UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EHAB KHALIL, on behalf of himself and all others similarly situated,

Plaintiffs,

vs.

BRISTOL-MYERS SQUIBB COMPANY, GIOVANNI CAFORIO, CHARLES BANCROFT, KAREN M. SANTIAGO, DAVID V. ELKINS, SAMIT HIRAWAT, 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. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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Plaintiff Ehab Khalil brings this complaint (the "Complaint") against Bristol-Myers Squibb Company ("Bristol" or "Bristol-Myers"), Giovanni Caforio, David V. Elkins, Samit Hirawat, 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, Karen H. Vousden, Charles Bancroft and Karen M. Santiago (the "Individual Defendants") (together, "Defendants").

Plaintiff's allegations are based upon personal knowledge as to his own acts, and upon information and belief as to all other matters, such information and belief having been informed by the independent investigation of his undersigned counsel. This investigation included a review and analysis of: (i) public filings submitted by Celgene Corporation ("Celgene") and 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) and 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. Plaintiff believes substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. Plaintiff brings this federal securities class action on behalf of (i) all former Celgene shareholders that received Bristol-Myers Squibb Contingent Value Rights ("CVRs") (NYSE:

BMY-RT) in exchange for their Celgene shares pursuant to Bristol's $74 billion acquisition of Celgene on November 20, 2019, and who were damaged thereby, and (ii) all persons who purchased CVRs between November 20, 2019 and December 31, 2020 (the "Class Period"), 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 Registration Statement (filed on or about February 20, 2019, and defined to include accompanying prospectuses and documents therein) made in violation of Sections 11 and 12(a)(2) of the Securities Act of 1933 ("Securities Act"); false and misleading statements and omissions of material fact made in the Joint Proxy (the relevant substance of which was also included in the Registration Statement, and which was filed on February 22, 2019) 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; and false and misleading statements and omissions of material fact made throughout the Class Period in violation of Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 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. 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. 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—but only if Bristol deceived investors into believing that it *was*, in fact, diligently aiming to hit its Milestone.

3. Bristol managed to successfully subvert the FDA regulatory approval through a

series of obstructive acts that it falsely passed off as innocent mistakes or as events out of its control. 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–and thus would make it more likely that Bristol would miss the Liso-cel Milestone and evade payment to CVR holders.

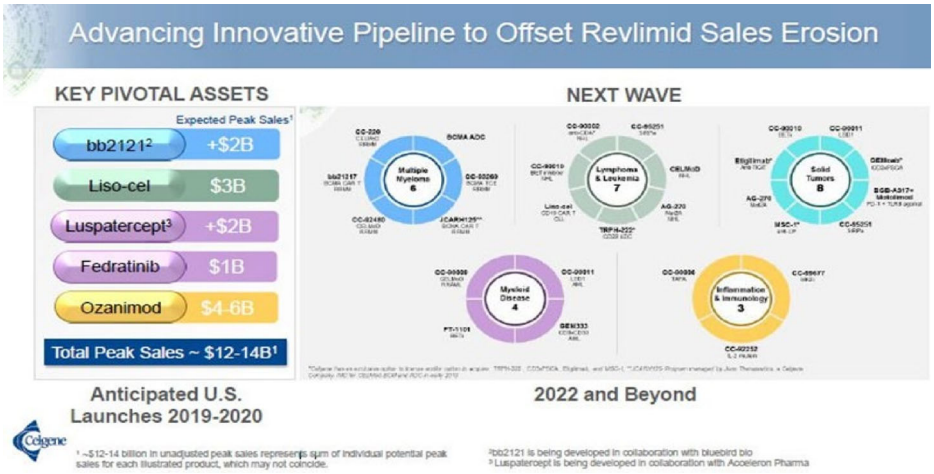
4. Bristol knew it would not or recklessly failed to take diligent efforts to obtain FDA approval for Liso-cel by the Milestone date of December 31, 2020. Accordingly, Defendants' statements in the Registration Statement and Joint Proxy and throughout the Class Period concerning the efforts Bristol would 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 Registration Statement and 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 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:

[1] https://news.bms.com/news/corporate-financial/2019/Bristol-Myers-Squibb-Issues-Statement-in-Response-to-Starboards-Letter/default.aspx



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 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 and Registration Statement, in December 2018, Bristol and Celgene 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.

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. But 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 atypical "all-or-nothing" approach, Bristol would make a payout of $9 to each CVR holder if three of Celgene's near-term, late-stage pipeline assets – (i) JCAR017 a/k/a Liso-cel, (ii) Ozanimod and (iii) bb2121 a/k/a Ide-cel – were approved 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 Registration Statement and Joint Proxy that falsely 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. Bristol issued a press release on December 18, 2019, announcing its submission of the BLA for Liso-cel. This press release omitted to disclose a key fact: the CMC portion of the BLA that Bristol had submitted was materially deficient.

16. FDA provisions governing the CMC portion of BLAs obligate applicants to

[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.

"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]

17. 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 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.

18. Bristol caused one inexcusable delay after another, all while falsely representing in statements to investors that they were working diligently to meet the Milestone date for Liso-Cel approval. On April 15, 2020, Bristol submitted Amendment 31 to the Liso-cel BLA remedying the

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

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.

19. 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.

20. 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.

21. The rescheduling of the outside approval date and the inspection of Liso-cel's manufacturing facilities made it less likely that the CVRs would 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. Yet, all the while, Defendants made statements about the approval process and the facilities inspections, assuring investors that they

were diligently pursuing regulatory approval and omitting that they were deliberately delaying the process and failing to prepare their facilities for inspection.

22. Regulatory documents released in connection with Liso-cel further reveal that the FDA found Bristol's responses to the FDA about its facilities to be "***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***."

23. 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

24. 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.

25. Myriad facts demonstrate that Bristol never intended to employ "diligent efforts" to obtain FDA approval for Liso-cel as represented in the Registration Statement and Joint Proxy and throughout the Class Period, and that its actions were commercially unreasonable when compared to its prior practices and industry peers.

26. 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 noted 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

27. 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
Liso-cel	***Bristol***	***96***
Kymriah	Novartis	70
Yescarta	Gilead (Kite)	61

28. 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

29. 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
Liso-cel	***Bristol***	***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

30. 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.

31. 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

32. 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

33. 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.

34. 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.

35. 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—and traded for by Class members throughout the Class Period—was $0.

36. Accordingly, the statements in the Registration Statement and 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 Registration Statement and 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 Registration Statement and Joint Proxy were materially false and misleading when made because Bristol knew, or should have known, the CVRs were worthless.

37. 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, Plaintiff alleges that Defendants violated Section 14(a) and 20(a) of the Exchange Act by filing a materially false and misleading Joint Proxy, as well as Section 11 and Section 12(a)(2) of the Securities Act by filing a materially false and misleading Registration Statement.

38. Furthermore, statements concerning the CVRs that Defendants made throughout the Class Period were false and misleading and/or contained material misrepresentations. As a result of these material misrepresentations and omissions, Plaintiff and other Class members were

led to believe that Bristol was working diligently toward timely FDA approval of Liso-cel and thus that the CVRs had value. Based upon these and other facts set forth below, Plaintiff alleges that Defendants violated Section 10(b) and 20(a) of the Exchange Act by making materially false and misleading statements.

II. JURISDICTION AND VENUE

38. The claims asserted herein arise under Sections 10(b), 14(a), and 20(a) of the Exchange Act, 15.U.S.C. §§ 78n(a), 78t(a), Rules 10b-5 and 14a-9 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5 and 17 C.F.R. § 240.14a-9, and Sections 11(a) and 12(a)(2) of the Securities Act.

39. This Court has jurisdiction over these claims pursuant to 28 U.S.C. §§ 1331 and 1337, Section 27 of the Exchange Act, and Section 22 of the Securities Act.

40. Venue is proper in this District pursuant to Section 27 of the Exchange Act, Section 22(a) of the Securities Act, and 28 U.S.C. § 1391(b), given that many of the acts and practices complained of herein occurred in this District, as Bristol-Myers' corporate headquarters are is in this District and the CVRs were traded on the NYSE. Venue is also proper in the District pursuant to Section 8.09 of the Bristol-Celgene Merger Agreement.

41. 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. Plaintiff

42. Plaintiff Ehab Khalil exchanged his Celgene shares and received the CVRs as partial consideration in connection with the Merger and purchased CVRs during the Class Period,

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

43. 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

1. Section 10(b) Individual Defendants

44. The following Defendants are subject to the claims brought under Section 10(b) of the Exchange Act (and Rule 10b-5 promulgated thereunder), as well as the claims brought under Section 20(a) of the Exchange Act.

45. Defendant Giovanni Caforio has served as Bristol Myers' Chief Executive Officer since 2015. Caforio signed the Registration Statement and Joint Proxy filed with the SEC in connection with the Merger, as well as the Forms 10-Q and Form 10-K filed by Bristol in 2020 that contained false and misleading statements and omissions.

46. Defendant David V. Elkins has served as Bristol Myers' Chief Financial Officer since June 2019. He signed the Forms 10-Q and Form 10-K filed with the SEC by Bristol in 2020 that contained false and misleading statements and omissions. He previously served as the Chief Financial Officer of Celgene.

47. Defendant Samit Hirawat has served as Bristol Myers' Executive Vice President, Chief Medical Officer, Global Drug Development, since 2019. He made several false and misleading statements and omissions during conference calls and presentations to investors during

the Class Period.

