UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., solely in its capacity as Trustee under the Contingent Value Rights Agreement by and between Bristol-Myers Squibb Company and Equiniti Trust Company, dated as of November 20, 2019, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, Defendant.	:	Case No. 1:21-cv-04897 (JMF)

ANSWER

Defendant Bristol-Myers Squibb Company ("BMS"), by its undersigned attorneys, hereby answers the complaint dated June 3, 2021 [ECF No. 1], filed in this action by plaintiff UMB Bank, N.A. (reserving all defenses, the "Trustee"). Except as otherwise expressly admitted herein, BMS denies each and every allegation in the complaint, including, without limitation, any allegations contained in the Trustee's prayer for relief, and the headings and subheadings of the complaint. This answer is based on BMS's investigation and understanding to date, and BMS expressly reserves the right to amend this answer to the fullest extent provided under applicable law. Without waiver of any rights or defenses, BMS answers the allegations in the complaint as follows:

NATURE OF ACTION

1. Bristol-Myers delayed the development and production of lisocabtagene maraleucel ("Liso-cel"), a life-saving cancer therapy that treats the most common form of Non-Hodgkin's lymphoma, with the hope of

eliminating its $6.4 billion liability under the CVR Agreement. In so doing, Bristol-Myers breached the CVR Agreement, which requires Bristol-Myers to use "Diligent Efforts" to secure approval from the Federal Drug Administration ("FDA") for Liso-cel by December 31, 2020. This suit seeks to hold Bristol-Myers accountable under the CVR Agreement for its blatant misconduct.

1. BMS denies the allegations contained in paragraph 1 of the complaint, except admits that the Contingent Value Rights Agreement dated November 20, 2019 (the "CVR Agreement") sets forth the terms and conditions governing any contingent payment to Holders (as defined in the CVR Agreement) of contingent value rights that were issued pursuant to that agreement (the "CVRs") and refers to the CVR Agreement for its provisions; and (ii) admits that lisocabtagene maraleucel, previously referred to as JCAR-017 and now referred to as Breyanzi® ("liso-cel"), is a prescription medicine used to treat large B-cell lymphoma, a type of non-Hodgkin lymphoma.

2. Bristol-Myers's $6.4 billion obligation under the CVR Agreement arises from its November 2019 acquisition of Celgene Corporation ("Celgene"), the pharmaceutical company that developed Liso-cel, also known as JCAR017 and by its trade name Breyanzi. Liso-cel is prescribed for patients suffering from notoriously aggressive large cell Non-Hodgkin's lymphoma who are not treated effectively by initial treatments or have relapses. Liso-cel is perceived to have lesser toxicity than other available treatments for patients with persistent lymphoma and to be particularly suitable for those who are older or frail. Time is of the essence for such patients.

2. BMS denies the allegations contained in paragraph 2 of the complaint, except: (i) admits that BMS entered into the CVR Agreement in November 2019 in connection with the closing of its merger with Celgene Corporation ("Celgene"); and (ii) admits that liso-cel is a groundbreaking treatment for patients with certain types of cancer, including large B-cell lymphoma, for whom prior treatments have not been successful.

3. The merger and CVR Agreement were announced in January 2019, following approximately six months of negotiations between Bristol-Myers and Celgene, in which the primary impediment was disagreement over

Celgene's valuation. Bristol-Myers proposed the CVR Agreement as a way to bridge the valuation gap: for each share of Celgene stock, the holder would receive a contingent value right ("CVR") requiring Bristol-Myers to pay $9 (the "Milestone Payment")—amounting to $6.4 billion in total—if the FDA approved the marketing applications, known as Biologics License Applications ("BLAs") or New Drug Applications, for three Celgene therapies—Liso-cel, the multiple sclerosis therapy Ozanimod, and the multiple myeloma therapy Ide-cel—by certain contractually set dates. Specifically, if the FDA approved (i) Liso-cel by December 31, 2020; (ii) Ozanimod by the same date; and (iii) Ide-cel by March 31, 2021 (collectively, the "Milestones"), then Bristol-Myers was obligated to pay $6.4 billion to CVR holders. If Bristol-Myers failed to achieve any Milestone, even by a day, it would pay $0.

3. BMS denies the allegations contained in paragraph 3 of the complaint, except: (i) admits that an agreement to complete a merger transaction between BMS and Celgene was announced in January 2019; and (ii) refers for its terms to the Agreement and Plan of Merger dated as of January 2, 2019, by and among BMS, Burgundy Merger Sub, Inc., and Celgene (the "Merger Agreement"), and to the CVR Agreement. The Merger Agreement was filed as an exhibit to a BMS Form 8-K filed on January 2, 2019 with the U.S. Securities and Exchange Commission ("SEC"). A version of the CVR Agreement is attached as Exhibit A to the complaint. A corrected version of the CVR Agreement was attached as Exhibit 4ccc to BMS's annual report on Form 10-K, filed with the SEC on February 24, 2020.

4. The CVR Agreement's binary structure, in the absence of provisions to protect the CVR holders' right to payment, creates a perverse economic incentive: if Bristol-Myers delayed at least one of the three therapies to miss a Milestone, it could rely on the resulting delay to argue it had eliminated its entire $6.4 billion liability. If Bristol-Myers's gambit were successful, it would obtain Celgene at a windfall market discount.

4. BMS denies the allegations contained in paragraph 4 of the complaint.

5. To protect the CVR holders, and to ensure that Bristol-Myers worked towards securing FDA approval for these life-saving therapies before the Milestones, the CVR Agreement required Bristol-Myers to "use Diligent Efforts to achieve the Milestone[s]." Ex. A § 7.8. This requirement meant that Bristol-Myers had to use the "efforts of a Person to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such Person 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." *Id.* § 1.1.

5. BMS denies the allegations contained in paragraph 5 of the complaint, except refers to the CVR Agreement for its terms.

6. When Celgene controlled Liso-cel and Ide-cel, they were on the fast track for approval. The FDA had designated both as Breakthrough Therapies and had designated Liso-cel as a Regenerative Medicine Advanced Therapy. These designations ensured an expedited development and review process. The FDA committed to provide intensive, interactive guidance during both therapies' development—with senior FDA personnel involved in a proactive, collaborative review of the therapies—so that both therapies could enter the market quickly and safely to begin saving lives. The FDA again recognized Liso-cel's critical importance to patients by granting it Priority Review status on February 13, 2020. Priority Review status shortens the Prescription Drug User Fee Act ("PDUFA") date, the FDA's target date for issuing a decision on a BLA, from ten months to six months. For BLAs with Priority Review, the FDA meets the PDUFA date nearly 100% of the time. The PDUFA date for Liso-cel was August 17, 2020, comfortably four months before the Liso-cel Milestone.

6. BMS denies the allegations contained in paragraph 6 of the complaint, except: (i) admits that the U.S. Food and Drug Administration ("FDA") designated each liso-cel and ide-cel as a "Breakthrough Therapy" and designated liso-cel as a Regenerative Medicine Advanced Therapy; and (ii) admits that in February 2020, several months after the closing of the Celgene merger, the FDA granted Priority Review for the biologics license application for approval of liso-cel, which set a targeted FDA action date of August 17, 2020 for the application under the Prescription Drug User Fee Act, as amended ("PDUFA").

7. The momentum toward approval that Celgene built was lost after Bristol-Myers assumed control. Bristol-Myers failed to use Diligent Efforts to achieve those Milestones, and the FDA approval process for Liso-cel and Ide-cel began to suffer setbacks. Bristol-Myers made a highly atypical decision to exclude critical and mandatory information in its initial filing of the Liso-cel BLA. It excluded data on critical tests needed to demonstrate the safety and efficacy of Liso-cel. Bristol-Myers also withheld details concerning the procedures it used to ensure the tests were valid. Bristol-Myers belatedly submitted this information through a "major amendment" to its BLA filed on

April 15, 2020—two months after the FDA had accepted Bristol-Myers's BLA for review and set the August 17, 2020 PDUFA date. This "major amendment" automatically extended the PDUFA date by three months to November 17, 2020. That placed the FDA's target approval date perilously close to the December 31, 2020 Liso-cel Milestone.

7. BMS denies the allegations contained in paragraph 7 of the complaint, except admits that a letter from the FDA to BMS in May 2015 deemed the submission of additional information to be a "major amendment" to the liso-cel application, which under applicable law resulted in an automatic three-month postponement of the PDUFA targeted action date until November 17, 2020, still more than six weeks before the applicable milestone date under the CVR Agreement.

8. At almost the same time, Bristol-Myers was also improperly delaying the approval process for Ide-cel. On May 13, 2020, following an initial review of the Ide-cel BLA, the FDA determined that the Ide-cel BLA was so materially deficient that the FDA took the exceedingly rare step of rejecting the Ide-cel BLA entirely.

8. BMS denies the allegations contained in paragraph 8 of the complaint, except refers for its contents to the FDA letter dated May 13, 2020 that is referred to in that paragraph.

9. Bristol-Myers's violation of its contractual obligation to use Diligent Efforts did not stop there. Given the delay the major amendment caused for the approval of the Liso-cel BLA, if it were to meet the contractually agreed Milestones set forth in the CVR Agreement, it was critical that Bristol-Myers ensure that the rest of the FDA approval process proceeded smoothly. Instead, Bristol-Myers failed to take the steps necessary to prepare two Liso-cel manufacturing facilities for the FDA's inspections.

