28. In addition to submitting an excessive quantity of BLA amendments relative to peer therapies with less efficacy, Bristol 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
<i>Liso-cel</i>	<i>Bristol</i>	<i>12/19/2019</i>	<i>2/5/2021</i>	<i>415</i>
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

29. As set forth in the above table, Bristol’s direct competitor Gilead submitted a BLA for its rival CAR-T therapy, Tecartus, on December 11, 2019, just 8 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.

30. Notably, Gilead obtained FDA approval for Tecartus during the height of the COVID-19 pandemic. At the same time, Bristol 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

31. 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 221.6 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	Opdivo	7/30/2014	12/22/2014	145
Bristol	Opdivo	7/30/2014	12/22/2014	145
Bristol	Evotaz	4/4/2014	1/29/2015	300
Bristol	Daklinza	3/31/2014	3/4/2015	338
Bristol	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	221.6

D. Bristol's Actions Demonstrate It Intended Never to Meet the Liso-cel Milestone

32. As set forth above, Bristol's BLA submission for Liso-cel inexcusably omitted volumes of basic information required by the FDA. No one, much less an experienced drug company like Bristol, would ever have omitted such key information had they truly intended to use "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 only plausible explanation is that Bristol never intended to complete the approval for Liso-cel in time to meet the CVR Milestone and, in fact, intended at all times to subvert and delay FDA approval to avoid payment on the CVR.

33. By Bristol's 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 needed to avoid billions of dollars in payments under the CVR Agreement. Bristol 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.

34. Bristol's true intent is 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 intended 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.

35. Accordingly, the statements in the Joint Proxy 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, as set forth below, the Joint Proxy's statements 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 Joint Proxy were materially false and misleading when made because Bristol knew, or should have known, the CVRs were worthless.

36. 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. Based upon these and other facts set forth below, Plaintiffs allege that Defendants violated Section 14(a) and 20(a) of the Exchange Act by filing a materially false and misleading Joint Proxy.

II. JURISDICTION AND VENUE

37. The claims asserted herein arise under Sections 14(a) and 20(a) of the Exchange Act, 15.U.S.C. §§ 78n(a), 78t(a), and Rule 14a-9 promulgated thereunder by the SEC, 17 C.F.R. § 240.14a-9. This Court has jurisdiction over the subject matter of the claims pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

38. Personal jurisdiction exists over each Defendant either because the Defendant conducts business in or maintains operations in this District or is an individual who is either present in this District for jurisdictional purposes or has sufficient minimum contacts with this District as to render the exercise of jurisdiction over Defendant by this Court permissible under traditional notions of fair play and substantial justice. In addition, Bristol Myers submitted itself to the personal jurisdiction of the State of New York under Section 8.11(b) of the Bristol-Celgene Merger Agreement (“Merger Agreement”).

39. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). Venue is also proper in the District pursuant to Section 8.09 of the Bristol-Celgene Merger Agreement.

40. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

III. PARTIES

A. Plaintiffs

41. Plaintiff SM Merger/Arbitrage, L.P. exchanged its Celgene shares and received Bristol CVRs as partial consideration in connection with the Merger, as set forth in the attached

certification. Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein.

42. Plaintiff SM Investors, L.P. exchanged its Celgene shares and received Bristol CVRs as partial consideration in connection with the Merger, as set forth in the attached certification. Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein.

43. Plaintiff SM Investors II, L.P. exchanged its Celgene shares and received Bristol CVRs as partial consideration in connection with the Merger, as set forth in the attached certification. Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein.

B. Corporate Defendant

44. Defendant Bristol Myers is a Delaware corporation, with its principal executive offices located at 430 East 29th Street, 14th Floor, New York, New York 10016. Bristol's common stock is listed and actively traded on the NYSE under the ticker symbol "BMY." Bristol Myers is one of the world's largest pharmaceutical companies and is consistently ranked on the Fortune 500 list of the largest U.S. corporations. As of September 2020, it had total revenue of \$39.3 billion.

C. Individual Defendants

45. Defendant Giovanni Caforio has served as Bristol Myers' Chief Executive Officer since 2015. Caforio signed the Joint Proxy filed with the SEC in connection with the Merger.

46. Defendant Vicki L. Sato served as Bristol Myers' Lead Independent Director at all relevant times.

47. Defendants Peter J. Arduini served as a Director of Bristol Myers at all relevant times.

48. Defendant Robert Bertolini served as a Director of Bristol Myers at all relevant times.

49. Defendant Matthew W. Emmens served as a Director of Bristol Myers at all relevant times.

50. Defendant Michael Grobstein served as a Director of Bristol Myers at all relevant times.

51. Defendant Alan J. Lacy served as a Director of Bristol Myers at all relevant times.

52. Defendant Dinesh C. Paliwal served as a Director of Bristol Myers at all relevant times.

53. Defendant Theodore R. Samuels served as a Director of Bristol Myers at all relevant times.

54. Defendant Gerald L. Storch served as a Director of Bristol Myers at all relevant times.

55. Defendant Karen H. Vousden served as a Director of Bristol Myers at all relevant times.

56. Defendants Caforio, Sato, Arduini, Bertolini, Emmens, Grobstein, Laxy, Paliwal, Samuels, Storch and Vousden are collectively referred to herein as the “Individual Defendants.”