2. Section 14(a), Section 11 and Section 12(a)(2) Individual Defendants

48. The following Defendants are subject to the claims brought under Section 14(a) of the Exchange Act (and Rule 14a-9 promulgated thereunder), as well as the claims brought under Section 20(a) of the Exchange Act. They are also subject to claims brought under Section 11 and Section 12(a)(2). Each signed the false and misleading Joint Proxy and Registration Statement.

49. Defendant Caforio, described above.

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

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

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

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

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

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

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

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

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

times.

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

3. Additional Sections 11 and 12(a)(2) Individual Defendants

60. In addition to the Individual Defendants described above in Section III.A.2, the following Individual Defendants set forth below are subject to the claims brought under Sections 11 and 12 of the Securities Act:

61. Defendant Charles Bancroft was Bristol's Chief Financial Officer prior to being replaced by Defendant Elkins in June 2019. He signed the false and misleading Registration Statement.

62. Defendant Karen M. Santiago was Bristol's Principal Accounting Officer. She signed the false and misleading Registration Statement.

* * *

63. All the Defendants set forth above are referred to collectively herein as the "Individual Defendants."

IV. FACTUAL BACKGROUND

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

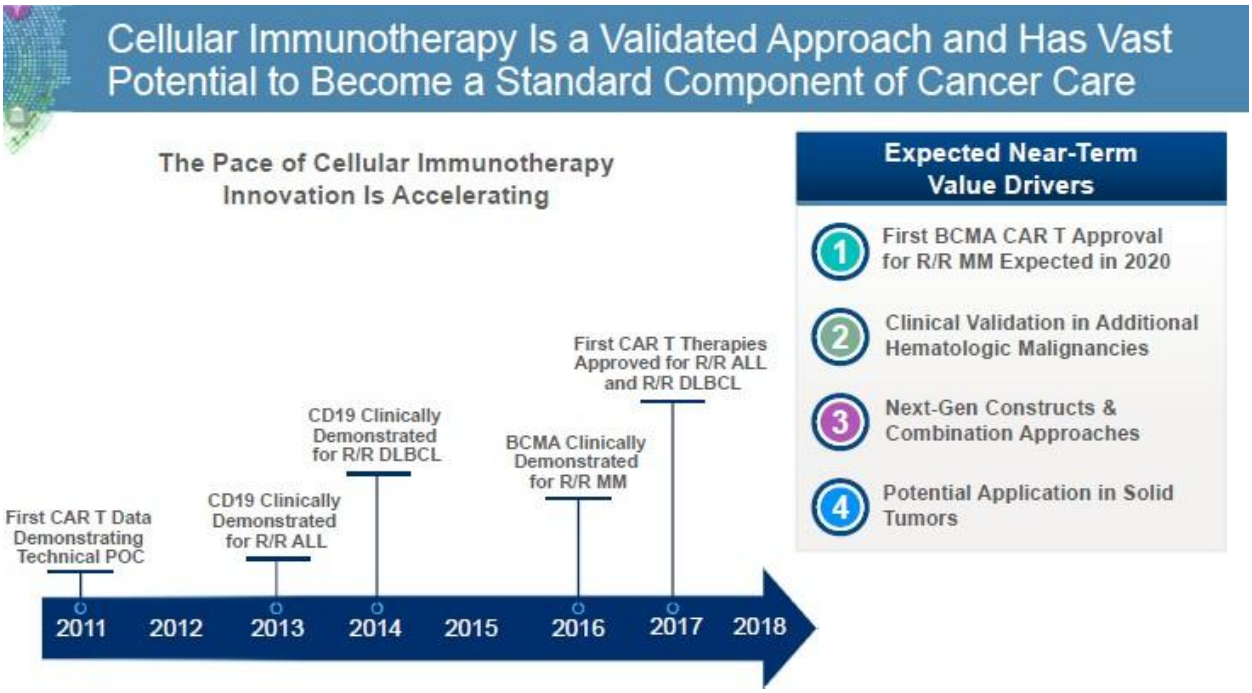
64. Prior to its acquisition by Bristol, Celgene was a global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases. Celgene did so through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation.

65. Celgene invested substantially in research and development in support of multiple

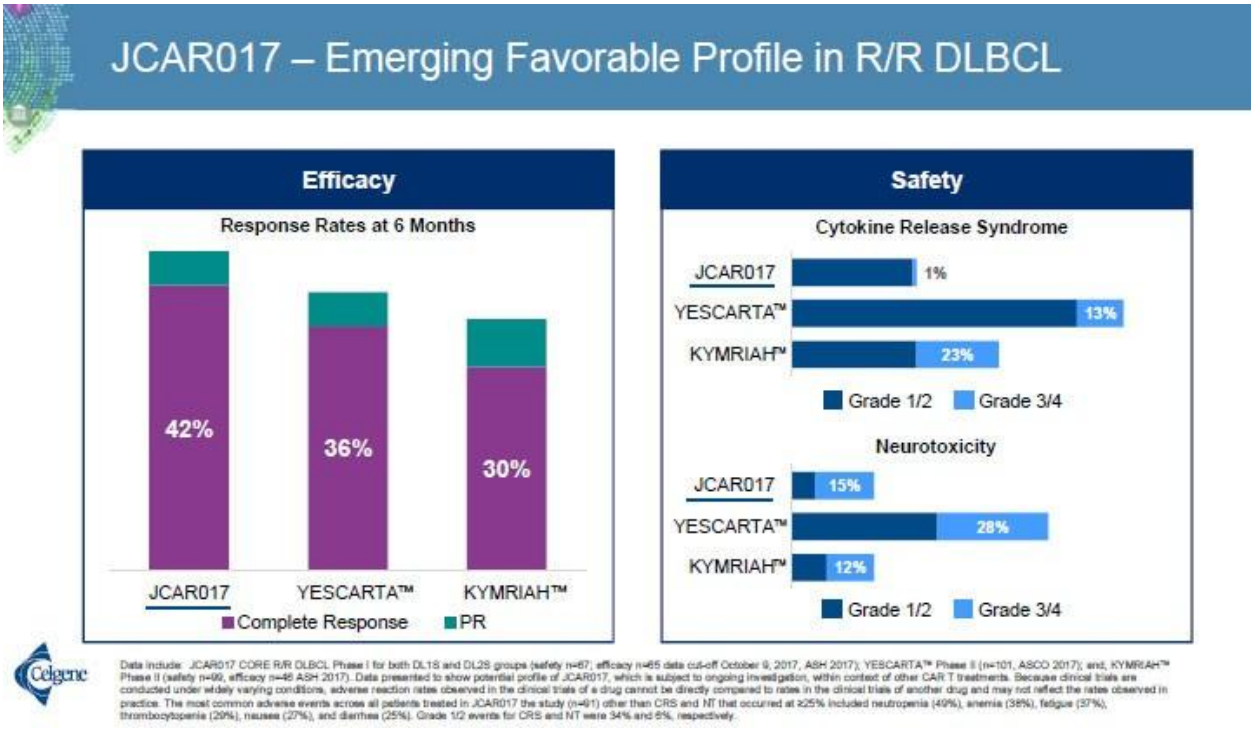
ongoing clinical development programs and, in the first through third quarters of 2018, Celgene spent $2.203 billion, $1.251 billion and $1.081 billion, respectively, on research and development. This research covered disease areas such as hematology, solid tumors, inflammation, and immunology.

66. 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.

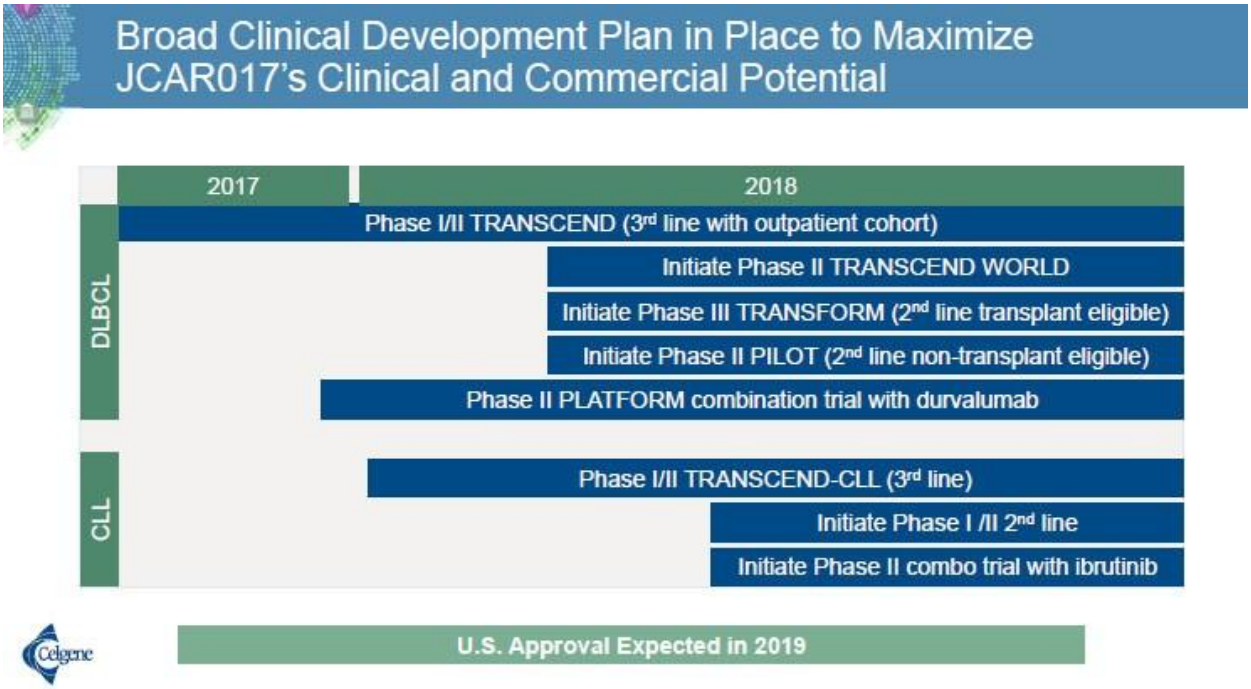
67. In January 2018, Celgene announced it had agreed to acquire Juno Therapeutics, a specialty biopharmaceutical company on the forefront of CAR-T immunotherapy. In the presentation discussing the acquisition, Celgene set forth the expected timeline for FDA approval of Juno's CAR-T candidates as follows:



68. 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 serious Cytokine Release Syndrome (a common but occasionally serious side effect), more than ten times less than the rival CAR-T therapies:



69. Celgene's management also set forth an aggressive timeline for comprehensive and exhaustive efficacy and response trials for Liso-cel, stating that approval of the drug in the U.S. was expected in 2019:



B. Prior to Finalization of the Merger, FDA Approval Of Liso-Cel Is On Track to be Completed Prior to the CVR Deadline.

70. 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.