9. BMS denies the allegations contained in paragraph 9 of the complaint.

10. From October 7, 2020 to October 16, 2020, the FDA inspected a Bristol-Myers facility in Bothell, Washington (the "Juno Facility") where Bristol-Myers produces Liso-cel. Even though Bristol-Myers had advance notice of the inspection, it inadequately prepared the Juno Facility, and the FDA inspectors found numerous, substantial deviations from known or readily determinable FDA regulations and guidelines. For example, the FDA found that Bristol-Myers had failed to: (i) implement appropriate procedures to ensure batches of Liso-cel conformed to appropriate quality standards; (ii) explain and document discrepancies between batches of Liso-cel; and (iii)

monitor the manufacturing environment to prevent the contamination of sterile drug products. Weeks later, Bristol-Myers responded to the FDA's findings, admitting that it would need to take remedial actions to improve its operations and quality control systems to comply with FDA regulations and guidelines. But the FDA found that even this response by Bristol-Myers contained "unclear and questionable points," resulting in more than a month of further delay. Ultimately, Bristol-Myers failed to provide an adequate response to the FDA's findings until December 18, 2020, just days before the Liso-cel Milestone.

10. BMS denies the allegations contained in paragraph 10 of the complaint, except: (i) admits that FDA representatives inspected the Juno Facility between October 7, 2020 and October 16, 2020; and (ii) refers for its contents to the Form 483 prepared by staff of the FDA with respect to the October 2020 inspection of the Juno Therapeutics facility in Bothell, Washington, a redacted version of which is attached as Exhibit B to the complaint.

11. From December 3, 2020 to December 10, 2020, the FDA performed an inspection of a facility in Houston, Texas owned by Lonza Group AG (the "Lonza Facility"), where a critical component of Liso-cel is manufactured. Bristol-Myers, as the manufacturer of Liso-cel, is responsible for ensuring that the Lonza Facility's practices complied with FDA requirements. Despite Bristol-Myers's prior experience and failings, including having the benefit of the findings from the Juno Facility inspection in October 2020, it still failed to ensure that the Lonza Facility complied with FDA requirements. The FDA's inspection of the Lonza Facility revealed numerous, egregious deviations from FDA regulations and guidelines—many of which mirrored the unacceptable conditions and procedures the FDA noted in the Juno Facility. For example, the FDA had found insufficient controls to check for microbiological contamination of sterile materials at the Juno Facility; the FDA observed similar inadequate controls to prevent microbial contamination at the Lonza Facility. And although Bristol-Myers knew from the inspection of the Juno Facility that its procedures for inspecting raw materials were deficient, the FDA cited the Lonza Facility for failing to inspect raw materials at all.

11. BMS denies the allegations contained in paragraph 11 of the complaint, except: (i) admits that FDA representatives inspected a Lonza Group AG manufacturing facility in Houston, Texas between December 3, 2020 and December 10, 2020; and (ii) refers for its contents

to the Form 483 prepared by staff of the FDA with respect to the December 2020 inspection of the Lonza facility, a redacted version of which is attached as Exhibit C to the complaint.

12. The FDA identified numerous other egregious violations at the Lonza Facility that occurred under Bristol-Myers's control. The FDA found (i) poorly maintained and carelessly organized freezer bins full of overturned and frosted-over bottles, (ii) unlocked freezer bins containing material that was supposed to be quarantined, and (iii) material that had expired more than seven months earlier that was never discarded. The FDA also reported that Bristol-Myers failed to institute procedures to prevent serious quality control errors. For instance, materials that passed quality control were labeled with the very same color and text as material that had been rejected, creating a high likelihood of confusion between the two. Similarly, material that had been rejected by quality control was stored in the same freezer as material that had passed quality control, and material intended for use within the United States were stored in the very same freezer as material intended for foreign markets with different manufacturing standards.

12. BMS denies the allegations contained in paragraph 12 of the complaint, except refers for its contents to the Form 483 prepared by staff of the FDA with respect to the December 2020 inspection of a Lonza facility located in Houston, Texas, a redacted version of which is attached as Exhibit C to the complaint.

13. As news of these mishandled inspections and further delays reached the public, certain CVR holders became concerned that Bristol-Myers was failing to exercise the diligence required under the CVR Agreement. They directed the Trustee, acting on their behalf under the CVR Agreement, to investigate Bristol-Myers's performance and, if appropriate, take action to enforce their rights under the CVR Agreement.

13. BMS denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 13 of the complaint.

14. The Trustee sought to exercise its contractual right to inspect Bristol-Myers's books and records on behalf of the CVR holders to assess whether Bristol-Myers was satisfying its obligation under the CVR Agreement to pursue the Milestones for Liso-cel and Ide-cel diligently, or whether there was evidence that Bristol-Myers had failed to do so purposefully or ineptly.

14. BMS denies the allegations contained in paragraph 14 of the complaint.

15. On December 29, 2020, shortly after UMB was appointed as the new Trustee under the CVR Agreement, UMB demanded to review Bristol-Myers's relevant books and records. Bristol-Myers refused to comply with the Trustee's proper demand under the CVR Agreement, which, upon information and belief, was a transparent attempt to conceal its inadequate or improper conduct under the terms of the CVR Agreement. Bristol-Myers's failure to permit the Trustee to inspect its relevant books and records was yet another violation of the CVR Agreement.

15. BMS denies the allegations contained in paragraph 15 of the complaint, except admits that a law firm purporting to act for UMB Bank, N.A. ("UMB Bank") sent a letter to BMS late in the day on December 29, 2020 that included a request to examine books and records.

16. On December 31, 2020, the Liso-cel Milestone lapsed with Bristol-Myers having failed to secure FDA approval. On January 1, 2021, Bristol-Myers issued a press release announcing the failure of the Liso-cel Milestone and stating that the CVR Agreement was terminated and the CVRs would be delisted.

16. BMS denies the allegations contained in paragraph 16 of the complaint, except (i) admits that the FDA did not approve the liso-cel application by December 31, 2020, which resulted in the termination of the CVR Agreement in accordance with its terms; and (ii) admits that BMS issued a press release concerning the CVR Agreement and the CVRs on January 1, 2021 and refers to that press release for its contents.

17. Approval came just thirty-six days later, on February 5, 2021. Had Bristol-Myers used Diligent Efforts, it would have avoided much more than thirty-six days of delay caused by, among other things, submitting the major amendment to supplement its inadequate BLA, failing to properly operate and prepare the Juno and Lonza Facilities to meet FDA approval requirements, and providing an inadequate response to the FDA's findings at the Juno Facility.

17. BMS denies the allegations contained in paragraph 17 of the complaint, except admits that on February 5, 2021 the FDA approved the biologics license application for liso-cel.

18. Other cellular therapies based on similar technology have received FDA approval without the issues and ineptitude that plagued Bristol-Myers, and in substantially less time. For example, the Gilead Sciences ("Gilead") therapy Yescarta and the Novartis International AG ("Novartis")

therapy Kymriah—both cellular therapies that, like Liso-cel, treat lymphoma—were approved in less than half the time. Another similar lymphoma therapy, Gilead's Tecartus, was submitted for FDA review just one week before Liso-cel but was approved more than six months sooner. Had Bristol-Myers used Diligent Efforts as required under the CVR Agreement, it would have avoided the thirty-six-day delay, and the Liso-cel Milestone would have been achieved.

18. BMS denies the allegations contained in paragraph 18 of the complaint, except denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 18 concerning other entities' applications for FDA approval of different product candidates.

19. With the Liso-cel Milestone missed and the CVRs delisted, Bristol-Myers no longer needed Ide-cel to miss its Milestone for it to assert that it had no obligation to pay $6.4 billion to the CVR holders. Bristol-Myers's lack of Diligent Efforts had taken the Ide-cel approval process right up to the deadline, with the FDA approving the Ide-cel BLA on March 26, 2021, just five days before the Ide-cel Milestone under the CVR Agreement.

19. BMS denies the allegations contained in paragraph 19 of the complaint, except admits that the FDA approved the biologics license application for ide-cel on March 26, 2021.

20. Thus, Bristol-Myers achieved two of the three Milestones, with only the Liso-cel Milestone left unfulfilled. Had Bristol-Myers made Diligent Efforts to achieve the Liso-cel Milestone, it would have been required to pay $6.4 billion to the CVR holders. Bristol-Myers's failure to exercise Diligent Efforts has, to date, allowed it to take control of three FDA-approved blockbuster therapies—Liso-cel, Ozanimod, and Ide-cel—at an enormous discount and at the CVR holders' expense. Bristol-Myers almost immediately put this windfall to use, announcing on February 4, 2021 the repurchase of $4 billion in debt.

20. BMS denies the allegations contained in paragraph 20 of the complaint, except refers for its contents to the BMS press release issued on February 4, 2021.

21. The Trustee brings this suit to hold Bristol-Myers accountable for its unlawful attempt to evade its obligation to pay CVR holders the $6.4 billion by delaying the delivery of a lifesaving treatment to patients facing terminal cancer.

21. BMS denies the allegations contained in paragraph 21 of the complaint.

THE PARTIES

22. Plaintiff UMB Bank, N.A., is a federally chartered national banking association with its main office, as listed in its articles of association, in Kansas City, Missouri. On December 18, 2020, UMB succeeded Equiniti Trust Company as Trustee of an express trust for the benefit of the holders of CVRs under the CVR Agreement.

22. BMS denies the allegations contained in paragraph 22 of the complaint, except denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of paragraph 22.

23. Defendant Bristol-Myers Squibb Company is a global biopharmaceutical company incorporated in the state of Delaware and headquartered in New York, New York.

23. BMS admits the allegations contained in paragraph 23 of the complaint.

JURISDICTION, VENUE, AND GOVERNING LAW

24. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, and the amount in controversy, exclusive of interests and costs, is at least $6.4 billion.

24. The allegations contained in paragraph 24 state legal conclusions as to which no responsive pleading is required. To the extent any response is deemed to be required, BMS denies the allegations contained in paragraph 24.

25. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2).

25. Paragraph 25 of the complaint states a legal conclusion as to which no responsive pleading is required.

26. Pursuant to Section 1.10 of the CVR Agreement, Bristol-Myers and the Trustee agreed to submit to the exclusive jurisdiction and venue of any state or federal court in Manhattan, New York.

26. BMS denies the allegations contained in paragraph 26 of the complaint, except admits that in section 1.10 of the CVR Agreement BMS agreed to jurisdiction and venue in the state or federal courts located in Manhattan, New York for disputes arising under that agreement.

27. Pursuant to Section 1.10 of the CVR Agreement, New York law applies to this action.

27. BMS admits the allegations in paragraph 27.

FACTUAL ALLEGATIONS

28. In September 2018, Bristol-Myers, an international pharmaceutical company, proposed a merger with its competitor Celgene that would result in Celgene becoming a wholly-owned subsidiary of Bristol-Myers. The merger negotiations stretched over approximately six months, with Celgene's valuation the main point of contention.

28. BMS denies the allegations contained in paragraph 28 of the complaint, except admits that on September 21, 2018, BMS proposed to Celgene a potential transaction in which Celgene would be acquired by BMS and that negotiations continued for several months following that meeting.

29. On December 27, 2018, to bridge this valuation gap, Bristol-Myers proposed issuing a contingent value right, known as a CVR, to Celgene stockholders as additional consideration for their shares. A CVR is a security that generally requires the issuer to make a payment to the holder of the security if contractually specified events occur by contractually specified dates. The initial proposal did not list all terms, but Celgene notified Bristol-Myers that it would accept the proposal so long as the CVR Agreement's terms were "clear, tied to near-term events, and aligned with the strategy of the combined company."

29. BMS denies the allegations contained in paragraph 29 of the complaint, except: (i) admits that in a discussion on December 27, 2018, BMS raised the possibility of including a contingent value right in the merger consideration for any merger transaction between BMS and Celgene without describing detailed terms of that proposal; and (ii) admits that, in general, a contingent value right is an instrument under which an acquiror conditionally agrees to pay

additional consideration if specified payment triggers are satisfied in the future and that therefore entails risk for the counterparty that the conditions to additional payments will not be met.

30. Intense negotiations over the terms of the potential CVR Agreement followed, including the amount that would be paid to Celgene stockholders and the events that would need to occur for the CVRs to become payable.

30. BMS denies the allegations contained in paragraph 30 of the complaint, except admits that BMS and Celgene engaged in negotiations concerning the terms that would govern the contingent value rights that would be included in the merger consideration for any merger transaction between BMS and Celgene.

31. Bristol-Myers and Celgene ultimately agreed that each CVR would carry a one-time $9 payment, contingent on the FDA approving the marketing applications, known as Biologics License Applications (or BLAs) for biologics and New Drug Applications for drugs, for three Celgene products (collectively, the "Milestone Therapies")—(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. The $9 per CVR payment was contingent on each of those Milestones being achieved by contractually specified dates.

FN 1:

Therapies referred to as drugs tend to be chemically synthesized and have a known chemical structure, whereas biologics are normally derived from the human body and generally do not have a known structure.

31. BMS denies the allegations contained in paragraph 31 of the complaint, except refers for their contents to the Merger Agreement and the CVR Agreement.

32. The dates for the Milestones were vigorously negotiated. The contracting parties agreed to deadlines that both sides believed were achievable: December 31, 2020 for Liso-cel and Ozanimod, and March 31, 2021 for Ide-cel. If all three Milestone Therapies were approved by their respective Milestones, Bristol-Myers would owe the CVR holders a total of $6.4 billion. If any Milestone were missed, Bristol-Myers would owe the CVR holders nothing.

32. BMS denies the allegations contained in paragraph 32 of the complaint, except refers for their contents to the Merger Agreement and the CVR Agreement.

33. The binary structure of the CVRs created perverse economic incentives for Bristol-Myers: once the merger became effective, Bristol-Myers would control the remaining development and marketing approval process for the Milestone Therapies, so it could effectively eliminate a $6.4 billion liability by slightly delaying the approval process for any of the Milestone Therapies and still retain substantially all the upside of the three Milestone Therapies. A delay of a few weeks, or even a few months, would have minimal impact on Bristol-Myers's ultimate profits from selling the Milestone Therapies but could be used to argue that Bristol-Myers had eliminated its $6.4 billion payment obligation.

33. BMS denies the allegations contained in paragraph 33 of the complaint.

34. To protect the CVR holders from Bristol-Myers's ability to manipulate the timeline for its exclusive benefit, the CVR Agreement requires Bristol-Myers to "use Diligent Efforts to achieve the Milestone[s]." Ex. A § 7.8. The CVR Agreement defines "Diligent Efforts" to mean, in relevant part, the "efforts of a Person to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such Person 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." *Id.* § 1.1. Thus, Bristol-Myers could not take steps to delay FDA approval of the Milestone Therapies or sit idly by when the FDA raised serious issues that could delay approval—either would be a breach of its obligation under the CVR Agreement to use Diligent Efforts to achieve the Milestones.

34. BMS denies the allegations contained in paragraph 34 of the complaint, except refers to the CVR Agreement for its terms.

35. Bristol-Myers controls much of the information relevant to determining whether Bristol-Myers complied with the CVR Agreement, including its covenant to use Diligent Efforts to achieve the Milestones. Thus, the CVR Agreement includes two provisions designed to create accountability and ensure Bristol-Myers cannot evade its obligations by hiding information that might reveal its non-compliance. First, the CVR Agreement requires Bristol-Myers and its subsidiaries "to use commercially reasonable efforts to keep true, complete and accurate records in reasonably sufficient detail to enable the [CVR] Holders to determine if [Bristol-Myers] has complied with its obligations under this CVR Agreement." *Id.* § 7.5. Second, the CVR Agreement authorizes the Trustee to obtain those records. Specifically, the CVR Agreement states that the Trustee "shall be entitled to examine the

pertinent books and records of [Bristol-Myers]" to investigate "the facts or matters stated in any ... statement, opinion, report, notice ... or other paper or document." *Id.* § 4.2(f).

35. BMS denies the allegations contained in paragraph 35 of the complaint, except refers to the CVR Agreement for its terms.

36. On January 3, 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 cash, and one CVR. Bristol-Myers announced that the merger would "creat[e] a leading focused biopharma company," which, among other things would be "positioned for long term leadership in hematology." Bristol-Myers stated that Liso-cel and Ide-cel were "high value near-term assets," and that Liso-cel, Ozanimod, and Ide-cel were three of "six near-term product launch opportunities with potential for greater than $15 [billion] in revenue." Bristol-Myers noted that the acquisition would yield approximately $45 billion in "free cash flow" for the first three years, and that it "expect[ed] to fulfill [the] CVR obligation with ongoing cash flow."

36. BMS denies the allegations contained in paragraph 36 of the complaint, except refers for their contents to the Merger Agreement dated as of January 2, 2019, and the press release issued jointly by Celgene and BMS on January 3, 2019.

37. Bristol-Myers and Celgene shareholders approved the merger on April 12, 2019.

37. BMS admits the allegations contained in paragraph 37 of the complaint.

38. Both the merger and the CVR Agreement became effective on November 20, 2019.

38. BMS admits the allegations contained in paragraph 38 of the complaint.

39. Before the merger, all three Milestone Therapies were on the fast track for approval well ahead of the Milestones, including Liso-cel. Liso-cel, also known as JCAR017 and by its trade name Breyanzi, is a lifesaving therapy for a highly vulnerable set of patients with advanced-stage cancer. It is a chimeric antigen receptor T-cell therapy ("CAR-T Therapy") that treats patients with diffuse large B-cell Non-Hodgkin's lymphoma, which is the most common Non-Hodgkin's lymphoma. Liso-cel is used to treat patients for whom prior courses of treatment have failed. Like other CAR-T Therapies, Liso-cel treats this terminal disease by extracting a cancer patient's T-cells, which are white blood cells that kill infected or cancerous cells, genetically

modifying them to target and kill B-cells that have become malignant, and then injecting the genetically modified T-cells into the patient, where they attack and kill malignant B-cells.

39. BMS denies the allegations contained in paragraph 39 of the complaint, except: (i) admits that liso-cel is a chimeric antigen receptor T-cell ("CAR-T") therapy for patients with certain types of cancer, including large B-cell lymphoma, for whom prior treatments have not been successful; and (ii) admits that liso-cel is produced by genetically modifying a patient's own T-cells, which are then reintroduced into the patient to attack and kill malignant cancer cells.

40. Although Liso-cel is not the first FDA-approved CAR-T Therapy for diffuse large B-cell Non-Hodgkin's lymphoma—Novartis received FDA approval for Kymriah in August 2017 and Gilead received FDA approval for Yescarta in October 2017—it is the most effective. Patients treated with Liso-cel have a remarkable overall response rate of 73% (meaning that in 73% of cases, the patient's cancer reduces) and have a complete response of 54% (meaning that in 54% of cases, all signs of cancer disappear). Kymriah and Yescarta both have lower overall response rates and complete response rates.

40. BMS denies the allegations contained in paragraph 40 of the complaint, except: (i) admits that liso-cel has been shown to be an effective treatment for certain types of refractory cancer; and (ii) denies that paragraph 40 sets forth a complete, accurate, and fair description of clinical study results for liso-cel and other therapies identified in that paragraph.