IV. FACTUAL BACKGROUND

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

57. Prior to its acquisition by Bristol, 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 did so through next-generation

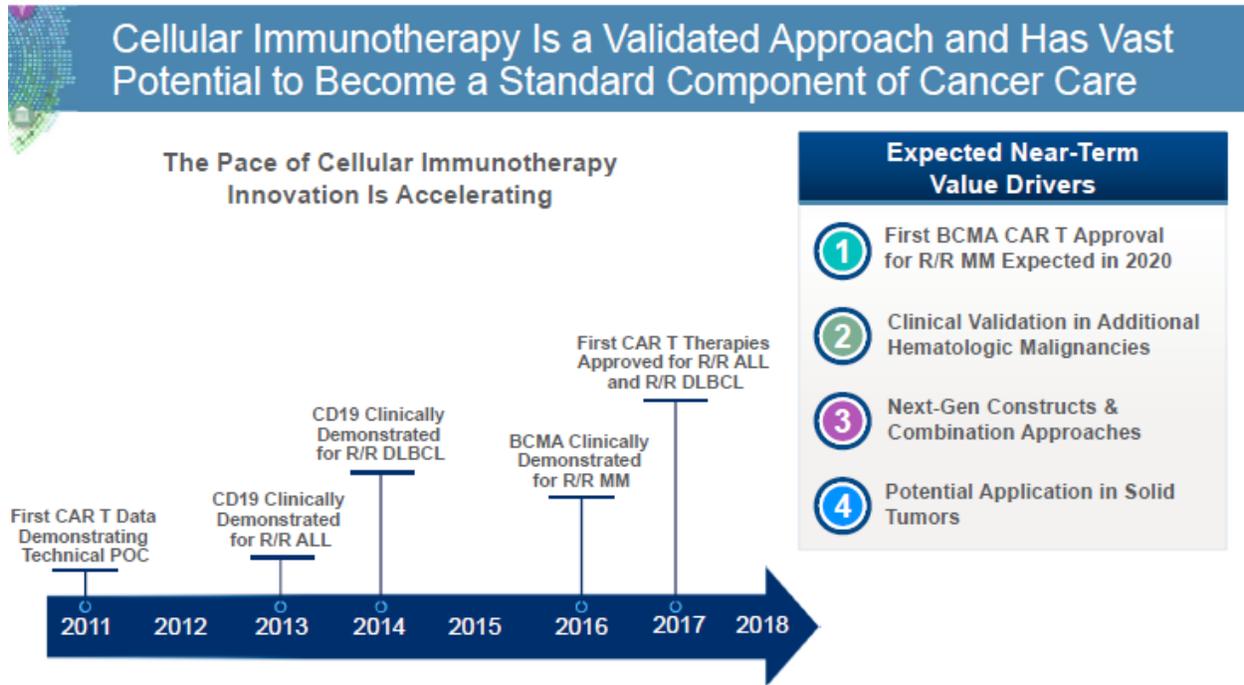
solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation.

58. 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.

59. At the time of its 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.

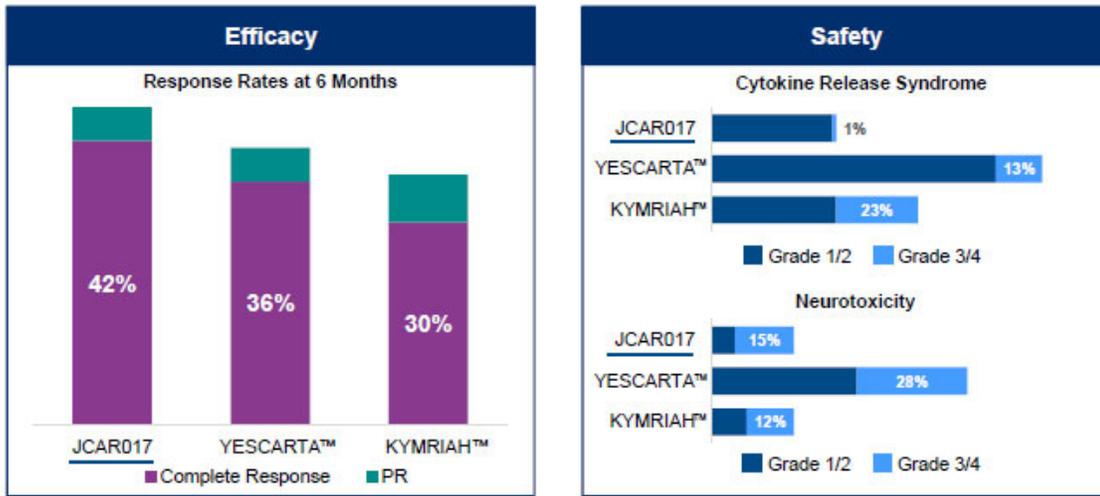
60. In 2018, Celgene sought to expand its immunology division by acquiring a business engaged in the development of products using novel CAR-T therapy. CAR-T is a revolutionary immunotherapy that programs a patient's immune system to recognize and fight cancer. During the treatment process, T-cells are 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.