71. 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."

72. 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."***

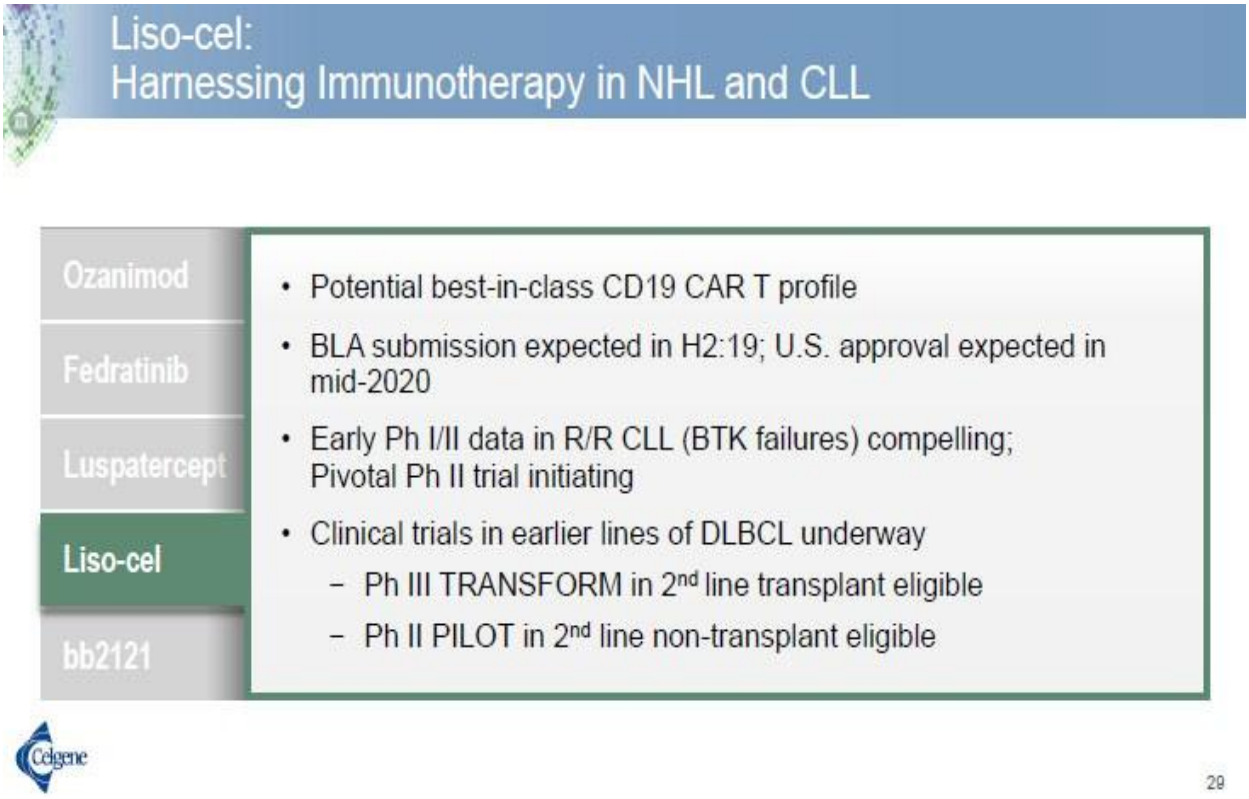
73. On the same call, Celgene's EVP of Global Pharmaceutical Development, Joanne T. Beck, stated:

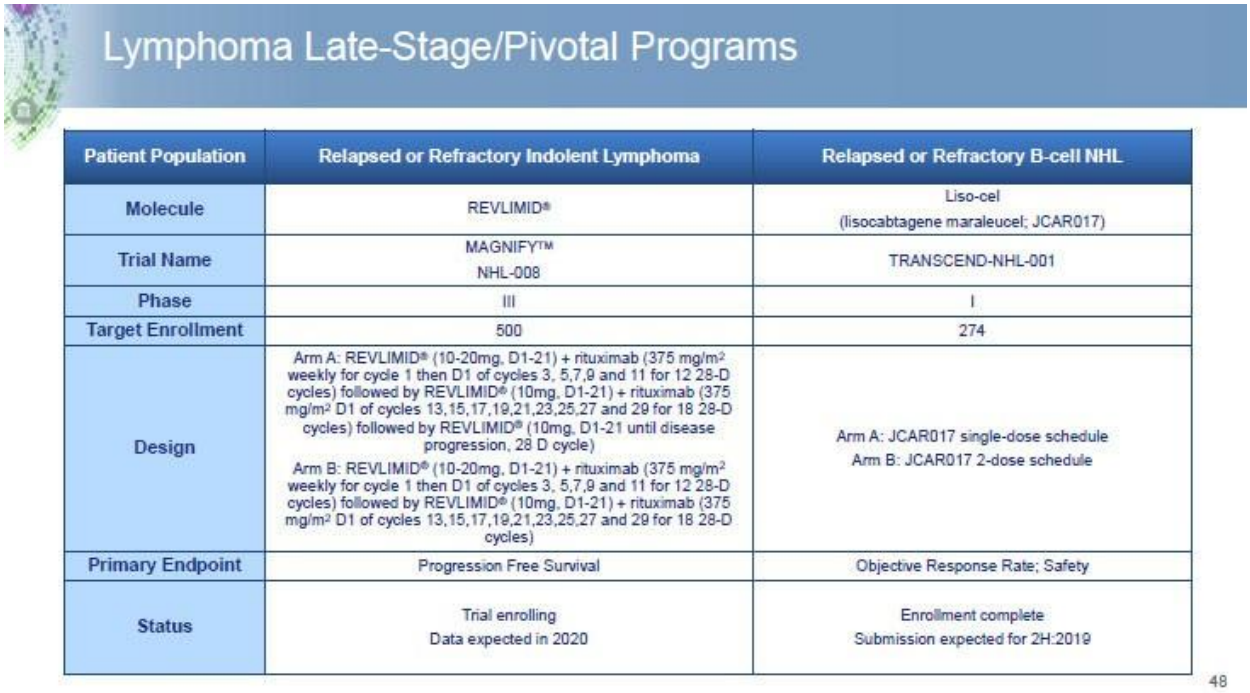
> Now we just wait. You know the data set. You know the safety profile. This is the point about being derisked ***liso-cel, we've had the pivotal data for about 6, 8months. Our focus is on the BLA, not updating the world about follow-up data, but on the regulatory submission for liso-cel.*** So when 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 theupside for the company.

74. 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.

75. 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:





