UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 13, 2024

2seventy bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40791**	**86-3658454**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
60 Binney Street, Cambridge, MA		**02142**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (339) 499-9300

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	TSVT	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

As previously announced, Philip Gregory, the chief scientific officer of 2seventy bio, Inc. (the "Company"), will be leaving the Company effective upon the closing of the transactions contemplated by the Asset Purchase Agreement by and between the Company and Regeneron Pharmaceuticals, Inc., dated January 29, 2024 (such closing, the "Closing"). In connection with Dr. Gregory's departure, on March 13, 2024, the Company and Dr. Gregory entered into a release and equity agreement (the "Release Agreement"), pursuant to which all of Dr. Gregory's currently outstanding equity awards will continue to vest for a period of twelve months from the date of the Closing in exchange for a release of claims against the Company.

The foregoing description of the Release Agreement is qualified in its entirety by the complete text of the Release Agreement, a copy of which is filed with this Current Report on Form 8-K as Exhibit 10.1 and incorporated herein by reference.

Item 8.01 Other Events

On March 15, 2024, the Company and Bristol Myers Squibb issued a press release announcing the that the Oncologic Drugs Advisory Committee ("ODAC") of the U.S. Food and Drug Administration ("FDA") voted positively (8 to 3) that *Abecma* demonstrated a favorable benefit/risk profile for patients with triple-class exposed relapsed or refractory multiple myeloma based on results from the pivotal Phase 3 KarMMa-3 study. The recommendation from ODAC will be considered by the FDA during its ongoing review of the supplemental Biologics License Application for *Abecma* for this patient population. A copy of the press release is being filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1	Release and Equity Agreement, by and between 2seventy bio, Inc. and Philip Gregory
99.1	Press release issued by 2seventy bio, Inc. on March 15, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 18, 2024

2seventy bio, Inc.

By: /s/ Chip Baird
Chip Baird
Chief Operating Officer
(Principal Financial and Accounting Officer)

March 11, 2024

Philip Gregory

Re: Release and Equity Agreement

Dear Philip:

As you know, 2seventy bio, Inc. (the "Company") greatly appreciates your efforts on the Company's behalf. In connection with the Transaction (as defined below), the Company is offering you the opportunity to receive certain compensation and benefits as set forth below (this "Agreement"). The last date of your employment with the Company is referred to as the "Separation Date."

1. Conditioned on Closing of Transaction. The effectiveness of this Agreement is conditioned on the closing of the transactions contemplated by the Asset Purchase Agreement by and between the Company and Regeneron Pharmaceuticals, Inc., dated January 29, 2024 (the "Transaction" and such closing, the "Closing"). If the Closing does not occur, this Agreement shall be null and void *ab initio*.

2. Continued Vesting of Equity Awards and Exercise Extension. (i) Notwithstanding anything to the contrary in the Company's 2021 Stock Option and Incentive Plan, as amended from time to time (the "Plan"), or the applicable award agreement thereunder (collectively, the "Equity Documents"); (ii) subject to the approval of the Company's Board of Directors (the "Board"); (iii) provided that the Company does not terminate your employment and you do not resign, in either case prior to the Closing (such Closing, the "Equity Date"); and (iv) if you sign, do not revoke and comply with this Agreement:

    a. All of your Company stock options and other stock-based awards that remain outstanding and unvested as of the Equity Date that are subject solely to time-based vesting (the "Time-Based Equity") shall remain outstanding and shall continue to vest during the 12-month period immediately following the Equity Date (the "Equity Continuation Period") in accordance with the terms of Equity Documents notwithstanding that you will not have a continued Service Relationship (as defined in the Plan) during the Equity Continuation Period (such continued vesting, the "Equity Continuation"). During the Equity Continuation Period, and in the event of a Sale Event as such term is defined in the Plan, Section 3(a) of the Plan shall continue to apply to your Time-Based Equity.

    b. The period during which you may exercise your vested and exercisable stock options shall be extended until the last day of the Equity Continuation Period, but in no event later than the original expiration date of the applicable option (the "Exercise Period Extension"). You acknowledge that, as a result of the Exercise Period Extension, to the extent your stock options were incentive stock options, your stock options will convert from incentive stock options to nonqualified stock options on the date the Board approves the Exercise Period Extension. You are advised to seek tax guidance from your personal tax advisors with regard to the effect of the Exercise Period Extension on the tax treatment of your stock options. Except for the Equity Continuation and the Exercise Period Extension, your Company equity awards remain subject to the Equity Documents in all respects.