41. Liso-cel's demonstrated efficacy in treating—and in some cases curing—diffuse large B-cell Non-Hodgkin's lymphoma caused the FDA to designate it as both a Breakthrough Therapy in 2016 and a Regenerative Medicine Advanced Therapy in 2017. Both designations expedite the development and review process. The FDA designates a therapy as a Breakthrough Therapy only if the therapy is expected to be a substantial improvement over existing treatments of a serious medical condition. The FDA provides a Breakthrough Therapy intensive, interactive guidance during the therapy's development, with senior FDA personnel involved in a proactive, collaborative review of the therapy. Because of the life-saving nature of a Breakthrough Therapy, such a designation allows the FDA to authorize a rolling review of the therapy's marketing application to allow the product to enter the market more quickly.

41. BMS denies the allegations contained in paragraph 41 of the complaint, except: (i) admits that the FDA designated liso-cel as a Breakthrough Therapy in 2016 and as a Regenerative Medicine Advanced Therapy in 2017; and (ii) refers to applicable law for the effects of such designations on the FDA's review and approval process.

42. A Regenerative Medicine Advanced Therapy designation provides, in addition to all the same benefits that a Breakthrough Therapy designation offers, broader avenues 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.

42. Paragraph 42 of the complaint states legal conclusions as to which no response is required.

43. Liso-cel continued its impressive trajectory following the FDA's designations of Liso-cel as a Breakthrough Therapy and a Regenerative Medicine Advanced Therapy. Clinical trials showed strong overall and complete response rates in patients suffering from diffuse large B-cell Non-Hodgkin's lymphoma, and most patients did not experience the two life-threatening side-effects associated with Kymriah and Yescarta, cytokine-release syndrome and neurotoxicity. The FDA concluded the clinical trials were "well-controlled" and "demonstrated high response rates and durability of [complete response] rate."

43. BMS denies the allegations contained in paragraph 43 of the complaint, except admits that prior to FDA approval the efficacy of liso-cel "was evaluated in TRANSCEND, a single-arm, open label multicenter trial" and that "[o]f the 192 patients evaluable for response, the overall response rate (ORR) per independent review committee was assessed at 73%. . . with a complete response (CR) rate of 54%."

44. Immediately after the CVR Agreement and the Celgene acquisition became effective, all signs continued to point to an expedited approval track for Liso-cel. Celgene, now fully controlled by Bristol-Myers, completed the filing of the Liso-cel BLA. A BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. Its issuance requires a determination that the product, the

manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity, and potency of the product. The BLA is the last step in the development process before a therapy can be brought to market.

44. BMS denies the allegations in paragraph 44 of the complaint, except: (i) admits that a biologics license application is an application for FDA authorization to introduce, or deliver for introduction, a biologic product into interstate commerce (*see* 21 C.F.R., § 601.2); and (ii) admits that BMS submitted the final module of the biologics license application for approval of liso-cel on December 18, 2019.

45. To enable the FDA to conduct its review, the BLA must include, among other things, clinical data demonstrating the safety and efficacy of the therapy, information concerning the manufacturing and controls for production, a detailed description of the manufacturing facility, and the proposed product label. Once the FDA has reviewed the BLA, conducted facilities inspections, and concluded that the therapy is efficacious, safe, and appropriately labeled, the FDA issues its approval.

45. Paragraph 45 of the complaint states legal conclusions as to which no response is required. To the extent any response is deemed to be required, BMS denies the allegations in paragraph 45 of the complaint.

46. Although Celgene had submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019, before the merger became effective, Bristol-Myers delayed submitting the most critical section of the BLA—the Chemistry, Manufacturing and Controls ("CMC") section, which specifies the manufacturing processes, product characteristics, and product testing upon which the manufacturer relies to ensure that its therapy is safe, effective, and consistently manufactured. Bristol-Myers failed to submit the CMC section until December 18, 2019, nearly a month after the merger became effective on November 20, 2019.

46. BMS denies the allegations contained in paragraph 46 of the complaint, except admits that, on December 18, 2019, BMS submitted to the FDA the final module of the rolling biologics license application for liso-cel, which addressed Chemistry, Manufacturing and Controls ("CMC").

47. Upon the submission of the Liso-cel BLA on December 18, 2019, the FDA had sixty days to conduct an initial review to determine whether the application was complete and—critically—to determine whether to grant Priority Review. 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.

47. Paragraph 47 of the complaint states legal conclusions as to which no response is required.

48. A "Priority Review" designation provides a substantial benefit to the manufacturer. In general, the FDA commits to endeavor to review and render a decision on a BLA by a set date, known as a PDUFA date. For non-priority BLAs, the FDA sets the PDUFA date at ten months after the FDA completes its initial sixty-day review. For BLAs slated for Priority Review, the FDA shortens the PDUFA date to six months after the initial review.

48. Paragraph 48 of the complaint states legal conclusions as to which no response is required. To the extent any response is deemed to be required, BMS denies the allegations in paragraph 48 of the complaint, except admits that 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."

49. The PDUFA date is of critical importance. The FDA has issued guidance stating that it strives to approve or deny BLAs and New Drug Applications by the PDUFA date at least 90% of the time. In reality, the FDA does even better. For the 155 BLAs and New Molecular Entity New Drug Applications (which are reviewed under the same program) granted Priority Review in fiscal years 2014 through 2018, the FDA made a decision by the PDUFA date in all but three instances, which is 98% of the time. For fiscal years 2016 to 2018, the FDA approved those applications by the PDUFA date 100% of the time.

FN 2:

BLAs and New Molecular Entity New Drug Applications are both reviewed under the FDA's "Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs," which sets out a defined review process and includes regular meetings between FDA officials and the applications' sponsors, "to promote the efficiency and effectiveness of the first

cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality new drugs and biologics."

49. BMS denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 49 of the complaint, except admits that, according to FDA guidance, biologics license applications and New Molecular Entity New Drug Applications are reviewed under the FDA's "Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs," the goal of which is "to improve the efficiency and effectiveness of the first cycle review process and decrease the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality new drugs and biologics."

50. The FDA completed its initial review of the Liso-cel BLA on February 13, 2020 and—because of Liso-cel's potential to improve Non-Hodgkin's lymphoma treatment significantly—granted it Priority Review, shortening the approval timeline from ten months to just six. This meant that the Liso-cel PDUFA date was August 17, 2020, four and a half months before the December 31, 2020 Liso-cel Milestone.

50. BMS denies the allegations contained in paragraph 50 of the complaint, except admits that, on February 13, 2020, the FDA granted Priority Review for the liso-cel application, which under PDUFA resulted in a target FDA action date of August 17, 2020.

51. When Bristol-Myers took control of Liso-cel following the merger, Liso-cel's development took a sudden and marked turn for the worse. The New Drug Application 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, for Bristol-Myers to have a basis to argue that it did not have a $6.4 billion liability to CVR holders 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 Milestones.

51. BMS denies the allegations contained in paragraph 51 of the complaint, except admits that the FDA approved the BMS new drug application for ozanimod on March 26, 2020.

52. That is precisely what Bristol-Myers did. Bristol-Myers's first steps to delay Liso-cel's approval occurred shortly after the merger closed. In the CMC section of the Liso-cel BLA submitted on December 18, 2019, Bristol-Myers made an extremely atypical decision. It chose to omit basic data detailing (i) the tests used to ensure that Liso-cel is safe and efficacious, referred to as assays, and (ii) the studies that assess whether those assays worked as they were supposed to, referred to as validation. These data are rigorously compiled over the course of developing a biologic and are routinely included in BLAs. As Bristol-Myers knew or should have known, they are fundamental components of a BLA, without which the FDA cannot make an informed decision, or any decision, on approval.

52. BMS denies the allegations contained in paragraph 52 of the complaint.

53. Predictably, on March 23, 2020, the FDA submitted an information request to Bristol-Myers seeking the missing data on assays and validation. On April 15, 2020, Bristol-Myers amended the CMC section of the BLA to provide the missing data. Within weeks, the FDA concluded what must have been glaringly obvious to Bristol-Myers: the new information Bristol-Myers provided in the amendment was so substantial that it rose to the level of a "major amendment." The "major amendment" designation automatically triggered a three-month extension of the PDUFA date— from August 17, 2020 to November 16, 2020, only weeks before the December 31, 2020 Liso-cel Milestone.

53. BMS denies the allegations contained in paragraph 53 of the complaint, except: (i) admits that the FDA made various requests for additional information with respect to the biologics license application for approval of liso-cel, including a request on or about March 23, 2020; (ii) admits that BMS provided the information requested by the FDA in that information request on or about April 15, 2020; (iii) refers for its contents to an FDA letter concerning the liso-cel application dated May 5, 2020; and (iv) admits that by operation of law, the FDA's "major amendment" determination resulted in a three-month extension of the target PDUFA date for the liso-cel application until November 16, 2020, which was before the contractual milestone date.

54. Major amendments are rare. Because a major amendment automatically extends the PDUFA date by three months, the FDA will declare a major amendment only 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.

54. BMS denies the allegations contained in paragraph 54 of the complaint, except admits that by operation of law a major amendment determination by the FDA extends the PDUFA target action date for an application by three months.

55. Practice bears out the FDA's reluctance to declare a major amendment. Of the 133 therapies approved in fiscal year 2019, only eighteen had a major amendment. And of the 177 therapies approved in fiscal year 2018, only twenty had a major amendment. The Government Accountability Office reported that from 2014 to 2018, just four out of fifty-three New Drug Applications (the drug equivalent of a BLA) designated for Priority Review had a major amendment filed. 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 exceedingly rare, since the purpose of such designations is to ensure the FDA is deeply involved in the therapy's development. Had Bristol-Myers satisfied its contractual obligation to exercise Diligent Efforts to achieve the Liso-cel Milestone, there would not have been a major amendment or the accompanying delay.

55. BMS denies the allegations contained in paragraph 55 of the complaint, except denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations concerning FDA decisions and practices that are contained in the first five sentences of paragraph 55.