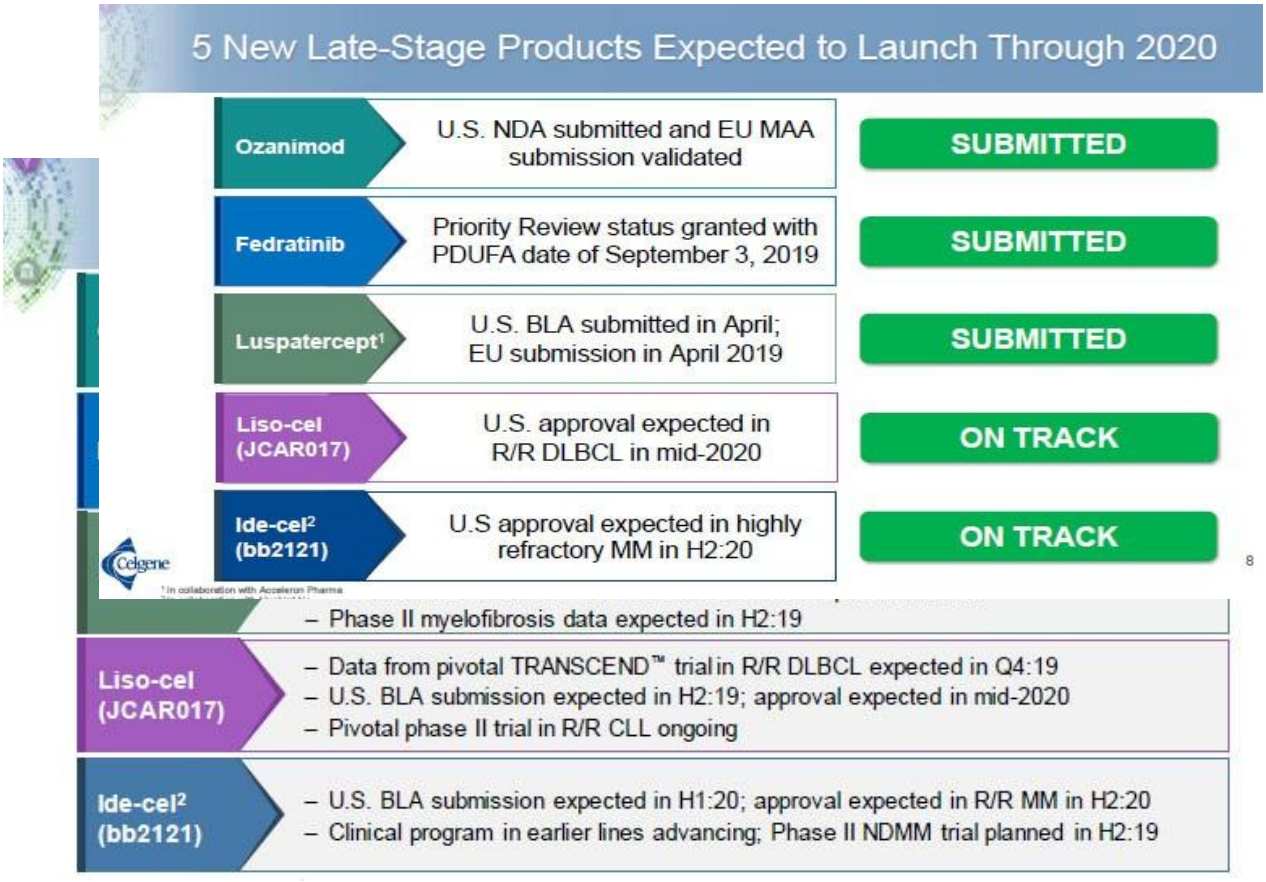
Lymphoma Late-Stage/Pivotal Programs

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	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) 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)	Arm A: JCAR017 single-dose schedule Arm B: JCAR017 2-dose schedule
Primary Endpoint	Progression Free Survival	Objective Response Rate; Safety
Status	Trial enrolling Data expected in 2020	Enrollment complete Submission expected for 2H:2019

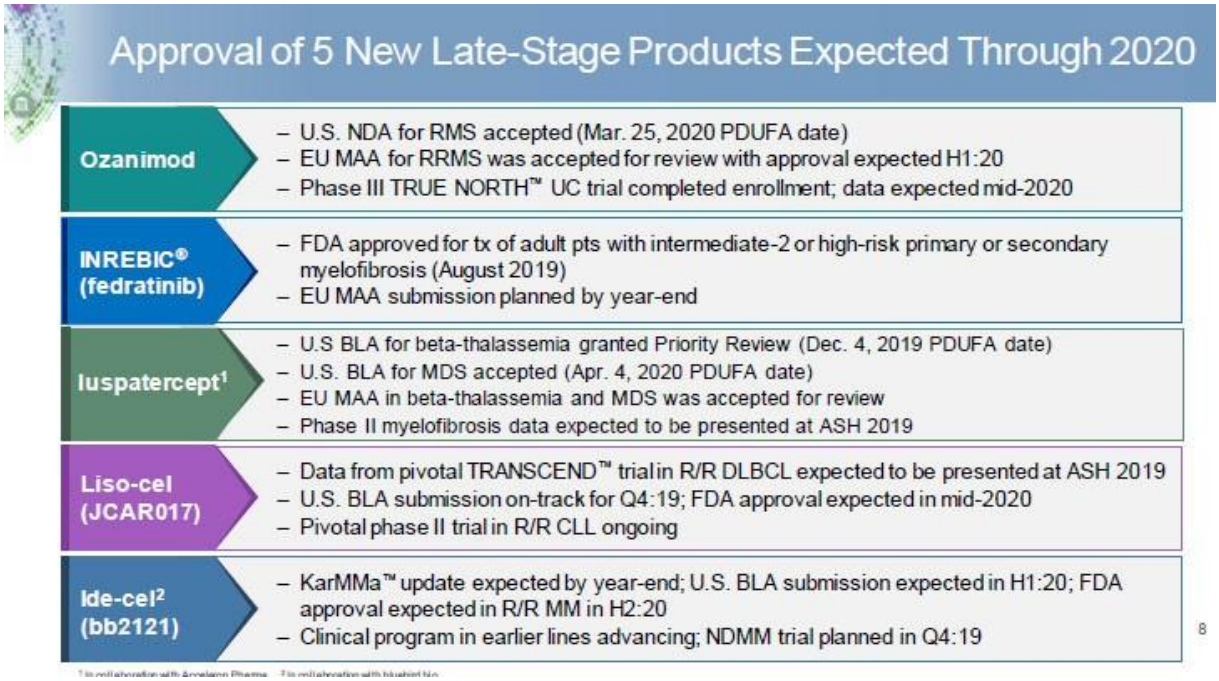
48

76. 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."

77. 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.



78. 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."



79. 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 to occur well before the December 31, 2020 CVR Milestone.

C. Celgene Accedes To Bristol's Demand To Issue CVRs To Celgene Shareholders In Exchange For Less Cash Consideration

80. 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.

81. 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.

82. 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.

83. 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.

84. 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.

85. 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."

86. 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 Issues The Materially False And Misleading Registration Statement and Joint Proxy

87. On February 20, 2019, Bristol, together with Celgene, filed a Registration Statement, which contained the relevant substance of the Joint Proxy. On February 22, 2019, Bristol, together with Celgene, filed the Joint Proxy, soliciting votes on the proposed Merger. The Joint Proxy and Registration Statement 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.

88. The Joint Proxy and Registration Statement 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 and 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." *Id*.

89. Critically, the Joint Proxy and Registration Statement told Celgene shareholders that Bristol would engage in "***diligent efforts***" to achieve the CVR Milestone dates. Specifically, the Joint Proxy and 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.

Id. at 219.

90. The Joint Proxy and Registration Statement also attached a Form CVR Agreement

which discloses the same to Celgene shareholders. *Id*. at B-2, B-22.

91. 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 Intentional or Reckless Actions To Delay FDA Approval

1. Bristol Files a BLA for Liso-cel Lacking Basic Information About Liso-cel's Chemistry, Manufacturing, and Controls

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

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 and Registration Statement, 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 Form483. 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.

104. Despite Bristol's delinquent and deficient submission of the CMC portion of its BLA, Bristol's deliberate failure to prepare for the Liso-cel facility site inspections, and Bristol's delayed responses to the FDA after the facility inspections, Defendants repeatedly made statements during the Class Period that led investors to believe that Bristol was diligently trying—and expecting—to achieve FDA approval of Liso-cel by the Milestone date.

F. Bristol Myers Misses The Liso-Cel Milestone Approval Date By Thirty-Six Days – Illustrating The Falsity Of Its Joint Proxy Disclosure And Subsequent Statements During The Class Period Indicating That It Would Make Diligent Efforts To Reach The Milestones

105. 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.

106. 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."

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

108. For these reasons, Bristol Myers issued a false and misleading Registration Statement and Joint Proxy, which stated that it would make "diligent efforts" to ensure that Liso-cel was approved before its Milestone date. It also made numerous statements during the Class Period indicating that it was working diligently to – and expected to – attain approval before the 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

109. 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.

A. False And Misleading Statements In The Registration Statement and Joint

Proxy

110. On February 20, 2019, Bristol, together with Celgene, filed a Registration Statement, which included the portions of the Joint Proxy at issue here. On February 22, 2019, Bristol, together with Celgene, filed the Joint Proxy, soliciting votes on the proposed Merger. The statements set forth below were repeated verbatim in both the Registration Statement filed February 20, 2019, and the Joint Proxy filed February 22, 2019.

111. The Joint Proxy and Registration Statement 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 and 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]***." Joint Proxy at 82. The Joint Proxy and 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%***." Joint Proxy at 157.

112. 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.

113. The Joint Proxy and Registration Statement also made a series of false and misleading statements regarding the value of the CVRs. The Joint Proxy and 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]***." Joint Proxy at 4, 217.

114. 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.

115. Critically, the Joint Proxy and Registration Statement misrepresented to Celgene shareholders that Bristol Myers would engage in "diligent efforts" to achieve the CVR Milestones. Specifically, the Joint Proxy and 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.

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

116. 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.

117. The Joint Proxy and Registration Statement also made a series of risk disclosures regarding the potential diminished value of the CVRs. Specifically, the Joint Proxy and 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." Joint Proxy at 50.

118. The Joint Proxy and 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.

Joint Proxy at 39.

119. 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.

B. Defendants' False And Misleading Statements And Omissions Throughout The Class Period

120. In addition to Defendants' false and misleading statements in the Joint Proxy and

Registration Statement, which artificially inflated the value of the CVRs from the moment they issued on November 20, 2019, Defendants made numerous false and misleading statements and omissions throughout the Class Period.

1. December 18, 2019 Press Release

121. On December 18, 2019, Bristol announced in a press release that it had submitted its BLA to the FDA for approval of Liso-cel:

> Bristol-Myers Squibb Company (NYSE: BMY) today announced the submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for lisocabtagene maraleucel (liso-cel), its autologous anti-CD19 chimeric antigen receptor (CAR) T-cellimmunotherapy comprising individually formulated CD8+ and CD4+ CAR T cells for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) after at least two prior therapies.
>
> The submission is based on the safety and efficacy results from the TRANSCEND NHL 001 trial, evaluating liso-cel in 269 patients with relapsed/refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL).