61. 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:



62. 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 ten times less than the rival CAR-T therapies:

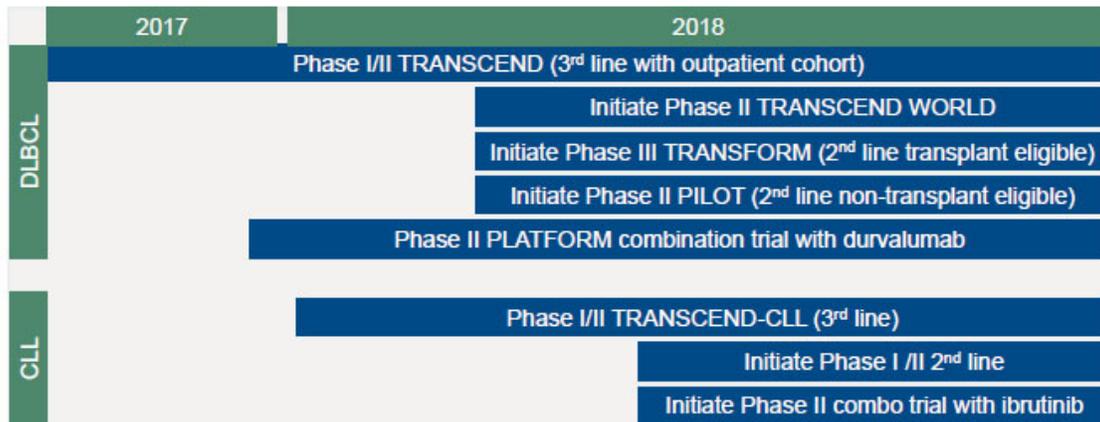
JCAR017 – Emerging Favorable Profile in R/R DLBCL



Data include: JCAR017 CORE R/R DLBCL Phase I for both DL1S and DL2S groups (safety n=67; efficacy n=65 data cut-off October 9, 2017, ASH 2017); YESCARTA™ Phase II (n=101, ASCO 2017); and KYMRIAH™ Phase II (safety n=99, efficacy n=48 ASH 2017). Data presented to show potential profile of JCAR017, which is subject to ongoing investigation, with respect to other CAR-T treatments. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The most common adverse events across all patients treated in JCAR017 the study (n=61) other than CRS and NT that occurred at ≥25% included neutropenia (40%), anemia (38%), fatigue (37%), thrombocytopenia (20%), nausea (27%), and diarrhea (25%). Grade 1/2 events for CRS and NT were 34% and 8%, respectively.

63. Celgene’s management also set forth an aggressive timeline for comprehensive and exhaustive efficacy and response trials for Liso-cel:

Broad Clinical Development Plan in Place to Maximize JCAR017’s Clinical and Commercial Potential



U.S. Approval Expected in 2019

B. Celgene Assures Investors FDA Approval of Liso-cel is On Track and Expected in 2020

64. Prior to its acquisition by Bristol, Celgene touted to investors 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.

65. 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."

66. Celgene's statements regarding the likelihood of Liso-cel approval continued following the announcement of the acquisition by Bristol. 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."*

67. 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.

68. 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 second-line studies TRANSFORM and PILOT in diffuse large B-cell lymphoma patients who are transplant eligible or nontransplant eligible, respectively.

69. 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:

Liso-cel: Harnessing Immunotherapy in NHL and CLL

Ozanimod	<ul style="list-style-type: none"> • Potential best-in-class CD19 CAR T profile • BLA submission expected in H2:19; U.S. approval expected in mid-2020 • Early Ph I/II data in R/R CLL (BTK failures) compelling; Pivotal Ph II trial initiating • Clinical trials in earlier lines of DLBCL underway <ul style="list-style-type: none"> – Ph III TRANSFORM in 2nd line transplant eligible – Ph II PILOT in 2nd line non-transplant eligible
Fedratinib	
Luspatercept	
Liso-cel	
bb2121	



