UNITED STATES DISTRICT COURT
FOR THE 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 November 20, 2019, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, Defendant.	Case No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

By and through its attorneys, Plaintiff UMB Bank, N.A., solely in its capacity as Trustee ("UMB" or the "Trustee") under the Contingent Value Rights Agreement dated November 20, 2019 (the "CVR Agreement"), by and between Bristol-Myers Squibb Company ("Bristol-Myers") and UMB's predecessor Equiniti Trust Company, alleges 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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

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.

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

FACTUAL ALLEGATIONS

I. Bristol-Myers Acquires Celgene, The Developer Of Liso-Cel, And Issues Contingent Value Rights To Bridge The Gap On The Merger Price

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.

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."

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.

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,[1] 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.

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.

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

[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.

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.

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.

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 com-

mercially 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).

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."

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

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

II. Before Bristol-Myers's Substantial Involvement, Liso-cel Was On The Fast Track For Approval

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.

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.

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.

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.

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."

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.

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.

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.

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.

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.

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,[2] 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.

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.

III. Bristol-Myers Engages In Egregious Misconduct That Delays FDA Approval

A. Bristol-Myers Submits A Major Amendment To The Liso-cel BLA That Delays FDA Approval By At Least Three Months

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

[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."

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.

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.

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.

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.

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.

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.

B. The FDA Refuses To Accept Bristol-Myers's Materially Deficient Ide-cel BLA

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.

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.

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.

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.

C. Bristol-Myers Fails To Prepare The Liso-cel Manufacturing Facilities, Delaying FDA Approval Further

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.

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.

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.

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.

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.

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.

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 identi-

fied. 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.

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.

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.

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.

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.

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.

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.

IV. Bristol-Myers Refuses To Reveal Any Information Concerning Its Efforts To Meet The Milestones Despite Its Contractual Obligation To Do So

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.

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.

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.

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.

V. Bristol-Myers Failed To Use Diligent Efforts To Achieve the Milestones, Causing It To Miss The Liso-cel Milestone Approval Date By Just Thirty-Six Days

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.

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."

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.

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.

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.

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.

84. Ultimately, Yescarta, Kymriah, and Tecartus were approved in a 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

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.

VI. The Trustee Sends Bristol-Myers A Notice Of Default, And Bristol-Myers Refuses To Cure Its Default

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.

COUNT I
Breach of Contract: Failure to Use Diligent Efforts

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

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.

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.

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

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.

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

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

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.

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.

COUNT II
Breach of Contract: Books and Records Inspection

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

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.

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.

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.

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

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

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

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.

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.

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.

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.

JURY DEMAND

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

Dated: New York, NY
June 3, 2021

Respectfully submitted,

SELENDY & GAY PLLC

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