122. This press release was materially false and misleading because it omitted that (i) the BLA for Liso-cel was deficient and would require supplemental information in the form of an amendment, and (ii) Bristol knew the supplemental information would be deemed a "major amendment," automatically triggering a three-month extension of the FDA target review date.

2. February 6, 2020 Earnings Call

123. On February 6, 2020 earnings call, Defendant Caforio stated that "we continue to advance our regulatory filings for liso-cel, ide-cel and CC486."

124. This statement was false and misleading because it omitted that Bristol was deliberately delaying the regulatory approval of Liso-cel, as it had already submitted a deliberately insufficient BLA and did not intend to meet the Milestone.

3. February 13, 2020 Press Release

125. On February 13, 2020, Bristol issued a press release announcing that the FDA had accepted its BLA for Priority Review:

> **Bristol-Myers Squibb Company (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review its Biologics License Application (BLA) for lisocabtagene maraleucel (liso-cel),** the company's autologous anti-CD19 chimeric antigen receptor (CAR) T-cell immunotherapy with a defined composition of purified CD8+ and CD4+ CAR T cells for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after at least two prior therapies. **The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of August 17, 2020.**
>
> "There remains a critical need for additional therapies in large B-cell lymphoma, particularly for relapsed or refractory patients," said Stanley Frankel, M.D., senior vice president, Cellular Therapy Development, Bristol-Myers Squibb. "Based on the TRANSCEND NHL 001 data, liso-cel has the potential to expand treatment options for those affected by this aggressive blood cancer who did not respond to initial therapies or whose disease has relapsed. **This BLA acceptance and Priority Review designation is an important step as we work to improve treatment for these patients in need**."
>
> * * *
>
> According to the FDA, a Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

126. This statement was false and misleading because it omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) the BLA for Liso-cel was deficient and would require supplemental information in the form of an amendment, and (iii) Bristol knew the supplemental information would be deemed a "major amendment" automatically triggering a three-month extension of the August 17, 2020 target date mentioned in this statement.

4. <u>February 24, 2020 Form 10-K</u>

127. On February 24, 2020, Bristol filed a Form 10-K with the SEC, signed by Defendants Caforio and Elkins, describing potential challenges for winning approval of Liso-cel and reiterating the FDA's target date of August 17, 2020:

> The development of novel approaches for the treatment of diseases, such as our acquisition in November 2019 of Celgene's and Juno's CAR T cell therapy programs, including liso-cel and ide-cel, presents many **new challenges and risks** due to the unique nature of genetic modification of patient cells ex vivo using certain viruses to reengineer these cells to ultimately treat diseases, **including obtaining regulatory approval from FDA and other regulatory agencies that have very limited experience with the development of cellular therapies** involving genetic modification of patient cells; developing and deploying consistent and reliable processes, while limiting contamination, for engineering a patient's cells ex vivo and infusing genetically modified cells back into the patient; developing processes for the safe administration of cellular therapies, including long-term follow-up for patients receiving cellular therapies; and sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process our potential CAR T products. **The use of reengineered cells as a potential cancer treatment is a recent development and may not be broadly accepted by the regulatory, patient or medical communities. Further, we may not be able to satisfactorily establish the safety and efficacy or the reliability of these therapies or demonstrate the potential advantages and side effects compared to existing and future therapies.** Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. Furthermore, certain payment models could impact the interest of appropriate treatment sites in administering CAR T cell therapies, thereby limiting patient access. To date, only a few products that involve the genetic modification of patient cells have been approved for commercial sale. Moreover, the safety profiles of cellular therapies may adversely influence public perception and may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians and payors to subscribe to these novel treatment approaches. **If we fail to overcome these and other challenges, or if significant adverse events are reported from similar therapies, our development of these novel treatment approaches may be hampered or delayed, which could adversely affect our future anticipated revenues and/or profitability related to these therapeutic programs.**
>
> * * *

> In 2019, we received regulatory approvals for Reblozyl and Inrebic and **submitted a regulatory application for liso-cel targeting Diffuse Large B-Cell Lymphoma**
>
> * * *
>
> Announced that the **FDA has accepted for Priority Review its BLA for lisocabtagene maraleucel (liso-cel)**, the company's autologous anti-CD19 CAR T-cell immunotherapy with a defined composition of purified CD8+ and CD4+ CAR T cells for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after at least two prior therapies. **The FDA has set a Prescription Drug User Fee Act goal date of August 17, 2020.**

128. This statement was false and misleading because it omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) the BLA submitted by Bristol for Liso-cel was deficient and would require supplemental information in the form of an amendment, and (iii) Bristol knew the supplemental information would be deemed a "major amendment" automatically triggering a three-month extension of the August 17, 2020 target date mentioned in the Form 10-K.

5. May 6, 2020 Press Release

129. On May 6, 2020, part of Bristol's fraud was revealed. Specifically, Bristol issued a press release announcing that its submission of additional information at the FDA's request to supplement its BLA had led to a Major Amendment that would extend the FDA's target approval date to November 16, 2020:

> Bristol Myers Squibb (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has extended the action date by three months for the biologics license application (BLA) for lisocabtagene maraleucel (liso-cel), a CD19-directed chimeric antigen receptor (CAR) T cell therapy for the treatment of adults with relapsed or refractory (R/R) large B-cell lymphoma after at least two prior therapies. The new Prescription Drug User Fee Act (PDUFA) action date set by the FDA is November 16, 2020.
>
> Subsequent to the submission and acceptance of the BLA and upon FDA request, the company submitted additional information to the FDA, which

> was deemed to constitute a major amendment to the application and will require additional time for FDA review.

130. However, in the same press release, Defendants continued to falsely maintain that it was working diligently to meet the Milestone for Liso-cel:

> **The company will work closely with the FDA to support the continued review of the BLA for liso-cel and is committed to bringing this therapy to patients.**
>
> * * *
>
> **The company is committed to working with FDA to progress both applications and achieve the remaining regulatory milestones required by the CVR.**

131. This statement was false and misleading because it omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) the BLA submitted by Bristol for Liso-cel had been deliberately deficient so as to require supplemental information in the form of an amendment, and (iii) Bristol had known the supplemental information would be deemed a "major amendment" that would automatically trigger a three-month extension of the FDA's target date.

132. Despite Defendants' statements falsely reassuring investors, by the close of the market on May 6, 2020, the value of the CVRs had dropped by 15% since closing the previous day—from $4.43 to $3.75 per share, with a volume of more than 11 million shares.

6. May 7, 2020 Form 10-Q

133. On May 7, 2020, Bristol filed a Form 10-Q with the SEC, signed by Defendants Caforio and Elkins, stating again that the FDA had extended the target approval date and citing COVID-19 as a possible cause of delay in the approval of Liso-cel:

> **Announced that the FDA has extended the PDUFA date by three months for the BLA for lisocabtagene maraleucel (liso-cel), a CD19-directed CAR T cell therapy for the treatment of adults with relapsed**

> **or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date set by the FDA is November 16, 2020. . . .**
>
> **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).**
>
> We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). **These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020**. We do not yet have a PDUFA date for ide-cel, but we expect an approval decision by March 31, 2021, which is the time period specified within the CVR Agreement. **It is possible that COVID-19 could impact FDA operations such that the review of either or both of these CVR assets could be delayed.** Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.

134. These statements were false and misleading because they omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) the BLA submitted by Bristol for Liso-cel had been deliberately or recklessly deficient so as to require supplemental information in the form of an amendment that would cause a postponement of the target approval date, and (iii) Bristol intended to continue to delay the approval process.

7. May 7, 2020 Earnings Call

135. On May 7, 2020, during an earnings call, Defendant Hirawat made statements about how Bristol was committed to—and confident of—receiving approval of Liso-cel in advance of the CVR Milestone:

> Samit Hirawat, Executive Vice President, Chief Medical Officer, Global Drug Development:
>
> Thank you, Nadim, and thanks, Terence for the question. As it relates to liso-cel, as you know that we had submitted the application with comprehensive datasets at the end of last year and the FDA accepted the

> Application for liso-cel and granted a priority review in February of this year. It now is just typical for the FDA to request additional information as they continue their review process, and after the company supplied information in response to several requests that the FDA has made, **FDA has decided that the information they have received constitute a major amendment, and that's why the PDUFA date has been extended by 3 months to 16th of November now. And we are obviously committed to ensuring this medicine is available to patients as soon as possible, and we continue to meet our CVR milestones.** Obviously we're not going to comment on the specifics of our regulatory discussions, but let me just remind that we remain very confident about the data for liso-cel for these patients with large B-cell lymphoma as it is an unmet medical need, and **we are truly looking forward to get approval of this therapy towards the end of the year.** Thank you. . . .
>
> For liso-cel, what we have said is that we remain confident in the data, we remain confident in the data that we submitted to the FDA. **It is very normal for the FDA to, as they review the file, to ask questions. Certainly, we are looking towards the approval date now to end November . . . .**

136. This statement was false and misleading because it omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) the BLA submitted by Bristol for Liso-cel had been deliberately or recklessly deficient so as to require supplemental information in the form of an amendment that would cause a postponement of the target approval date, and (iii) Bristol intended to continue to delay the approval process.

8. May 19, 2020 UBS Virtual Global Healthcare Conference Presentation

137. On May 19, 2020, during a presentation at the UBS Virtual Global Healthcare Conference, Defendant Hirawat stated that "we look towards hopefully approval of liso-cel towards the end of this year and we continue to go forward."

138. This statement was false and misleading because it omitted that Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, as it had already submitted a deficient BLA in order to delay the approval date.