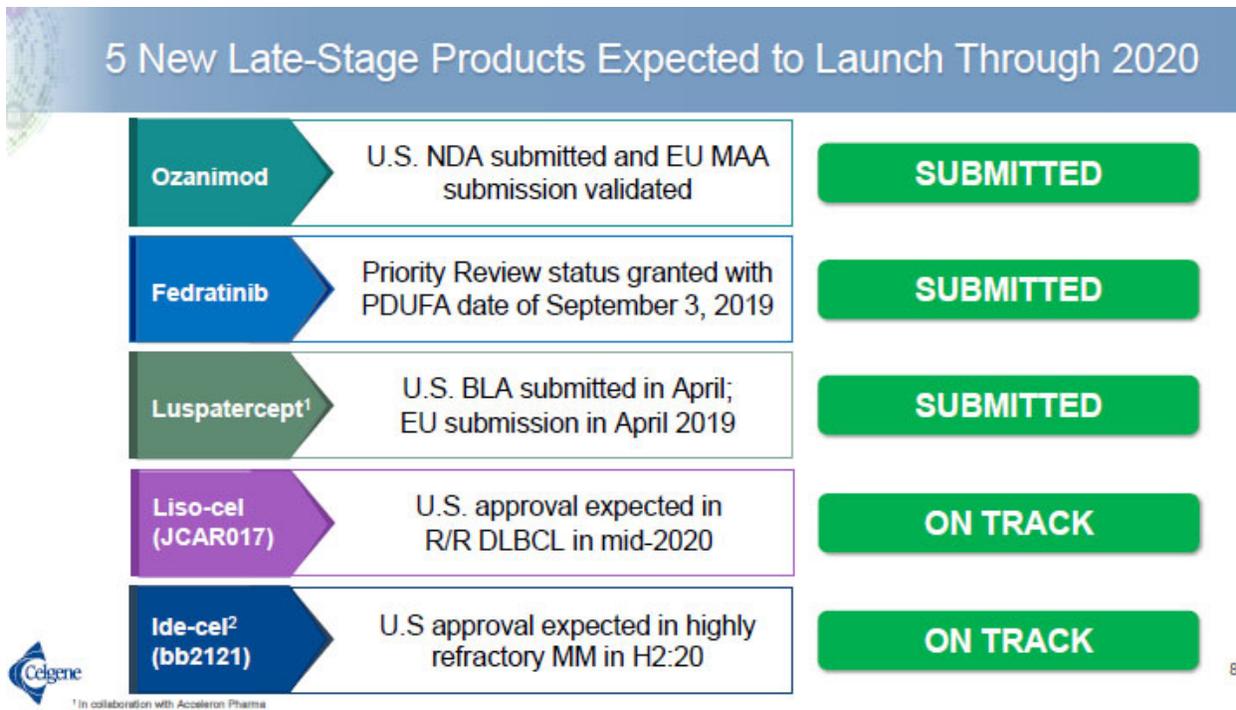
29

Lymphoma Late-Stage/Pivotal Programs

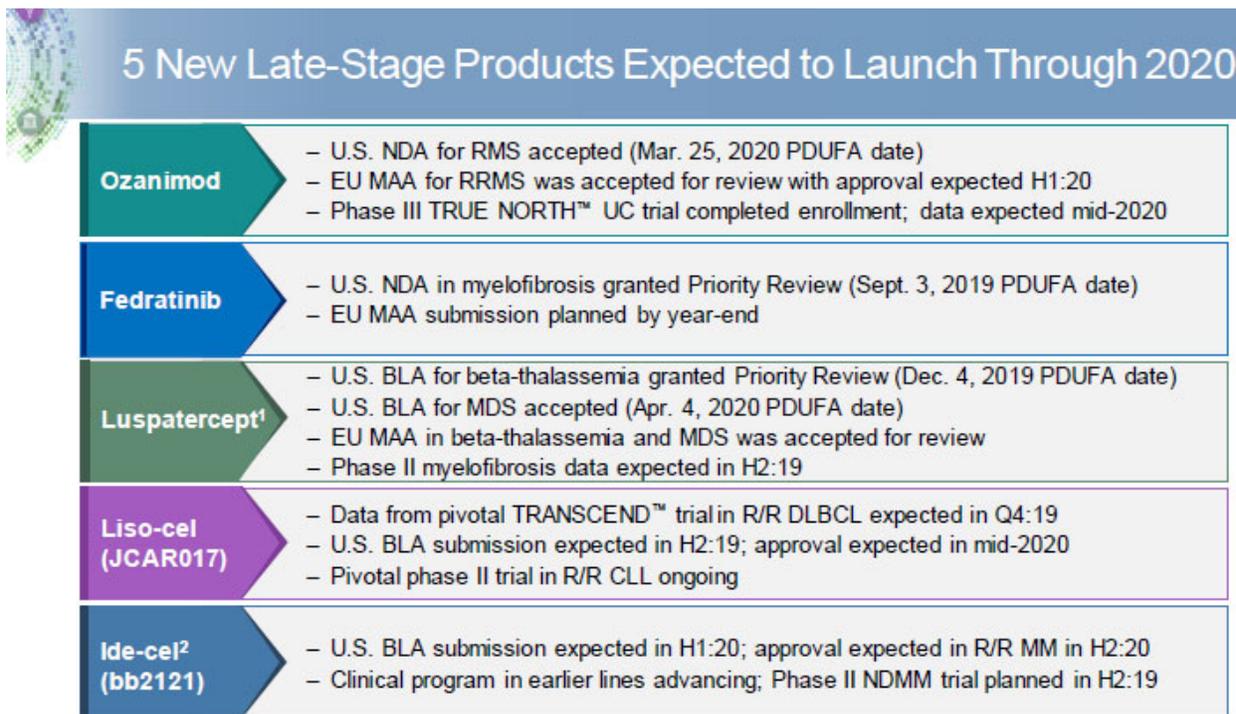
Patient Population	Relapsed or Refractory Indolent Lymphoma	Relapsed or Refractory B-cell NHL
Molecule	REVLIMID®	Liso-cel (lisocabtagene maraleucel; JCAR017)
Trial Name	MAGNIFY™ NHL-008	TRANSCEND-NHL-001
Phase	III	I
Target Enrollment	500	274
Design	<p>Arm A: REVLIMID® (10-20mg, D1-21) + rituximab (375 mg/m² weekly for cycle 1 then D1 of cycles 3, 5,7,9 and 11 for 12 28-D cycles) followed by REVLIMID® (10mg, D1-21) + rituximab (375 mg/m² D1 of cycles 13,15,17,19,21,23,25,27 and 29 for 18 28-D cycles) followed by REVLIMID® (10mg, D1-21 until disease progression, 28 D cycle)</p> <p>Arm B: REVLIMID® (10-20mg, D1-21) + rituximab (375 mg/m² weekly for cycle 1 then D1 of cycles 3, 5,7,9 and 11 for 12 28-D cycles) followed by REVLIMID® (10mg, D1-21) + rituximab (375 mg/m² D1 of cycles 13,15,17,19,21,23,25,27 and 29 for 18 28-D cycles)</p>	<p>Arm A: JCAR017 single-dose schedule</p> <p>Arm B: JCAR017 2-dose schedule</p>
Primary Endpoint	Progression Free Survival	Objective Response Rate; Safety
Status	Trial enrolling Data expected in 2020	Enrollment complete Submission expected for 2H:2019