56. The market understood the implication of a major amendment for the Liso-cel Milestone. The CVR, which had been trading at $4.50 at the end of April 2020, dropped to just $3.00 in the days following Bristol-Myers's announcement of the major amendment.

56. BMS denies the allegations contained in paragraph 56 of the complaint, except denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 56 concerning market prices for the CVRs.

57. Bristol-Myers's failure to exercise Diligent Efforts, however, was not isolated to Liso-cel. Bristol-Myers also stalled the development of Ide-cel, the other Milestone Therapy that the FDA had not yet approved. Like Liso-cel, Ide-cel had been granted Breakthrough Therapy designation, putting it on the fast-track to approval.

57. BMS denies the allegations contained in paragraph 57 of the complaint, except admits that the FDA designated ide-cel a Breakthrough Therapy.

58. On May 13, 2020, just one week after the FDA recognized Bristol-Myers's Liso-cel amendment as a major amendment, the FDA announced it had issued a refuse-to-file decision for Ide-cel. This decision meant that the BLA Bristol-Myers submitted on March 31, 2020 for Ide-cel was so materially deficient that the FDA would not review it. The FDA issues a refuse-to-file decision only if there is a "clear omission of information or sections of required information," "omission of critical data, information or analyses needed to evaluate safety, purity and potency or provide adequate directions for use," or "[i]nadequate content, presentation, or organization of information such that substantive and meaningful review is precluded." Refuse-to-file decisions are exceedingly rare: only 98 out of 2,475 BLAs and New Drug Applications submitted between 2008 and 2017 received a refuse-to-file decision. Such decisions generally reflect an applicant's unfamiliarity with the basics of the FDA application process, and so are far rarer for major pharmaceutical companies like Bristol-Myers—and rarer still for therapies designated as Breakthrough Therapies or Regenerative Medicine Advanced Therapies. For those few refuse-to-file decisions, FDA review takes substantially longer—approximately sixteen to eighteen additional months—than for BLAs and New Drug Applications that do not receive refuse-to-file decisions.

58. BMS denies the allegations contained in paragraph 58 of the complaint, except: (i) admits that in a letter dated May 13, 2020, the FDA provided BMS notice of its decision not to accept for filing the biologics license application for ide-cel; (ii) denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 58 concerning the FDA's issuance of refusal-to-file decisions between 2008 and 2017; and (iii) refers for its contents to FDA guidance referred to in paragraph 58 concerning the issuance of refusal-to-file decisions.

59. After receiving the refuse-to-file decision, Bristol-Myers did not immediately correct the deficient BLA. Instead, it delayed refiling for over two months, finally resubmitting the BLA on July 31, 2020. This refiling restarted the FDA's two-month initial review process in which the FDA determines whether the BLA is complete.

59. BMS denies the allegations contained in paragraph 59 of the complaint, except admits that BMS filed a revised application for FDA approval of ide-cel on July 31, 2020, and avers that the FDA approved ide-cel on March 26, 2021, before the applicable milestone date in the CVR Agreement.

60. Had Bristol-Myers satisfied its obligation to exercise Diligent Efforts in submitting an adequate BLA in the first place, the FDA's formal review process would have commenced by at least May 2020. Because of Bristol-Myers's lack of Diligent Efforts, the FDA did not start its formal review until September 22, 2020. This avoidable delay does not reflect Diligent Efforts and instead served to increase the odds of missing the Ide-cel Milestone and eliminating a $6.4 billion obligation to the CVR holders.

60. BMS denies the allegations contained in paragraph 60 of the complaint.

61. Bristol-Myers's misconduct continued during the next step in the Liso-cel BLA review process: 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.

61. BMS denies the allegations contained in paragraph 61 of the complaint, except refers to applicable law for discussion of the purposes of a pre-licensing facility inspection by the FDA.

62. Bristol-Myers knew that the Pre-License Inspections were critical to timely FDA approval of the Liso-cel BLA. The FDA had announced that, in response to the COVID-19 pandemic, it would selectively deploy its resources to inspect manufacturing facilities for BLAs and New Drug Applications. The FDA rescheduled the June 2020 Pre-License Inspections for Liso-cel's manufacturing facilities after the major amendment pushed the PDUFA date three months.

62. BMS denies the allegations contained in paragraph 62 of the complaint, except: (i) admits that the FDA postponed pre-licensing inspections for facilities to be used in the production of liso-cel; and (ii) refers for its contents to the FDA's press release dated March 18, 2020, "Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections."

63. Nevertheless, the FDA understood the life-saving importance of Liso-cel, so it rescheduled the Pre-License Inspection for the two facilities involved in the manufacturing of Liso-cel for later in 2020. The two facilities that were to be inspected were the Juno Facility in Bothell, Washington and the Lonza Facility in Houston, Texas. Bristol-Myers completes the production of Liso-cel at the Juno Facility and develops the viral vector—the component of Liso-cel that identifies malignant B-cells—at the Lonza Facility. Bristol-Myers is responsible for ensuring that both facilities comply with FDA regulations, including through monitoring and instructing its contract vendor Lonza concerning FDA compliance.

63. BMS denies the allegations contained in paragraph 63 of the complaint, except: (i) admits that a Juno Therapeutics facility in Bothell, Washington and a Lonza Group AG facility in Houston, Texas were to be used in the production of liso-cel components, including a viral vector; (ii) admits that the FDA required both facilities to be inspected in person before the liso-cel application could be approved; and (iii) denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 63 concerning the FDA's understandings or internal deliberations.

64. 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. Bristol-Myers was thus well aware of the upcoming Pre-License Inspections and had ample time to prepare both facilities. But despite this notice and opportunity to prepare, both facilities were woefully unprepared. Shortly after Bristol-Myers acquired Celgene, it described Liso-cel's manufacturing facilities in public presentations as "launch ready." But after a year of Bristol-Myers's control, those facilities fell short on basic safety and regulatory requirements.

64. BMS denies the allegations contained in paragraph 64 of the complaint, except refers for their contents to materials accompanying a BMS presentation on December 8, 2019 at the annual meeting of the American Society of Hematology that are the apparent source of the allegations in the fourth sentence of paragraph 64.

65. The Juno Facility inspection occurred from October 7, 2020 to October 16, 2020. Following that inspection, the FDA issued a Form 483, a form in which the FDA documents "significant" issues identified during an

inspection that may violate FDA regulations because they pose a risk that the therapy could be adulterated and harm patients. These observations must be addressed to the FDA's satisfaction before approval is granted.

65. BMS denies the allegations contained in paragraph 65 of the complaint, except: (i) admits that the FDA inspected the Juno Therapeutics facility in Bothell, Washington between October 7, 2020 and October 16, 2020; and (ii) admits that the FDA issued a Form 483 following the inspection and refers to the Form 483 for its contents (a redacted version of which is attached as Exhibit B to the complaint).

66. In the Form 483 for the Juno Facility, the FDA identified numerous, easily avoidable deficiencies. The FDA observed, for example:

a. Bristol-Myers failed to enforce procedures at the Juno Facility designed to prevent contamination of sterile drug products. Ex. B at 3.

b. 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. *Id.* at 4.

c. 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. *Id.*

d. Bristol-Myers failed to ensure the reliability of third-party vendors' Certificates of Analysis, which certify compliance with product specifications. *Id.* at 1.

e. 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. *Id.* at 1.

66. BMS denies the allegations contained in paragraph 66 of the complaint, except refers to the Form 483 issued by the FDA with respect to its October 2020 inspection of the Juno Therapeutics facility in Bothell, Washington for its contents.

67. Bristol-Myers's overt failures to comport with basic FDA standards for safe and reliable manufacturing further delayed the FDA's

approval of Liso-cel. On November 5, 2020, nearly a month after the FDA began its inspection, Bristol-Myers responded to the Form 483 and acknowledged many of the failures the FDA identified. Bristol-Myers stated that it would take actions "to further enhance" its "processes and controls and improve the overall effectiveness of [its] operations and quality system." But the FDA pointed to "unclear and questionable points" in Bristol-Myers's response and required Bristol-Myers to supplement its response further. Bristol-Myers did not complete its Form 483 response until December 18, 2020, over two months after the FDA inspection, a month after the PDUFA date, and a matter of days before the Liso-cel Milestone. The FDA could not complete its review of the Liso-cel BLA until this response was complete. Had Bristol-Myers used Diligent Efforts, such further delay would have been avoided.

67. BMS denies the allegations contained in paragraph 67 of the complaint, except refers for its contents to the correspondence between BMS and the FDA that is referred to in paragraph 67.

68. The host of issues the FDA identified during the Juno Facility inspection should have demonstrated to Bristol-Myers that the Liso-cel BLA was in jeopardy. Bristol-Myers knew or should have known that it needed to make every effort to ensure that the Lonza Facility inspection—the last facility inspection in the FDA approval process—went smoothly. Bristol-Myers did not do so.

68. BMS denies the allegations contained in paragraph 68 of the complaint.

69. Following the FDA's inspection of the Lonza Facility from December 3, 2020 to December 10, 2020, the FDA 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 the Juno Facility inspection, the FDA had identified deficiencies in the timing and inspection of raw materials and in the procedures designed to monitor the manufacturing environment for risks of microbiological contamination of purportedly sterile products. Ex. B at 3. During the Lonza Facility inspection, the FDA observed a complete failure to inspect raw materials and inadequate microbial contamination controls. Ex. C at 4.

69. BMS denies the allegations contained in paragraph 69 of the complaint, except refers for its contents to the Form 483 issued by the FDA with respect to its December 2020 inspection of the Lonza facility in Houston, Texas (Exhibit C to the complaint).