9. June 25, 2020 Investor Day Series Presentation

139. On June 25, 2020, during a presentation as part of Bristol-Myers' Investor Day Series, Defendant Hirawat made statements portraying the deficiencies in the CMC portion of the BLA for Liso-cel as unintentional and indicating that Bristol intended to achieve approval by the new target date of November 16, 2020:

> Liso-cel has a best-in-class CD19 targeting profile with the high affinity and differentiated safety. **We look forward to bring this call to patients soon because we have a PDUFA date of November 16 this year**. . . .
>
> Maybe I can start off and certainly then either Giovanni or Rupert, others can chime in. From the refusal to file perspective, certainly, every time we get a discussion with the agency or hear back from the agency, we learn the nuances. **So what we learned, as we said on the call, around the refusal to file, there were a lot many more questions around the data required in the filing from a CMC perspective.** So those are the learnings from there that we will be implementing in our future filings that we provide a more comprehensive view on the protocols utilized from a CMC perspective as well as on the data that we are providing in cell summaries to the -- to a larger format, so to say, in the module three. And then, of course, even during the review process, when we get information requests from the agency, we continue to improve on those as well in our subsequent filings so that we don't have repetition of the similar questions for every file. So a good question from you and certainly a learning for us as we continue to evolve. Let me start off and tee off the CVR question. And then certainly, either Giovanni or others can chime in on that. If you recall, the questions around ozanimod were related to certain data that were certainly -- that required a little bit more work to be done in terms of the pharmacology and/or clinical pharmacology, et cetera. So that was one aspect of it**. For liso-cel, there are specific questions that were asked that required for us to provide more data that were considered to be large enough that the agency needed to do the scientific review of it and extended the time line through a major amendment.** And the third case for ide-cel, basically, there was a lot more data that was required instead of the summary reports we had included in the file. So there are, I think, different issues. But overall, if you think about it, Celgene has had a huge and long history of filing and getting products approved, whether it be Reblozyl, Inrebic, Revlimid, pomalidomide and so on and so forth, or OTEZLA in the old days. So it is not that is an issue with the Celgene regulatory process. And by the way, some of these products have been filed when the companies became one as Celgene plus BMS or total BMS. So we all collectively contribute to the learning and contribute to this filing, and so I don't think it is an issue of a

> singular company having an issue with the regulatory part of it. Hopefully, that answers your question. Thank you.

140. Defendant Caforio then reiterated that they felt confident about achieving approval in time for the CVR Milestone, stating that "**we feel really good about where we are from a regulatory perspective. So that applies to products that may be included in the CVR** as well as the rest of the portfolio."

141. These statements were false and misleading because they omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) the BLA submitted by Bristol for Liso-cel had been deliberately or recklessly deficient so as to require supplemental information in the form of an amendment that would cause a postponement of the target approval date, and (iii) Bristol intended to continue to delay the approval process.

10. August 6, 2020 Form 10-Q

142. On August 6, 2020, Bristol filed a Form 10-Q with the SEC, signed by Defendants Caforio and Elkins, stating again that the FDA had extended the target approval date and citing COVID-19 as a possible cause of delay in the approval of Liso-cel:

> Announced that **the FDA has extended the action date by three months for the liso-cel BLA for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date is November 16, 2020**. . .
>
> **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).**
>
> We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). **These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020.** We do not yet have a PDUFA date for ide-cel, but we continue to expect an approval decision by March 31, 2021, which is the time period specified within the

> CVR Agreement. **It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed.** Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.

143. This statement was false and misleading because it omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) the BLA submitted by Bristol for Liso-cel had been deliberately or recklessly deficient so as to require supplemental information in the form of an amendment that would cause a postponement of the target approval date, and (iii) Bristol intended to continue to delay the approval process.

11. August 6, 2020 Earnings Call

144. On August 6, 2020, during an earnings call, Defendant Caforio stated that "in the very near term, **we are looking forward to the U.S. PDUFA dates for CC-486 in September and Liso-cel in November**. And of course beyond our new launches, we have a pipeline full of promise."

145. This statement was false and misleading because it omitted that Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel.

12. September 8, 2020 Citibank 15th Annual BioPharma Conference Presentation

146. On September 8, 2020, during a presentation at Citibank's 15th Annual BioPharma Conference, Defendant Hirawat made statements about Bristol's commitment to achieving approval of Liso-cel and about the necessary site inspection:

> Samit Hirawat, Chief Medical Officer and Head of Global Drug Development:
> [W]e do believe that differentiation and the profile of liso-cel compared with many of the competitive products is very, very clear. I think it is well understood also by the health authorities, and thus far our discussions with the FDA. We are very encouraged by the way they've looked at it. So that is all going in a good direction. As you very well mentioned in the 10-Q, **we have certainly disclosed that the site inspection for the cell therapy facilities has not been completed.** And certainly with the evolution of the COVID-19, as well as the challenges it has posed, both for us and for the FDA, it does pose a risk because the FDA staff, like many of us, are operating under those significant constraints on travel because of COVID. Now with that said, while we typically don't provide any details on regulatory discussions, what I can say today is the FDA has informed us that they will require inspection of both our facilities in Washington State as well as the manufacturing organization for the vector, which is located in Texas. **These inspections have not yet taken place.** We are working very closely with the FDA to keep this application on track. **And as you know, the PDUFA date is in November, we still have some time to go. But at the same time, we are aware that some of the people -- same people who are at the FDA who will be working or working right now on liso-cel, will also be pulled into the inspection related activities that might be coming along for the COVID-related vaccines.** Now FDA is very well aware of that. They are juggling multiple things. As this is a public health crisis and they need to manage, as well as the diseases that are life-threatening, they also need to manage that. So those are all running in parallel. **I don't think we can say anything more except that the importance of this application is very, very high for us. I think it is also as important from the FDA perspective. And we will continue to work closely with them, so that we can bring this product to the patients as soon as possible.**

147. These statements were false and misleading because they omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, and (ii) as part of that deliberate or reckless delay, Bristol was not preparing its facilities to pass the FDA's site inspections.

13. <u>September 17, 2020 Morgan Stanley 18th Annual Global Health Care Conference Presentation</u>

148. On September 17, 2020, during a presentation at Morgan Stanley's 18th Annual Global Healthcare Conference, Defendant Caforio responded to a question about the timing of the

Liso-cel facilities inspections by blaming the COVID-19 pandemic for jeopardizing timely approval by the FDA by delaying site inspections:

> David Risinger, Analyst:
>
> Got it. So, that just -- yeah since you mentioned about the uncertain COVID environment, I just hinted that quickly with a question before then returning to your TYK2. The FDA seems to be focusing most of its attention on COVID vaccines and therapeutics. Is there any indication from the FDA that it will be able to inspect the two liso-cel facilities in coming weeks?
>
> Giovanni Caforio, Chief Executive Officer and Chairman of the Board:
>
> Yeah, Dave, thank you for the question. So this is obviously a very important filing for us and as you know, we made a number of comments in our quarterly disclosures and at a meeting last week. **I would say the overall process with the FDA is going well. At the same time, as we mentioned last week, the FDA has informed us that they will want to inspect, they will need to inspect both of our work plans during the review process** and when we presented last week, those inspections had clearly not yet occurred. So obviously **there's the COVID and the complexity of travel during this time and I would say that is a main concern, somewhat increases the risk to the process.** I don't think there's much I can add at this point. I can tell you **we're working very actively with the FDA to keep the review and the inspection process moving because we want to get the product to patients as soon as possible** and we've updated the market last week and there's nothing I can add at this point.

149. These statements were false and misleading because they omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, and (ii) as part of that deliberate or reckless delay, Bristol was not preparing its facilities to pass the FDA's site inspections.

14. November 5, 2020 Form 10-Q

150. On November 5, 2020, another part of Bristol's fraud was revealed. Specifically, Bristol filed a Form 10-Q with the SEC, signed by Caforio and Elkins, which revealed that one of the necessary site inspections had not even been scheduled. This constituted a partial disclosure or materialization of risk of the fraud, as the delay was the direct result of deliberate or reckless

actions by Bristol to delay the FDA approval process that Defendants had concealed in their prior statements:

> Contingent Value Right Update
>
> We have filed BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction that have not been approved by the FDA. The applications are under review by the FDA. The third CVR asset, Zeposia, was approved earlier this year. Liso-cel has a PDUFA date of November 16, 2020 and ide-cel has a PDUFA date of March 27, 2021. Unless the FDA approves liso-cel for the treatment of relapsed-refractory diffuse large B cell lymphoma in humans by December 31, 2020 and ide-cel for the treatment of relapsed/refractory multiple myeloma in human by March 31, 2021, no payment will be made under the CVRs and the CVRs will expire valueless. **The FDA has informed us that inspections of two manufacturing facilities are required before they can issue a decision on the liso-cel application. One of those inspections has occurred; the other has not yet been scheduled. We do not believe that the scheduling of the second site inspection is dependent on the outcome of the first site's inspection, as they are independent facilities. See risk factor on the Company's risk factors resulting from the COVID-19 pandemic included under "Part II—Item 1A. Risk Factors—**

151. However, in the same Form 10-Q, Defendants falsely claimed that the delays were out of their control and the result of the COVID-19 pandemic, concealing Bristol's own continuing role in causing delay:

> **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on the CVRs that we issued in connection with the Celgene transaction."**
>
> * * *
>
> ***It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on the CVRs that we issued in connection with the Celgene transaction.***
>
> *We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020 and ide-cel has a PDUFA date of*

> *March 27, 2021.* ***It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed.*** *Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.*

152. These statements were false and misleading because they omitted that (i) Bristol was deliberately or recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, (ii) as part of that deliberate delay, Bristol had not prepared its facilities to pass the FDA's site inspections, and (iii) the delays in the approval process were not caused by the COVID-19 pandemic.