48

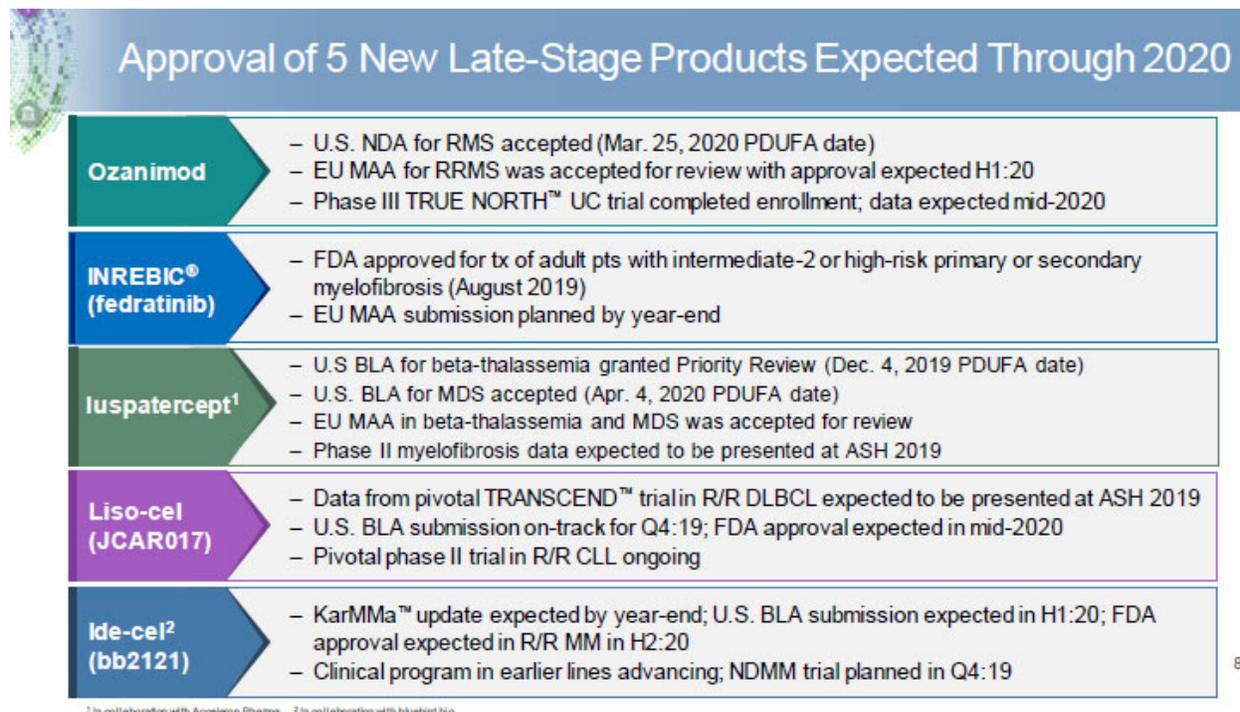
70. Similarly, in Celgene's First Quarter earnings presentation published April 25, 2019, it represented to investors that Liso-cel was "on track" and that U.S. approval was expected in "mid-2020."



71. 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:



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



73. Simply put, prior to and following the announcement of the Merger, the submission of the BLA for Liso-cel was on track and FDA approval for Liso-cel was reasonably expected in mid-2020.

C. Celgene Accedes to Bristol's Demand to Issue CVRs to Celgene Shareholders in Exchange for Less Cash Consideration

74. 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.

75. In December 2018, Bristol proposed introducing a CVR component to the merger consideration for purposes of bridging a reduction in the upfront aggregate value per Celgene share. In the course of 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. This proposal would provide a payout to CVR holders even if Bristol 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.

76. After intense negotiations over the terms of the CVR Agreement, Bristol and Celgene came to an agreement on the price, catalyst events and dates for CVR payments. 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 each of the Milestones being achieved by December 31, 2020 for Liso-cel and Ozanimod, and March 31, 2021 for Ide-cel. If all three were approved by their respective Milestone dates, Bristol would owe the CVR holders a total of \$6.4 billion. If any Milestone were missed – even by a single day – Bristol would owe the CVR holders nothing.