70. Following the Juno Facility inspection, Bristol-Myers, a gigantic pharmaceutical company that regularly files BLAs and New Drug Applications, could have no reasonable doubt concerning what systems the FDA would be scrutinizing. Bristol-Myers could have—and should have—ensured that Lonza corrected these issues before the Lonza Facility inspection, but it chose not to.

70. BMS denies the allegations contained in paragraph 70 of the complaint.

71. The other issues the FDA observed at the Lonza Facility, while different from those at the Juno Facility, reflected the opposite of Diligent Efforts. For example:

a. The FDA observed that materials intended for use within the United States were stored in the same bin within the same freezer that stored not only materials intended for foreign markets with different manufacturing requirements—but also materials that had been rejected by quality control. *Id.* at 1.

b. 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 bottles. *Id.*

c. 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. *Id.*

d. 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. *Id.* at 2.

71. BMS denies the allegations contained in paragraph 71 of the complaint, except refers for its contents to the Form 483 issued by the FDA with respect to its December 2020 inspection of the Lonza facility in Houston, Texas.

72. Bristol-Myers first responded to the Form 483 for the Lonza Facility on December 18, 2020, the same day it submitted its supplemental

response to the Juno Facility Form 483. This response, like the first response to the Juno Facility Form 483, was deficient and required Bristol-Myers to submit additional information, which it did on December 23, 2020, just days before the Liso-cel Milestone and in the middle of the winter holidays.

72. BMS denies the allegations contained in paragraph 72 of the complaint, except refers for its contents to the correspondence between BMS and the FDA that is referred to in paragraph 72.

73. Had Bristol-Myers used Diligent Efforts, the myriad violations identified by the FDA at the Juno Facility and Lonza Facility—and the delay that resulted—would not have happened and the Liso-cel Milestone would have been achieved.

73. BMS denies the allegations contained in paragraph 73 of the complaint.

74. When these developments became public knowledge, certain CVR holders became concerned that Bristol-Myers had not complied with the CVR Agreement. They directed the Trustee, acting on their behalf under the CVR Agreement, to investigate Bristol-Myers's compliance with the CVR Agreement and, if appropriate, to take action to enforce their rights.

74. BMS denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 74 of the complaint.

75. To that end, the Trustee sent Bristol-Myers a letter on December 29, 2020, notifying Bristol-Myers that the Trustee was exercising its contractual right to inspect Bristol-Myers's books and records. Ex. A § 4.2(f). Specifically, the Trustee requested:

a. All documents constituting or concerning communications with the FDA concerning the amendment which resulted in the FDA extending the PDUFA date for Liso-cel, including any communications prior to May 13, 2020 concerning any manufacturing or other issues raised in any FDA communication relating to such extension;

b. All documents constituting or concerning communications with the FDA concerning inspection of any facility identified in the BLA as a manufacturing site for Liso-cel;

c. All documents addressing the risk of delay for approval of the Liso-cel BLA generated by Bristol-Myers or Celgene

Corporation either before or after the CVR Agreement execution date;

d. Documents sufficient to show all contingency planning for the manufacture of Liso-cel to avoid any risk of delay or failure of a Pre-License Inspection;

e. All documents constituting or concerning any analysis done in the last 120 days concerning the impact on the financial statements or prospects of Bristol-Myers in the event the Liso-cel Milestone was not achieved;

f. All documents constituting or concerning efforts by Bristol-Myers to educate relevant employees as to Bristol-Myers's obligations to use Diligent Efforts to achieve the Liso-cel Milestone.

75. BMS denies the allegations contained in paragraph 75 of the complaint, except: (i) admits that on December 29, 2020 a law firm purporting to act for UMB Bank sent a letter to BMS; and (ii) refers to that letter for its contents.

76. Providing the information requested should have been easy for Bristol-Myers. As noted above, the CVR Agreement specifically requires Bristol-Myers to "use commercially reasonable efforts to keep, and [to] cause it Subsidiaries to use commercially reasonable efforts to keep, true, complete and accurate records in reasonably sufficient detail to enable the [CVR] Holders to determine if [Bristol-Myers] has complied with its obligations under this CVR Agreement." Ex. A § 7.5.

76. BMS denies the allegations contained in paragraph 76 of the complaint.

77. To date, Bristol-Myers has refused to provide any information, breaching its obligation under the CVR Agreement. Bristol-Myers knows that complying with this contractual obligation would make plain its failure to use Diligent Efforts to meet the Liso-cel Milestone. Bristol-Myers has rejected the Trustee's request, falsely claiming that the CVR Agreement has terminated. The CVR Agreement provides that the termination of the CVR Agreement "does not relieve any Party of any liability arising from any material breach of its obligations ... occurring prior to the Termination Date." Ex. A § 1.16. The Trustee requested the information before the date on which Bristol-Myers asserts the CVR Agreement terminated. Bristol-Myers cannot escape its obligation to comply with the Trustee's request by running out the clock.

77. BMS denies the allegations contained in paragraph 77 of the complaint.

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

78. BMS denies the allegations contained in paragraph 78 of the complaint, except admits that the FDA did not approve the biologics license application for liso-cel until after the December 31, 2020 milestone date for that application provided in the CVR Agreement.

79. In stark contrast to the delay Bristol-Myers exhibited throughout the Liso-cel approval process, Bristol-Myers wasted no time in announcing that it no longer owed $6.4 billion to the CVR holders. On New Year's 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."

79. BMS denies the allegations contained in paragraph 79 of the complaint, except admits that BMS issued a press release on January 1, 2021, and refers to that press release for its contents.

80. Thirty-six days later, the FDA approved the Liso-cel BLA. Had Bristol-Myers used Diligent Efforts to achieve the Liso-cel Milestone—efforts which would have avoided a major amendment that caused at least a three-month delay and two Forms 483 that caused several more months of delay—Bristol-Myers would have met the deadline.

80. BMS denies the allegations contained in paragraph 80 of the complaint, except admits that the FDA approved liso-cel on February 5, 2021.

81. Had Bristol-Myers used Diligent Efforts to reach the Liso-cel Milestone, Bristol-Myers would be obligated to pay $6.4 billion to CVR holders under the CVR Agreement.

81. BMS denies the allegations contained in paragraph 81 of the complaint.

82. Bristol-Myers did not use Diligent Efforts. That much is evident by examining the FDA approval process for Gilead's therapies Yescarta and Tecartus and Novartis's therapy Kymriah. These three therapies, each designated as a Breakthrough Therapy, are CAR-T therapies that use a

similar process as Liso-cel to treat lymphoma. Each therapy has equivalent or lower projected revenue, is less efficacious, has a higher likelihood of side effects, and is priced lower than Liso-cel. As Bristol-Myers has explained, it is Liso-cel that is "best-in-class"—not Yescarta, Kymriah, or Tecartus. Thus, Bristol-Myers had even more incentive to obtain FDA approval for Liso-cel quickly so that Liso-cel could be marketed and sold.

82. BMS denies the allegations contained in paragraph 82 of the complaint.

83. Nevertheless, Yescarta, Kymriah, and Tecartus moved through the FDA approval process with substantially more ease. Neither Gilead nor Novartis submitted a major amendment to any BLA. Overall, each submitted 40% to 80% fewer amendments to the respective BLAs than Bristol-Myers submitted for Liso-cel. And although Yescarta and Kymriah received Forms 483, no responses were reported as containing "unclear and questionable points," nor are there any reports that the FDA requested additional responses to the Yescarta or Kymriah Forms 483 because initial responses were deficient.

83. BMS denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 83 of the complaint.

84. Ultimately, Yescarta, Kymriah, and Tecartus were approved in substantially shorter periods than Liso-cel:

Therapy	BLA Submission Date	FDA Approval Date	Days from Submission to Approval
Yescarta	March 31, 2017	October 19, 2017	202 Days
Kymriah	March 28, 2017	August 30, 2017	155 Days
Tecartus	December 11, 2019	July 24, 2020	226 Days
Liso-cel	December 19, 2019	February 5, 2021	415 Days

84. BMS denies the allegations contained in paragraph 84 of the complaint, except: (i) admits that BMS filed the final module of the rolling application for FDA approval of liso-cel on December 18, 2019, and the FDA approved liso-cel on February 5, 2021; and (ii) denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 84 concerning other companies' FDA applications.

85. Had Bristol-Myers used Diligent Efforts to achieve the Liso-cel Milestone—as it was contractually obligated to do—the Liso-cel Milestone would have been met.

85. BMS denies the allegations contained in paragraph 85 of the complaint.

86. On March 4, 2021, the Trustee notified Bristol-Myers that Bristol-Myers was in Default under the CVR Agreement because, among other things, Bristol-Myers had breached its obligations to use Diligent Efforts to achieve the Liso-cel Milestone and to allow the Trustee to investigate Bristol-Myers's books and records. Bristol-Myers has not cured these breaches for over ninety days. Bristol-Myers's breaches have ripened into an Event of Default under the CVR Agreement.

86. BMS denies the allegations contained in paragraph 86 of the complaint, except refers for its contents to the letter to BMS dated March 4, 2021 that is alleged in paragraph 86.

COUNT I
(Breach of Contract: Failure to Use Diligent Efforts)

87. The Trustee incorporates the preceding paragraphs as if fully set forth herein.

87. BMS repeats and realleges its responses to paragraphs 1 through 86 of the complaint as if fully restated in response to paragraph 87 of the complaint.

88. Section 7.8 of the CVR Agreement, which is incorporated by reference in each CVR, requires Bristol-Myers to use Diligent Efforts to achieve the Milestones set forth in the CVR Agreement.

88. BMS denies the allegations contained in paragraph 88 of the complaint, except refers for its contents to section 7.8 of the CVR Agreement.