153. Despite Defendants' continued treatment of the COVID-19 pandemic as the sole cause of delay, by the close of the market on November 5, 2020, the value of the CVRs had dropped by 64% since closing the previous day—from $3.40 to $1.22 per share, with a volume of more than 72 million shares.

15. November 16, 2020 Press Release

154. On November 16, 2020, Bristol issued a press release announcing that the FDA had delayed its inspection of the Lonza Facility. This constituted another partial corrective disclosure or materialization of risk, as the fact of this delay occurring so near the Milestone resulted from Defendants own efforts to delay the approval process, which they had concealed in their prior statements.

> The FDA was unable to conduct an inspection of a third-party manufacturing facility in Texas during the current review cycle due to travel restrictions related to the COVID-19 pandemic. Therefore, the FDA is deferring action on the application until the inspection can be completed. The application remains under review. The FDA did not provide a new anticipated action date.

155. However, this press release, with a quote from Defendant Hirawat, continued to falsely present Bristol as committed to achieving approval in time for the Milestones:

> **"Bristol Myers Squibb continues to work closely with the FDA to support the ongoing review of the BLA for liso-cel** said Samit Hirawat, M.D., executive vice president, chief medical officer, global drug development, Bristol Myers Squibb. "We are committed to bringing liso-cel to patients with relapsed or refractory large B-cell lymphoma who still have significant unmet need."
>
> * * *
>
> U.S. FDA approval of liso-cel by December 31, 2020 is one of the required remaining milestones of the Contingent Value Rights issued upon the close of the Celgene acquisition in the fourth quarter of 2019. The other is U.S. FDA approval of Idecabtagene Vicleucel (ide-cel) by March 31, 2021. **The company is committed to working with the FDA to progress both applications to achieve the remaining regulatory milestones required by the CVR.**

156. These statements were false and misleading because they omitted that (i) Bristol was deliberately and recklessly delaying the approval process so as not to reach the Milestone for Liso-cel, and (ii) as part of that deliberate or reckless delay, Bristol had not prepared its facilities to pass the FDA's site inspections.

157. Despite Defendants' false reassurances, by the close of the market on November 16, 2020, the value of the CVRs had dropped by 42% since closing the previous day—from $1.40 to $0.80 per share, with a volume of more than 38 million shares.

VI. ADDITIONAL SCIENTER ALLEGATIONS

158. The allegations in this section concern only the claims brought under Sections 10(b) and 20(a) of the Exchange Act—not the claims brought under Section 14(a) of the Exchange Act, which are brought under a negligence standard, or the claims brought under Sections 11 and 12(a)(2) of the Securities Act, which are brought under a strict liability standard.

159. As alleged herein, Defendants acted with scienter when making the challenged

false and misleading statements during the Class Period. Each Defendant knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of Bristol Myers were materially false and misleading and omitted material information; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Bristol, their control over, and/or receipt and/or modification of Bristol's allegedly materially misleading misstatements and/or their associations with Bristol which made them privy to confidential proprietary information concerning Bristol, participated in the fraudulent scheme alleged herein.

160. As alleged herein, Bristol's blatantly deficient submissions to FDA and its utter failure to prepare its sites for preparation—which together caused the unprecedentedly slow approval of Liso-cel—show that Defendants deliberately delayed the approval process.

161. Defendants were also highly motivated to materially misrepresent their intention and actions relating to FDA approval of Liso-cel, because Bristol could avoid a payment of $6.4 billion to CVR holders if Bristol was seen as having made a diligent effort to obtain approval for Liso-cel by December 31, 2020.

VII. LOSS CAUSATION – EXCHANGE ACT CLAIMS

162. As described herein, Defendants made materially false and misleading statements and omissions of material facts in the Joint Proxy. These statements caused Plaintiff 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, Plaintiff and other Class members suffered an economic loss (*i.e.*, damages under the federal

securities laws).

163. During the Class Period, Defendants continued to make false and misleading statements that inflated the price of the CVRs and operated as a deceit on acquirers of those CVRs. As detailed above, throughout the Class Period, Defendants represented that Bristol was diligently working toward FDA approval of Liso-cel before the CVR Milestone of December 31, 2020, despite Defendants' knowing that Bristol was intentionally delaying the approval process so that approval would come after the Milestone.

164. As various delays in the approval process were announced during the Class Period, the artificial inflation slowly dissipated.

165. On May 6, 2020, the price of CVRs declined by 15% from the prior day, from $4.43 to $3.75 per share, in response to the press release in which Bristol announced that the FDA's target approval date for_Liso-cel had been pushed back from August 17 to November 16, 2020.

166. On November 5, 2020, the price of CVRs declined by 64% from the prior day, from $3.40 to $1.22 per share, in response to statements by Bristol in its Form 10-Q revealing that only one of its Liso-cel facilities has been inspected and that the other facility's inspection had yet to be scheduled.

167. On November 16, 2020, the price declined further, from $1.40 to $0.80 per share, in response to the passing of the FDA's target date and Bristol's announcement that the inspection of the Lonza Facility had been further delayed.

168. When the December 31, 2020 CVR Milestone for Liso-cel passed without Bristol having obtained FDA approval for Liso-Cel, the remaining artificial inflation dissipated and the CVRs lost all remaining value.

169. When the December 31, 2020 CVR Milestone for Liso-cel passed without Bristol having obtained FDA approval for Liso-Cel, the remaining artificial inflation dissipated and the CVRs lost all remaining value.

170. The declines in the value of the CVRs in response to delays in the approval process—and in response the passing of the CVR Milestone for Liso-cel approval on December 31, 2020—were the direct result of Defendants' fraudulent misrepresentations and omissions, which had concealed Bristol's deliberate or reckless efforts to delay the process and had led investors to believe that Bristol was making a diligent effort to achieve approval by the time of the Milestone. Thus, the economic loss, *i.e.*, damages, suffered by Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to deceive investors while deliberately ensuring that Bristol would not have to pay out the $6.4 billion for the CVRs.

VIII. PRESUMPTION OF RELIANCE

171. Class members who purchased the CVRs during the Class Period did so in reliance on Defendants' false and misleading statements.

172. At all relevant times, the market for the CVRs was an efficient market for the following reasons, among others:

a) The CVRs met the requirements for listing and were listed and actively traded on the New York Stock Exchange, a highly efficient and automated market.

b) Bristol communicated with public investors via established market communication mechanisms, including dissemination of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the

financial press and other similar reporting services;

c) Bristol was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

d) Unexpected material news about Bristol was reflected in and incorporated into the price of CVRs during the Class Period.

173. As a result of the foregoing, the market for the CVRs promptly digested current information from all publicly available sources and reflected such information in the CVRs' price. Under these circumstances, all purchasers of the CVRs during the Class Period suffered similar injury through their purchase of the CVRs at artificially inflated prices, and a presumption of reliance applies.

174. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

IX. CLASS ACTION ALLEGATIONS

175. Plaintiff brings this action on behalf of (i) all 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, and (ii) all persons who purchased the

CVRs during the Class Period and were damaged thereby.

176. 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.

177. 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 the federal securities laws were violated by Defendants' conduct as alleged herein;

(b) Whether the Registration Statement, Joint Proxy, and other public statements disseminated to the investing public during the Class Period contained material misstatements or omitted to state material information;

(c) Whether and to what extent the market prices of CVRs were artificially inflated and/or distorted during the Class Period due to the non-disclosures and/or misstatements complained herein;

(d) Whether, solely with respect to the claims under Section 10(b) of the Exchange Act, Defendants acted with scienter;

(e) Whether, solely with respect to the claims under Section 10(b) of the Exchange Act, reliance may be presumed;

(f) Whether Bristol and the Section 12(a)(2) Individual Defendants are sellers under Section 12(a)(2) of the Securities Act;

(g) Whether Defendants are liable to Plaintiff under Section 11 and/or Section 12(a)(2) of the Securities Act;

(h) Whether Plaintiff is entitled to rescission; and

(i) Whether the members of the Class have sustained damages as a result of the conduct complained of herein, and if so, the proper measure of damages.

178. Plaintiff's claims are typical of those of the Class because Plaintiff and the other members of the Class sustained damages from Defendants' wrongful conduct.

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

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

X. INAPPLICABILITY OF STATUTORY SAFE HARBOR

181. 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.

XI. STATUTE OF LIMITATIONS

182. Plaintiff could not have learned about Bristol's false statements in the Registration Statement and Joint Proxy and during the Class Period 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. Plaintiff's

claims are, therefore, brought within the applicable statute of limitations.

COUNT I

On Behalf of Plaintiff and the Class Against Defendants Bristol-Myers, Caforio, Sato, Arduini, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, and Vousden ("Section 14(a) Defendants") for Violations of Section 14(a) of the Exchange Act and Rule 14a-9 Promulgated Thereunder

183. Plaintiff incorporates each and every allegation set forth above as if fully set forth herein, except that for purposes of this claim, Plaintiff expressly excludes and disclaims any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on negligence.

184. The Section 14(a) 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.

185. The Section 14(a) Defendants were at least negligent in issuing a false and misleading Joint Proxy. Plaintiff, while reserving all rights, expressly disclaims and disavows at this time any allegation in this Complaint that could be construed as alleging fraud against the Section 14(a) Defendants in connection with this Count. This claim sounds in negligence based on the failure of the Section 14(a) Defendants to exercise reasonable care to ensure the Joint Proxy did not contain the material misstatements and omissions alleged herein.