77. 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 also designated Liso-cel as a “Breakthrough Therapy” in 2016, which expedites the development and review process. Upon such designation, senior FDA personnel become involved in a proactive, collaborative review of a Breakthrough Therapy throughout its development and provide intensive,

interactive guidance to the applicant. The designation allows the FDA to authorize a rolling review of a therapy's marketing application to allow the product to enter the market more quickly.

78. The FDA also designated Liso-cel as a "Regenerative Medicine Advanced Therapy" in 2017. This also 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.

79. 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."

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

D. Bristol Myers and Celgene Issue The Materially False and Misleading Joint Proxy

81. On February 22, 2019, Bristol and Celgene issued the Joint Proxy soliciting votes on the proposed Merger. The Joint Proxy stated that if shareholders approved the Merger, Celgene

shareholders would receive one share of Bristol Myers common stock, \$50.00 in cash and one CVR for each outstanding share of Celgene stock they owned.

82. The Joint Proxy also explained the agreement between Bristol 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.” Joint Proxy at 217. The Joint Proxy 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.” *Id.*

83. Critically, the Joint Proxy told Celgene shareholders that Bristol would engage in “*diligent efforts*” to achieve the CVR Milestone dates. Specifically, the Joint Proxy 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.

Id. at 219.

84. The Joint Proxy also attached a Form CVR Agreement which discloses the same to Celgene shareholders. *Id.* at B-2, B-22.

85. Relying upon the statements in the Joint Proxy, Bristol Myers and Celgene shareholders approved the Merger on April 12, 2019.

E. Bristol Assumes Control of the Liso-cel Approval Process and Takes Actions With No Legitimate Business Purpose Other Than to Delay FDA Approval: Bristol Sabotages the Process

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

86. 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 FDA issues its approval once it has reviewed the BLA, conducted facility inspections and concluded that the therapy is efficacious, safe and appropriately labeled.

87. 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.

88. Bristol Myers did so by failing to submit Liso-cel's Chemistry, Manufacturing and Controls data, *the most important section of the BLA*, until December 18, 2019. At that point, the FDA had only sixty days to conduct an initial review to determine whether the application was complete and whether to grant "Priority Review" for Liso-cel.

89. 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.

90. 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's 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.

91. However, soon after completing its initial review of the Liso-cel BLA, the FDA found significant additional omissions in the application. Bristol Myers omitted 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. On March 23, 2020, the FDA submitted an information request to Bristol Myers seeking the missing data on assays and validation. Bristol Myers amended the CMC section of the BLA to provide the missing information on April 15, 2020.

92. Within weeks, the FDA concluded that the new information Bristol Myers provided in the amendment was so substantial that it rose to the level of a “major amendment” to the Liso-cel BLA. 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.

93. Yet, Liso-cel’s “major amendment” designation automatically triggered the three-month extension of the FDA’s target review date — from August 17, 2020 to November 16, 2020, only weeks before the December 31, 2020 Liso-cel Milestone date. 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 Further Delays FDA Approval By Failing To Prepare The Liso-cel Manufacturing Facilities

94. 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.

95. 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.

96. 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's control, those facilities fell far short on basic safety and regulatory requirements. Despite the FDA's inspection notice and Bristol's opportunity to get ready and address any deficiencies, both facilities were left woefully unprepared.

97. The Juno Facility inspection occurred from October 7, 2020 to October 16, 2020. 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.

98. 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.

99. 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.

100. Remarkably, Bristol Myers repeated many of the same issues during the inspection of the Lonza Facility. 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 deficiencies in the inspection of raw materials and inadequate microbial contamination controls. 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.

101. 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.

102. 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 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's response and required it to supplement the response further. Bristol 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. The FDA could not complete its review of the Liso-cel BLA until this response was complete. Had Bristol Myers actually used diligent efforts as represented in the Joint Proxy, such further delay would have been avoided.

103. 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 did so on December 23, 2020 – again, *just days* before the Liso-cel Milestone and in the middle of the winter holidays.

F. Bristol Myers Misses the Liso-cel Milestone Approval Date By Thirty-Six Days – Illustrating The Falsity of Its Joint Proxy Disclosure that It Would Make Diligent Efforts to Reach the Milestones

104. Following the three-month delay caused by Bristol 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.

105. 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.”

106. Thirty-six days later, the FDA approved the Liso-cel BLA.

107. For these reasons, Bristol Myers issued a false and misleading Joint Proxy 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.

V. **THE MATERIALLY FALSE AND MISLEADING STATEMENTS IN THE JOINT PROXY**

108. As set forth below, Defendants made numerous materially false statements and omissions of material fact concerning the CVRs and the development and approval of Liso-cel.

109. The Joint Proxy falsely and misleadingly stated there was a strong possibility that the Milestones would be met, and that Bristol would in good faith use diligent efforts to meet them. Specifically, the Joint Proxy 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].*” Joint Proxy at 82. The Joint Proxy 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%.*” Joint Proxy at 157.

110. The above statements were materially false and misleading and/or omitted material facts because, among other things: (i) Bristol planned to submit a materially deficient BLA for Liso-cel that would require supplemental information in the form of an amendment; and (ii) Bristol never intended to meet the Milestone.

111. The Joint Proxy also made a series of false and misleading statements regarding the value of the CVRs. The Joint Proxy 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].*” Joint Proxy at 4, 217.