89. Bristol-Myers failed to use Diligent Efforts to achieve the Liso-cel Milestone by, among other things, submitting an inadequate Liso-cel BLA to the FDA, causing a major amendment to the Liso-cel BLA (which, in turn, triggered a three-month extension to the Liso-cel PDUFA date), failing to maintain the Juno Facility and Lonza Facility adequately, failing to prepare those facilities for inspection by the FDA, and inadequately responding to at least some of the FDA's findings.

89. BMS denies the allegations contained in paragraph 89 of the complaint.

90. Each of these demonstrates Bristol-Myers's failure to exercise Diligent Efforts in violation of Section 7.8 of the CVR Agreement.

90. BMS denies the allegations contained in paragraph 90 of the complaint.

91. As a result of Bristol-Myers's breach of its obligation to use Diligent Efforts to achieve the Milestones, the FDA did not approve the Liso-cel BLA by December 31, 2020.

91. BMS denies the allegations contained in paragraph 91 of the complaint.

92. The Trustee notified Bristol-Myers of Bristol-Myers's breach on March 4, 2021.

92. BMS denies the allegations contained in paragraph 92 of the complaint.

93. Over ninety days have passed since the Trustee notified Bristol-Myers of Bristol-Myers's breach without Bristol-Myers curing the breach.

93. BMS denies the allegations contained in paragraph 93 of the complaint.

94. Bristol-Myers's breach of Section 7.8 of the CVR Agreement has ripened into an Event of Default pursuant to Section 8.1(b) of the CVR Agreement.

94. BMS denies the allegations contained in paragraph 94 of the complaint.

95. As a result, the Trustee, as trustee of an express trust for the benefit of the CVR holders, has suffered damages in an amount to be determined at trial.

95. BMS denies the allegations contained in paragraph 95 of the complaint.

COUNT II
(Breach of Contract: Books and Records Inspection)

96. The Trustee incorporates the preceding paragraphs as if fully set forth herein.

96. BMS repeats and realleges its responses to paragraphs 1 through 95 of the complaint as if fully restated in response to paragraph 96 of the complaint.

97. Section 4.2(f) of the CVR Agreement allows the Trustee to initiate inquiries or investigations into Bristol-Myers's compliance with its obligations under the CVR Agreement and entitles the Trustee to examine Bristol-Myers's books and records as may be reasonably necessary for its inquiry or investigation.

97. BMS denies the allegations contained in paragraph 97 of the complaint, except refers for its contents to section 4.2(f) of the CVR Agreement.

98. On December 29, 2020, the Trustee, pursuant to Section 4.2(f) of the CVR Agreement, requested to investigate representations made in documents concerning delays in the approval process for the Milestone Therapies.

98. BMS denies the allegations contained in paragraph 98 of the complaint, except: (i) admits that on December 29, 2020, a law firm purporting to act for UMB Bank sent a letter to BMS; and (ii) refers to that letter for its contents.

99. To date, Bristol-Myers has failed to provide the Trustee access to its books and records to allow the Trustee to conduct its inquiry or investigation into Bristol-Myers's compliance with its obligations under the CVR Agreement.

99. BMS denies the allegations contained in paragraph 99 of the complaint, except: (i) admits that BMS has not made books and records available to UMB Bank in response to its lawyer's letter dated December 29, 2020; and (ii) refers to its defenses with respect to the same.

100. Bristol-Myers's refusal to cooperate with the Trustee's requests constitutes a breach of Section 4.2(f) of the CVR Agreement.

100. BMS denies the allegations contained in paragraph 100 of the complaint.

101. The Trustee notified Bristol-Myers of Bristol-Myers's breach on March 4, 2021.

101. BMS denies the allegations contained in paragraph 101 of the complaint, except refers for its contents to a letter dated March 4, 2021 that is alleged in that paragraph.

102. Over ninety days have passed since the Trustee notified Bristol-Myers of Bristol-Myers's breach without Bristol-Myers curing the breach.

102. BMS denies the allegations contained in paragraph 102 of the complaint.

103. Bristol-Myers's breach of Section 4.2(f) of the CVR Agreement has ripened into an Event of Default pursuant to Section 8.1(b) of the CVR Agreement.

103. BMS denies the allegations contained in paragraph 103 of the complaint.

104. The Trustee has incurred expenses to engage in an investigation that would have been obviated or reduced in scope had Bristol-Myers complied with its obligations.

104. BMS denies the allegations contained in paragraph 104 of the complaint.

105. As a result, the Trustee, as trustee of an express trust for the benefit of the CVR holders, has been damaged in an amount to be determined at trial.

105. BMS denies the allegations contained in paragraph 105 of the complaint.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court grant the following relief:

a. An award of monetary damages in an amount to be proven at trial on Count I;

b. An award of monetary damages in an amount to be proven at trial on Count II;

c. An award of pre- and post-judgment interest (including pursuant to the statutory rates of interest set under New York law);

d. An award of reasonable attorney's fees and costs of suit; and

e. An award of any and all other such relief, legal or equitable, as the Court may deem just and proper under the circumstances.

BMS denies that the Trustee is entitled to any relief against BMS, including without limitation the relief set forth in the prayer for relief.

JURY DEMAND

Plaintiff demands a trial by jury for all issues so triable as a matter of right.

BMS denies any allegations of the Trustee's demand for a jury trial, except admits that the Trustee purports to demand a jury trial to the extent set forth in that paragraph.

DEFENSES

Without assuming the burden of proof, production, or persuasion as to any matter where any of those burdens rest with the Trustee, BMS asserts the following affirmative and other defenses based on knowledge as for itself and its own actions and upon information and belief as to all other matters. The defenses set forth below are based on information reasonably available to BMS at this time. BMS reserves the right to revise these defenses, or to assert additional defenses, after further investigation and as a result of discovery taken in this action.

FIRST DEFENSE

The complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

UMB Bank, N.A. lacks the capacity to sue BMS for breach of the CVR Agreement.

In an "Instrument of Removal, Appointment and Acceptance dated as of December 9, 2020" (the "Instrument") certain alleged Holders purported to remove Equiniti Trust Company ("Equiniti") as trustee and to appoint UMB Bank as successor trustee under the CVR Agreement. *See* CVR Agreement § 4.10(c). The Instrument did not include sufficient information to permit a determination that it was an "act of the Majority Holders." On December 31, 2020, UMB Bank delivered additional information to BMS and Equiniti seeking to establish that alleged Holders who provided their consents to the Instrument were beneficial owners of CVRs as of December 9, 2020, which the cover letter asserted was the alleged "record date" for a consent solicitation organized for that purpose by an alleged Holder, Pentwater Capital Management LP ("Pentwater").

The consent solicitation did not comply with requirements of the CVR Agreement. Under section 1.4(a) of the CVR Agreement, a record date for any consent by Holders must be set by BMS. But BMS did not establish a record date for the consent solicitation by Pentwater. In such circumstances, the CVR Agreement provides that "the record date for determining the Holders

entitled to consent to any action in writing without a meeting shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Company." CVR Agreement § 1.4(a). The record date for the consent solicitation by Pentwater therefore was December 18, 2020, because that was the "first date on which a signed written consent" was delivered to BMS.

All of the Holder consents to remove Equiniti and appoint UMB Bank were from Holders as of the wrong record date. Those consents were from Holders of CVRs as of December 9, 2020, not the actual record date of December 18, 2020. The consents were not valid, because only Persons who were Holders of the CVRs as of the record date fixed in accordance with the CVR Agreement were "entitled to take such action by vote or consent[.]" CVR Agreement, § 1.4(a).

For these reasons, the removal of Equiniti as trustee, and the appointment of UMB Bank as successor trustee, were not valid acts of the Majority Holders. UMB Bank is not a valid trustee under the CVR Agreement and therefore lacks the capacity to bring this lawsuit.

THIRD DEFENSE

BMS performed its obligations under the CVR Agreement in accordance with the terms of that agreement and therefore cannot be liable for the Trustee's claims of breach of contract.

FOURTH DEFENSE

At all times relevant to the claims asserted in the complaint, BMS used Diligent Efforts to achieve the Milestones, as those terms are defined in the CVR Agreement, through the actions of BMS and through the actions of its agents and representatives.

FIFTH DEFENSE

The Trustee's claims are barred because there was no Event of Default under the CVR Agreement. *See* CVR Agreement § 8.1.

There was no material default in the performance by BMS, or breach by BMS in any material respect, of any covenant or warranty in the CVR Agreement, including without limitation the covenant to use Diligent Efforts (section 7.8) and the agreement to permit examination of pertinent books and records (section 4.2(f)). CVR Agreement § 8.1(b). Further, there was no continuance of any such default or breach for a period of ninety (90) days after there had been given to BMS, by registered or certified mail, a timely written notice specifying such default or breach and requiring it to be remedied and stating that such notice was a "Notice of Default." *Id.*

Neither the Trustee nor any Holder provided written notice of any alleged material default or breach of the CVR Agreement by BMS before the CVR Agreement terminated in accordance with its terms at 12:01 a.m. on January 1, 2021. A letter from the Trustee's counsel to BMS dated March 4, 2021, which the Trustee alleges provided the required notice, did not comply with the requirements of the CVR Agreement and did not give rise to an Event of Default. The letter was not sent until months after the CVR Agreement terminated. Further, the March 4, 2021 letter did not state that it was a "Notice of Default."

No default or breach of BMS's obligations under either section 7.8 (Diligent Efforts) or section 4.2(f) (examination of books and records) of the CVR Agreement continued, or could have continued, for a period of ninety (90) days after the date of the Trustee's letter because neither section 7.8 nor section 4.2(f) survived the termination of the CVR Agreement, which occurred months before the letter was sent.