186. The Proxy was prepared, reviewed and/or disseminated by the Section 14(a) Defendants. By virtue of their positions within Bristol Myers, the Section 14(a) Defendants were aware of this information and their duty to disclose this information in the Joint Proxy.

187. 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.

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

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

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

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

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

COUNT II

On Behalf of Plaintiff and the Class Against Defendants Bristol-Myers, Caforio, Elkins, and Hirawat ("Section 10(b) Defendants") for Violations of Section 10(b) of the Exchange Act

193. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

194. During the Class Period, the Section 10(b) Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

195. The Section 10(b) Defendants:

a) employed devices, schemes, and artifices to defraud;

b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and

c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the CVRs during the Class Period.

196. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the CVRs. Plaintiff and the Class would not have purchased the CVRs at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by the Section 10(b) Defendants' misleading statements or omissions.

197. As a direct and proximate result of the Section 10(b) Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases and acquisitions of the CVRs during the Class Period.

COUNT III

On Behalf of Plaintiff and the Class Against Defendants Caforio, Sato, Arduini, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, Vousden, Elkins, and Hirawat for Violations of Section 20(a) of the Exchange Act

198. Plaintiff incorporates each and every allegation set forth above as if fully set forth herein.

199. The Section 14(a) Individual Defendants disseminated a false and misleading Joint Proxy in violation of Section 14(a) of the Exchange Act and Rule 14a-9, promulgated thereunder. The Section 10(b) Individual Defendants also made false and misleading statements or omitted material information throughout the Class Period in violation of Sections 10(b) of the Exchange

Act and Rules 10b-5, promulgated thereunder.

200. The Section 14(a) Individual Defendants and the Section 10(b) 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 made during the Class Period and contained in the Joint Proxy filed with the SEC, the Section 14(a) Individual Defendants and the Section 10(b) 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 during the Class Period and in the Joint Proxy that Plaintiff contends are false and misleading.

201. The Section 14(a) Individual Defendants were provided with or had unlimited access to copies of the Joint Proxy, and the Section 10(b) Individual Defendants were provided with or had unlimited access to other statements alleged by Plaintiff 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.

202. In particular, these 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. In regard to the Joint Proxy, the misrepresented information identified above was reviewed by the Section 14(a) Individual Defendants prior to the shareholder vote on the Merger. The Joint Proxy at issue contains the unanimous recommendation of the Section 14(a) Individual Defendants to approve the Merger and the Joint Proxy was issued on behalf of each of them. They were thus directly involved in the making of the Joint Proxy.

203. By virtue of the foregoing, the Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants have violated Section 20(a) of the Exchange Act.

204. As set forth above, the Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants had the ability to exercise control over and did control a person or persons who have each violated Sections 10(b) and 14(a) of the Exchange Act and Rule 10b-5 and 14a-9, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of those Defendants' conduct, Plaintiff and the Class were irreparably harmed.

COUNT IV

On Behalf of Plaintiff and the Class Against Defendants Bristol-Myers, Caforio, Sato, Arduini, Bancroft, Santiago, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, and Vousden ("Section 11 Defendants") Violations Of Section 11 Of The Securities Act

205. Plaintiff incorporates each and every allegation set forth above as if fully set forth herein, except that for purposes of this claim, Plaintiff expressly excludes and disclaims any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on strict liability.

206. This count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of Plaintiff and the other members of the Class, against the Section 11 Defendants for issuing the Registration Statement that omitted or contained false and misleading information as described herein. Section 11 makes the issuer of securities pursuant to a registration statement absolutely liable for damages as defined therein where such registration statement contained an untrue statement of material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein no misleading. This count is not alleging fraud or

intentional conduct or recklessness.

207. Plaintiff and the other members of the class acquired the CVRs issued pursuant to the Registration Statement.

208. Bristol is the registrant for the CVRs offered in the Registration Statement. As issuer of the securities, Bristol is strictly liable to Plaintiff and the Class for the misstatements and omissions contained in the Registration Statement.

209. At the time of each offering, the Registration Statement for the offering contained untrue statements of material fact, omitted to state facts necessary to make the statements made therein not misleading, and failed to disclose required material information.

210. Bristol is strictly liable pursuant to Section 11 of the Securities Act for any material misstatements of fact or failure to disclose facts necessary to make the statements made in the Registration Statement not materially misleading.

211. In connection with the offering, Bristol used the means and instrumentalities of interstate commerce and the United States mails.

212. By reasons of the conduct herein alleged, Bristol and the Section 11 Defendants violated Section 11 of the Securities Act.

213. By virtue of these violations, Plaintiff and the other members of the Class have sustained damages.

214. Less than one year has elapsed from January 1, 2021 (the time that Plaintiff could have discovered the facts for each element of the claims upon which this complaint is based) to the time that plaintiff filed the complaint. Less than three years elapsed between the time that the securities upon which this count is brought were offered and the time plaintiff filed her complaint.

COUNT V

On Behalf of Plaintiff and the Class Against Defendants Bristol-Myers, Caforio, Sato, Arduini, Bancroft, Santiago, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, and Vousden ("Section 12(a)(2) Defendants") for Violations of Section 12(a)(2) of the Securities Act

215. Plaintiff incorporates each and every allegation set forth above as if fully set forth herein, except that for purposes of this claim, Plaintiff expressly excludes and disclaims any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on strict liability.

216. This count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2), on behalf of the Class. This count is not alleging fraud or intentional conduct or recklessness.

217. Bristol is a "seller" for purposes 12(a)(2) of the Securities Act pursuant to 17 C.F.R. §230.159a.

218. Bristol and the Section 12(a)(2) Defendants had direct and active participation in the solicitation of Plaintiff's and Class members' purchase and communicated directly with Plaintiff and the Class through the offering materials for its own financial interest pursuant to the Registration Statement. Bristol, the issuer, is also a "statutory seller" under Section 12(a)(2).

219. Plaintiff and the other members of the Class acquired CVR shares solicited and sold pursuant to the Registration Statement.

220. As alleged above, the Registration Statement contained untrue statements of material fact, omitted to state other facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein.

221. The Section 12(a)(2) Defendants owed to acquirers of their securities, including Plaintiff and the other Class members, the duty to make a reasonable and diligent investigation of the statements contained in the Registration Statement to ensure that such statements were accurate

and that they did not contain any misstatement or omission of material fact. Bristol, in the exercise of reasonable care, should have known that the Registration Statement and related documents contained misstatements and omissions of material fact. The Section 12(a)(2) Individual Defendants did not make a reasonable investigation or possess reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts necessary to make such statements not misleading.

222. Plaintiff and the other members of the class acquired CVRs solicited by and pursuant to the Registration Statement and neither Plaintiff nor the other Class members knew, or in the exercise of reasonable diligence could have known, of the untruths, inaccuracies and omissions contained in those offering document.

223. By reasons of the conduct herein alleged, the Section 12(a)(2) Defendants violated Section 12(a)(2) of the Securities Act.

224. By virtue of these violations, Plaintiff and the other members of the Class have sustained damages. Accordingly, Plaintiff and the other members of the Class who acquired CVRs pursuant to the Registration Statement have a right to rescind and receive their consideration paid, and hereby elect to rescind and tender their CVRs to Bristol. Members of the Class who have sold or had forfeited their CVRs are entitled to compensatory damages.

225. Less than one year has elapsed from the time that Plaintiff discovered the facts upon which this complaint is based to the time that Plaintiff filed the complaint. Less than three years elapsed between the time that the securities upon which this count is brought were offered to the public and the time plaintiff filed this complaint.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays 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 10(b), 14(a) and/or 20(a) of the Exchange Act, as well as Rules 10b-5 and 14a-9 promulgated thereunder, and Sections 11 and 12(a)(2) of the Securities Act and;

D. Awarding Plaintiff's 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: December 3, 2021

Respectfully Submitted,

By: /s/ *Michael B. Eisenkraft*

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CERTIFICATION

I, Ehab Khalil hereby certifies as follows:

1. I have reviewed the Class Action Complaint in this matter and authorize the filing of this Certification and Lead Plaintiff Motion.

2. I am willing to serve as a representative party on behalf of the Class (as defined in the Complaint), including providing testimony at deposition and trial, if necessary.

3. During the Class Period (as defined in the Complaint), I purchased and/or sold the securities that are the subject of the Complaint as set forth on the attached Schedule A.

4. I did not engage in the foregoing transactions at the direction of counsel or in order to participate in any private action arising under the Securities Act of 1933 (the "Securities Act") or the Securities Exchange Act of 1934 (the "Exchange Act").

5. I have not sought to serve, or served, as a representative party on behalf of a class in any private action arising under the Securities Act or the Exchange Act filed during the three-year period preceding the date of my signing this Certification.

6. I will not accept any payment for serving as a class representative on behalf of the class beyond its *pro rata* share of any recovery, except such reasonable costs and expenses (including lost wages) relating to the representation of the class or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief. Executed this 3 day of December, 2021.

DocuSigned by:
Ehab Khalil
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Ehab Khalil

SCHEDULE A

Trade Date	Transaction Type	Shares	Share Price ($)
11/21/2019	Purchase (Merger)	4,206	2.2500
11/21/2019	Purchase (Merger)	70	2.2500
4/9/2020	Purchase	8,000	4.1200
12/31/2020	Sale	(300)	0.6790
12/31/2020	Sale	(1,184)	0.6710
12/31/2020	Sale	(1,400)	0.6780
12/31/2020	Sale	(4,252)	0.6847
12/31/2020	Sale	(5,140)	0.6800