3. Release. In consideration for, among other terms, your eligibility for the Equity Continuation and the Exercise Period Extension, to which you acknowledge you would otherwise not be entitled, you voluntarily release and forever discharge the Company its affiliated and related entities, their respective predecessors, successors and assigns, their respective employee benefit plans and fiduciaries of such plans, and their current and former officers, directors, shareholders, employees, managers, members, trustees, attorneys, accountants and agents, in each case in their official and personal capacities (collectively referred to as the "Releasees") generally from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown ("Claims") that, as of the date when you sign this Agreement, you have, ever had, now claim to have or ever claimed to have had against any or all of the Releasees. This release includes, without limitation, all Claims relating to your employment by with the Company; under tort, contract or other common law; of retaliation or discrimination under federal, state or local law; under any other federal or state statute (including, without limitation, Claims of discrimination

or retaliation under the Age Discrimination in Employment Act, the Americans with Disabilities Act, Title VII of the Civil Rights Act of 1964, the New York State Human Rights Law, the New York Labor Law, the New York State Correction Law, the New York State Civil Rights Law, Section 125 of the New York Workers' Compensation Law, the New York City Human Rights Law and the New Jersey Conscientious Employee Protection Act); under MGL c. 151B; for wages, bonuses, incentive compensation, commissions, stock, stock options, vacation pay or any other compensation or benefits, either under the Massachusetts Wage Act, M.G.L. c. 149, §§148-150C, or otherwise; and for damages or other remedies of any sort, including, without limitation, compensatory damages, punitive damages, injunctive relief and attorney's fees. This Section does not release claims that cannot be released under applicable law.

You agree not to accept damages of any nature, other equitable or legal remedies for your own benefit or attorney's fees or costs from any of the Releasees with respect to any Claim released by this Agreement. As a material inducement to the Company to enter into this Agreement, you represent that you have not assigned any Claim to any third party.

4. Confidentiality. Subject to the "Protected Activities" Section below, since the Company has not offered the Equity Continuation and the Exercise Period Extension to all employees, you agree not to disclose the existence or terms of this arrangement to any other person or entity, except as necessary for addressing any matters concerning the administration of the Equity Continuation and the Exercise Period Extension or unless otherwise required by applicable law.

5. Nondisparagement. Subject to the "Protected Activities" Section below, you agree not to make any disparaging statements concerning the Company or any of its affiliates or current or former officers, directors, shareholders, employees or agents. These nondisparagement obligations shall not in any way affect your obligation to testify truthfully in any legal proceeding.

6. Resignations from Other Positions; Transition of Information and Access. In connection with the ending of your employment, you hereby (i) resign from any officer or other position you occupy at the Company, or any of its affiliates, effective as of the Separation Date (or such earlier date as the Company requests); (ii) agree to execute such documentation as the Company or its applicable affiliate reasonably requires to effectuate such resignations; and (iii) take such steps as the Company (or its applicable affiliate) reasonably requests to ensure the transition of any account access, systems access, password access, customer access, confidential information, Company property, customer information or customer relationships to the Company or its applicable affiliate.

7. Ongoing Obligations. Notwithstanding anything to the contrary set forth in your confidentiality and restrictive covenant obligations to the Company (the "Ongoing Obligations") you hereby agree that: (i) you are not eligible for any garden leave pay or other noncompetition consideration under the Ongoing Obligations, (ii) any post-employment noncompetition obligations to the Company, and your other obligations to the Company, under the Ongoing Obligations nevertheless remain in full effect; are fully enforceable, regardless of the circumstances of your termination; and are incorporated herein as if newly entered-into. You agree that your eligibility for compensation under this Agreement constitutes mutually agreed upon, fair and reasonable consideration for each of the Ongoing Obligations that is separate from your employment with the Company. You agree that you had the opportunity to review the Ongoing Obligations and this Agreement with the legal counsel of your choosing. The Ongoing Obligations, as modified herein, are incorporated herein by reference.

8. Protected Activities. Nothing contained in this Agreement or in any other agreement with the Company limits your ability to: (i) file a charge or complaint with any federal, state or local governmental agency or commission, including without limitation the Equal Employment Opportunity Commission, the National Labor Relations Board or the Securities and Exchange Commission (a "Government Agency"); (ii) communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency; (iii) exercise any rights you may have under Section 7 of the National Labor Relations Act, including any rights you may have under such provision to assist co-workers with or discuss any employment issue, dispute or term or condition of employment as part of engaging in concerted activities for the purpose of mutual aid or protection; (iv) discuss or disclose information about unlawful acts in the workplace, such as harassment or

discrimination or any other conduct that you have reason to believe is unlawful; or (v) testify truthfully in a legal proceeding, in any event with or without notice to or approval of the Company so long as such communications and disclosures are consistent with applicable law and the information disclosure was not obtained through a communication that was subject to the attorney client privilege (unless disclosure of that information would otherwise be permitted consistent with such privilege). If you file any charge or complaint with any Government Agency and if the Government Agency pursues any claim on your behalf, or if any other third party pursues any claim on your behalf, you waive any right to monetary or other individualized relief (either individually or as part of any collective or class action) but the Company will not limit any right you may have to receive an award by an order of a Government Agency pursuant to the whistleblower provisions of any applicable law or regulation for providing information to the SEC or any other Government Agency.