112. However, Defendants knew that the CVRs were worthless as Bristol Myers had no intention of meeting the Milestones and paying any value for the CVRs.

113. Critically, the Joint Proxy misrepresented to Celgene shareholders that Bristol Myers would engage in “diligent efforts” to achieve the CVR Milestones. Specifically, the Joint Proxy 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.

Joint Proxy at 219. The Joint Proxy also attached the Form CVR Agreement which disclosed the same to Celgene shareholders. *Id.* at B-2, B-22.

114. The above statements were materially false and misleading and/or rendered misleading by the omission of material facts because, among other things: (i) Bristol never had any intention of employing “diligent efforts” to achieve the Liso-cel Milestone; (ii) Bristol planned to submit a materially deficient BLA for Liso-cel that would require supplemental information in the form of an amendment; (iii) Bristol knew the supplemental information would be deemed a “major amendment” automatically triggering a three-month extension of the FDA target review date; and (iv) Bristol failed to prepare Liso-cel manufacturing facilities for inspection, which caused predictable delays in the FDA approval process.

115. The Joint Proxy also made a series of risk disclosures regarding the potential diminished value of the CVRs. Specifically, the Joint Proxy 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.*” Joint Proxy at 50.

116. The Joint Proxy 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.

Joint Proxy at 39.

117. These statements were materially false and misleading as Defendants knew, or should have known, that the CVRs were worth nothing since Bristol Myers had no intention of

meeting the Milestone dates, employing “diligent efforts” to achieve them, or paying anything for the CVRs.

VI. LOSS CAUSATION

118. As described herein, Defendants made materially false and misleading statements and omissions of material facts in the Joint Proxy. Defendants’ materially false and misleading statements as set forth above caused Plaintiffs and other members of the Class to accept Merger consideration that failed to adequately value Celgene’s shares. As a result of their possession and exchange of Celgene common stock in the Merger, Plaintiffs and other Class members suffered an economic loss (*i.e.*, damages under the federal securities laws).

VII. CLASS ACTION ALLEGATIONS

119. Plaintiffs bring this action on behalf of themselves and all other former Celgene shareholders that received CVRs in exchange for their Celgene shares pursuant to Bristol Myers’ acquisition of Celgene on November 20, 2019 and were damaged thereby.

120. The Class is so numerous that joinder of all members is impracticable. As of the close of business on the Merger record date — March 1, 2019 — approximately 702,450,444 shares of Celgene common stock were outstanding and entitled to vote on the Merger. Those shares were held by hundreds, if not thousands, of individuals and entities located throughout the country.

121. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether Defendants violated the Exchange Act;
- (b) Whether Defendants omitted and/or misrepresented material facts in the

Joint Proxy;

(c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether Defendants disregarded that their statements and/or omissions were false and misleading;

(e) Whether Defendants' conduct caused the members of the Class to sustain damages; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

122. Plaintiffs' claims are typical of those of the Class because Plaintiffs and the other members of the Class sustained damages from Defendants' wrongful conduct.

123. Plaintiffs will adequately protect the interests of the Class and have retained counsel experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

124. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

VIII. INAPPLICABILITY OF STATUTORY SAFE HARBOR

125. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pled in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward-looking, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Further, to the extent that the statutory safe harbor is determined to apply to any

forward-looking statements pled herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading and/or the forward-looking statement was authorized or approved by an executive officer of Bristol Myers who knew that the statement was false when made.

IX. STATUTE OF LIMITATIONS

Plaintiffs could not have learned about Bristol's false statements in the Joint Proxy until the CVR Agreement terminated and Bristol failed to achieve the Milestone on December 31, 2020 at the earliest. The complaint in this action was filed within one year of the discovery of the facts constituting the claim. Plaintiffs' claims are, therefore, brought within the applicable statute of limitations.

COUNT I

**On Behalf of Plaintiffs and the Class Against All Defendants for
Violations of Section 14(a) of the Exchange Act and Rule 14a-9 Promulgated Thereunder**

126. Plaintiffs incorporate each and every allegation set forth above as if fully set forth herein.

127. The Defendants disseminated a materially false and misleading Joint Proxy containing statements that, in violation of Section 14(a) of the Exchange Act and Rule 14a-9, and in light of the circumstances under which they were made, misrepresented or omitted material facts necessary to make the statements therein not materially false or misleading.

128. The Defendants were at least negligent in issuing a false and misleading Joint Proxy. Plaintiffs, while reserving all rights, expressly disclaim and disavow at this time any allegation in this Complaint that could be construed as alleging fraud against Defendants in connection with this Count. This claim sounds in negligence based on the failure of these

Defendants to exercise reasonable care to ensure the Joint Proxy did not contain the material misstatements and omissions alleged herein.

129. The Proxy was prepared, reviewed and/or disseminated by Defendants. By virtue of their positions within Bristol Myers, these Defendants were aware of this information and their duty to disclose this information in the Joint Proxy.

130. The omissions and false and misleading statements in the Joint Proxy are material in that a reasonable shareholder would have considered them important in deciding how to vote on the Merger. In addition, a reasonable investor would view a full and accurate disclosure as significantly altering the total mix of information made available in the Joint Proxy and in other information reasonably available to Celgene shareholders.