SIXTH DEFENSE

For the reasons stated in the Fifth Defense, which are incorporated herein, the Trustee's claims are barred based on the failure of a condition precedent. An Event of Default is a required condition precedent to the Trustee's suit. There was no Event of Default for the reasons stated in the Fifth Defense, including but not limited to, plaintiff's failure to provide the required written

notice of any alleged material default or breach of the CVR Agreement by BMS before the CVR Agreement terminated in accordance with its terms at 12:01 a.m. on January 1, 2021. A letter from the Trustee's counsel to BMS dated March 4, 2021, which the Trustee alleges provided the required notice, did not comply with the requirements of the CVR Agreement.

SEVENTH DEFENSE

For the reasons stated in the Fifth Defense, the Trustee's claims are barred by the doctrine of waiver. Neither Holders nor the Trustee provided BMS with written notice of any alleged material default or breach of the CVR Agreement by BMS before the CVR Agreement terminated in accordance with its terms at 12:01 a.m. on January 1, 2021.

EIGHTH DEFENSE

BMS cannot be held liable for breach of section 4.2(f) of the CVR Agreement because UMB Bank, purportedly acting in its capacity as successor trustee, did not first request to examine allegedly pertinent BMS books and records until a letter sent by its counsel at the close of business on December 29, 2020, two days before the Initial Milestone Target Date. Given UMB Bank's own delayed actions, BMS was not provided sufficient time before the CVR Agreement terminated at 12:01 a.m. on January 1, 2021 to comply with the examination request in a manner that would "not unreasonably interfere with the normal business operations of the Company or any of its Affiliates."

BMS had no obligation to respond to a request for examination of books and records from UMB Bank when there had not been a determination that it had replaced Equiniti as trustee under the CVR Agreement. As of the time of the December 29, 2020 letter to BMS, neither Holders nor UMB Bank had provided information to BMS and Equiniti sufficient to permit a determination that the Instrument purporting to remove Equiniti as trustee and to appoint UMB Bank as successor trustee was "an act of the Majority Holders" under section 4.10(c) of the CVR Agreement. In the

afternoon on December 31, 2020, the Initial Milestone Target Date under the CVR Agreement, UMB Bank purported to provide information to show that the removal and replacement of Equiniti as trustee was "an act of the Majority Holders."

Substantially more time would have been required to comply with section 4.2(f) of the CVR Agreement than was permitted by UMB Bank's untimely examination request. Under section 4.2(f), BMS was not "required to provide any books or records to the extent that doing so (i) would, as reasonably determined based on the advice of outside counsel, jeopardize any BMS attorney-client privilege; or (ii) would contravene any Law or any contract or agreement to which the Company or any of its Affiliates is subject or bound." CVR Agreement, § 4.2(f). To ensure that materials to be produced for examination did not fall within an excluded category, BMS would have needed time to undertake a review of potentially responsive materials in advance of examination and first would have been required to identify and collect such materials.

Compounding the need for substantial time to comply, the letter from UMB Bank's lawyers dated December 29, 2020 was not narrowly tailored to seek "pertinent books and records of" BMS. The letter purported to request six broad categories of information which would require extensive searches and collection of materials before they could be reviewed for privilege and to ensure that their disclosure would not "contravene any Law or agreement[.]"

As a result of all of the foregoing, no breach of section 4.2(f) arose, or could have arisen, before the CVR Agreement terminated in accordance with its terms at 12:01 a.m. on January 1, 2021.

NINTH DEFENSE

The inability of the FDA to approve the biologics license application for liso-cel on or before the Initial Milestone Target Date was not caused by any breach of the CVR Agreement by BMS. Instead, the timing for FDA approval of liso-cel resulted from the FDA's own operational

decisions and from external factors arising from the Sars-CoV-2 ("COVID-19") pandemic that were beyond the control of any party and that were not, and could not have been, anticipated at the time of the Merger Agreement or the CVR Agreement.

In a press release issued on March 18, 2020, the FDA announced significant operational changes to protect the health and safety of FDA staff and their families given the COVID-19 pandemic. The FDA announced that it had "directed all eligible FDA employees to begin teleworking" and would adjust its approach to a number of activities, "including facility inspections for all FDA-regulated products," including biological products. The FDA's operational limitations in response to the pandemic continued throughout the remainder of 2020 and had a significant impact, including in the reduced number of biologics license applications that were approved during that year.

The FDA insisted on in-person pre-approval inspections of two manufacturing facilities used in the production of liso-cel. Those facilities were located in regions that experienced high rates of transmission of COVID-19 in the second half of 2020, when the facilities involved in production of liso-cel were due to be inspected. During that period, to protect the safety of its employees, the FDA restricted travel of its personnel to or within areas experiencing high transmission rates for COVID-19 infections.

These factors delayed the FDA's facility inspections until November and December 2020. FDA memoranda documenting the approval of the two manufacturing facilities explicitly recognized that the COVID-19 pandemic prevented the FDA from completing its inspections of the facilities earlier.

The FDA's CMC BLA review memorandum approving the Juno Therapeutics facility located in Bothell, Washington stated: "The prelicense inspections (PLI) were postponed due to

COVID-19-related travel restrictions and the action due date of November 16, 2020 was missed. Since that time, the PLIs have been completed and inspection-related issues are resolved. The CMC review team recommends approval."

The CMC BLA review memorandum with respect to the Lonza Group AG facility located in Houston, Texas similarly acknowledged that "due to the ongoing COVID-19 pandemic restrictions, all of the pre-license inspections have not been completed yet. The outcome of the inspections and its impact on the BLA review will be documented in an addendum memo." In a later Addendum memorandum approving the Lonza facility for production of liso-cel components, the FDA acknowledged that: "Due to the ongoing COVID-19 public health emergency, the pre-license inspection (PLI) of the [] facility and evaluation of the [Form] 483 responses to the observations from the Juno facility inspection could not be completed by the BLA action due date (ADD) and therefore the due date was missed."

TENTH DEFENSE

For the reasons set forth in the Ninth Defense, which are incorporated by reference herein, the Trustee's claim for alleged breach of the covenant to use Diligent Efforts, CVR Agreement § 7.8, is barred by the doctrine of impossibility.

ELEVENTH DEFENSE

The claims asserted against BMS in this action are barred because UMB Bank was appointed as successor trustee in bad faith – in violation of the implied covenant of good faith and fair dealing – with the sole intention of suing BMS for alleged breach of the CVR Agreement if any milestones were missed, and without regard to whether the failure of any milestone was due to an alleged breach of contract.

TWELFTH DEFENSE

The claims asserted against BMS are barred under the doctrine of champerty. UMB Bank, in concert with the alleged Holders who purported to appoint UMB Bank as successor trustee, itself or by its officers, agents, or employees, did "solicit, buy or take an assignment of," or was "in any manner interested in buying or taking an assignment of" a security, thing in action, or claim or demand, "with the intent and for the purpose of bringing an action or proceeding thereon," namely, this action.

THIRTEENTH DEFENSE

BMS denies that it has taken any act, or omitted to take any act, for which damages can be awarded in this action, but any damages, to the extent awarded, must be strictly limited to exclude CVRs purportedly acquired in transactions that are neither recorded in the Security Register nor cleared and settled through the securities settlement and clearance system maintained by the Depository Trust and Company, which is the Depositary under the CVR Agreement. *See* CVR Agreement, § 3.8.

Without limiting the generality of the foregoing, on January 1, 2021, BMS issued a press release announcing that the FDA had not approved the liso-cel application by the December 31, 2020 milestone date, that the CVR Agreement had terminated in accordance with its terms, and that the CVRs no longer would trade on the NYSE. Thereafter, the NYSE suspended trading in, and delisted the CVRs, and the Depositary, or its affiliates, removed the CVRs from the Depositary's system for clearance and settlement of securities transactions. Any person who engaged in transactions purporting to acquire CVRs following the January 1, 2021 press release did so with knowledge of these facts, actual or constructive, and therefore assumed the risk that his, her, or its ownership of CVRs would not be recognized.

FOURTEENTH DEFENSE

Any alleged damages in this action are impermissibly speculative because they are predicated on the assumption that an alleged failure by BMS to use Diligent Efforts was the reason that one of three contractual contingencies for payment under the CVR Agreement was not met. That theory of damages depends on an assertion that Holders would have received payment for their CVRs if BMS had taken different actions. Speculative damages that depend on matters that cannot be proven objectively are barred under New York law.

FIFTEENTH DEFENSE

BMS denies that it has taken any act, or omitted to take any act, for which damages can be awarded in this action, but any damages, to the extent awarded, must be strictly limited to exclude damages with respect to CVRs as to which the owner or beneficial owner would receive duplicate or partially duplicate recovery.

CONCLUSION

WHEREFORE, BMS demands judgment dismissing the complaint, requiring the Trustee to post an undertaking for the payment of the costs of this suit, awarding attorneys' fees and costs and other, further, and different relief as the Court deems just and proper.

Dated: New York, New York
July 8, 2022

DLA PIPER LLP (US)

By: /s/ John J. Clarke, Jr.

John J. Clarke, Jr.
john.clarke@dlapiper.com
Jessica A. Masella
jessica.masella@dlapiper.com
Steven M. Rosato
steven.rosato@us.dlapiper.com
Jessica Park Wright
jessica.wright@dlapiper.com

1251 Avenue of the Americas
New York, New York 10020-1104
(212) 335-4500

Attorneys for Defendant
Bristol-Myers Squibb Company

CERTIFICATE OF SERVICE

I certify that on July 8, 2022, I caused a copy of the foregoing to be filed with the Court's ECF system, which will cause notice of its filing to be served electronically upon all counsel who have appeared in this action.

/s/ John J. Clarke, Jr.
John J. Clarke, Jr.