131. As a result of the material misstatements and omissions, Celgene shareholders voted in favor of the Merger.

132. The Joint Proxy was an essential link in causing Celgene shareholders to approve the Merger.

133. By reason of the foregoing, Defendants violated Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder.

134. Because of the false and misleading statements in the Joint Proxy, Plaintiffs and the other members of the Class were harmed by an uninformed shareholder vote approving the Merger.

135. This claim is brought within the applicable statute of limitations.

COUNT II

On Behalf of Plaintiffs and the Class Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act

136. Plaintiffs incorporate each and every allegation set forth above as if fully set forth herein.

137. Defendants disseminated a false and misleading Joint Proxy in violation of Section 14(a) of the Exchange Act and Rule 14a-9, promulgated thereunder.

138. The Individual Defendants acted as controlling persons of Bristol Myers within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their positions and participation in and/or awareness of Bristol Myers' operations and/or intimate knowledge of the false and misleading statements contained in the Joint Proxy filed with the SEC, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Bristol Myers, including the content and dissemination of the various statements in the Joint Proxy that Plaintiffs contend are false and misleading.

139. The Individual Defendants were provided with or had unlimited access to copies of the Joint Proxy and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

140. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of Bristol Myers, and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the Exchange Act violations alleged herein, and exercised the same. The misrepresented information identified above was reviewed by the Individual Defendants prior to the shareholder vote on the Merger. The Joint Proxy at issue contains the unanimous recommendation of the Individual Defendants to approve the Merger and the Joint Proxy was issued on behalf of each Individual Defendant. They were thus directly involved in the making of the Joint Proxy.

141. By virtue of the foregoing, the Individual Defendants have violated Section 20(a) of the Exchange Act.

142. As set forth above, the Individual Defendants had the ability to exercise control over and did control a person or persons who have each violated Section 14(a) of the Exchange Act and Rule 14a-9, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' conduct, Plaintiffs and the Class were irreparably harmed.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and relief as follows:

- A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding compensatory damages in favor of Plaintiffs and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre and post-judgment interest thereon;
- C. Declaring that Defendants violated Sections 14(a) and/or 20(a) of the Exchange Act, as well as Rule 14a-9 promulgated thereunder;
- D. Awarding Plaintiffs the costs of this action, including reasonable allowance for Plaintiffs' attorneys' and experts' fees; and
- E. Granting such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all issues so triable.

DATED: October 6, 2021
New York, New York

Respectfully Submitted,

/s/ Vincent R. Cappucci

Vincent R. Cappucci
ENTWISTLE & CAPPUCCI LLP
230 Park Avenue, 3rd Floor
New York, New York 10169
Telephone: (212) 894-7200

-and-

Andrew J. Entwistle
ENTWISTLE & CAPPUCCI LLP
Frost Bank Tower
401 Congress Avenue, Suite 1170
Austin, TX 78701
Telephone: (512) 710-5960

David J. Schwartz
Francis P. McConville
LABATON SUCHAROW LLP
140 Broadway
New York, New York 10005
Telephone: (212) 907-0700

Counsel for Plaintiffs

CERTIFICATION

I, Salvatore Muoio, on behalf of S. Muoio & Co. LLC, hereby certify, as to the claims asserted under the federal securities laws, that:

1. I am the Managing Member of S. Muoio & Co. LLC, the general partner to and investment advisor of SM Merger/Arbitrage, L.P., SM Investors, L.P. and SM Investors II, L.P. (the "SM Funds"), and have authority to execute this certification on their behalf. I have reviewed the complaint and the motion for appointment as lead plaintiff to be filed in this action and have authorized their filing.

2. SM Funds did not acquire any of the Contingent Value Rights that are the subject of this action at the direction of their counsel or in order to participate in this or any other litigation under the securities laws of the United States.

3. SM Funds are willing to serve as representative parties on behalf of a class in this matter, including providing testimony at deposition and trial, if necessary.

4. SM Funds received Contingent Value Rights that are the subject of this action as reflected in the attached Schedule A.

5. SM Funds have not, within the three years preceding the date of this certification, sought to serve or served as a representative party on behalf of a class in an action involving alleged violations of the federal securities laws, except in the matter of *Sayce v. Forescout Technologies, Inc. et al*, No. 3:20-cv-00076 (N.D. Cal. Jan 02, 2020) (S. Muoio & Co. LLC).

6. SM Funds will not accept any payment for serving as representative parties on behalf of the class beyond their *pro rata* share of any recovery, except reasonable costs and expenses directly related to the class representation, as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 4th day of October 2021


By: Salvatore Muoio, C.F.A.
Managing Member,
S. Muoio & Co. LLC,
General Partner to and Investment Advisor
of SM Merger/Arbitrage, L.P., SM
Investors, L.P. and SM Investors II, L.P.

Schedule A**Contingent Value Rights ("CVRs") Received
in Exchange for Celgene Corporation Common
Shares in Connection With the Merger of
Celgene Corporation and Bristol Myers-
Squibb Company**

Fund	CVRs
SM Merger/Arbitrage, L.P.	24,000
SM Investors, L.P.	10,750
SM Investors II, L.P.	16,250
Total	51,000