9. Preservation of At-Will Employment. Nothing in this letter changes the at-will nature of your employment with the Company.

10. Time for Consideration; Effective Date. You acknowledge that you have been given the opportunity to consider this Agreement for twenty-one (21) days before signing it (the "Consideration Period") and that you have knowingly and voluntarily entered into this Agreement. You acknowledge that the above release of claims expressly includes without limitation claims under the Age Discrimination in Employment Act. You are advised to consult with an attorney before signing this Agreement. To accept this Agreement, you must return a signed original or a signed PDF copy of this Agreement so that it is received by the undersigned at or before the expiration of the Consideration Period. If you sign this Agreement before the end of the Consideration Period, you acknowledge by signing this Agreement that such decision was entirely voluntary and that you had the opportunity to consider this Agreement for the entire Consideration Period. For the period of seven (7) business days from the date when you sign this Agreement (the "Revocation Period"), you have the right to revoke this Agreement by written notice to the undersigned. For such a revocation to be effective, it must be delivered so that it is received by the undersigned at or before the expiration of the Revocation Period. This Agreement shall not become effective or enforceable during the Revocation Period.

11. Governing Law; Jurisdiction; Amendment and Waiver. This letter shall be governed by Massachusetts (the "State") law, excluding laws relating to conflicts or choice of law. You, the Company submit to the exclusive personal jurisdiction and venue of the federal and state courts located in the State in connection with any dispute relating to this letter. This letter may not be modified or amended, and no breach shall be deemed to be waived, unless agreed to in writing by you and the Chief Executive Officer of the Company.

12. 409A. It is intended that the benefits provided under this Agreement shall comply with the provisions of Section 409A of the Internal Revenue Code ("Section 409A") or qualify for an exemption from Section 409A, and this Agreement shall be construed and interpreted in accordance with such intent. Any payments that qualify for the "short term deferral" exception or another exception under Section 409A shall be paid under the applicable exception. Each payment provided under this Agreement shall be treated as a separate payment for Section 409A purposes. Neither the Company (or its affiliates) or any employee, officer or director of the Company (or its affiliates) shall be held liable for any taxes, interest, penalties or other monetary amounts owed by you as a result of this Agreement.

13. No Severance. To avoid doubt, in entering into this Agreement, in consideration for the opportunity to receive the Equity Continuation and the Exercise Period Extension provided herein, you hereby waive any right or potential right you may have to receive any severance or change in control compensation or benefits under your employment agreement, under any Company severance plan or under any other agreement or arrangement with the Company.

14. Assignment. The Company may assign its rights and obligations under this Agreement without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets. You may not assign this Agreement.

15. Integration. This Agreement, together with the Equity Documents (as modified by this Agreement) constitutes the entire agreement between you and the Company specifically with respect to the subject matter herein, and supersedes any prior communications, understandings or agreements with respect to the subject matter herein. In signing this Agreement, you agree that you are not relying on any promise, agreement or representation of or with the Company, except as is expressly contained herein. Nothing in this Agreement affects your restrictive covenant obligations and your other ongoing obligations to the Company and its affiliates (as applicable), each of which obligation remains in effect and is hereby reaffirmed.

The Company hopes that this letter encourages your continued effective commitment to the Company.

Sincerely,

The Company

/s/ Nick Leschly

Nick Leschly
Chief Executive Officer

ACCEPTED AND AGREED:

/s/ Philip Gregory
Philip Gregory

FDA Advisory Committee Votes in Favor of Bristol Myers Squibb's and 2seventy bio's *Abecma* for Triple-Class Exposed Multiple Myeloma in Earlier Lines of Therapy

The supplemental Biologics License Application for* Abecma *in this indication remains under review with the FDA; Abecma has been approved in Japan and Switzerland and received a positive CHMP Opinion by the European Medicines Agency based on KarMMa-3

(PRINCETON, N.J., & CAMBRIDGE, Mass., March 15, 2024) – Bristol Myers Squibb (NYSE: BMY) and 2seventy bio, Inc. (Nasdaq: TSVT) today announced that the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) voted positively (8-3) that *Abecma* (idecabtagene vicleucel) demonstrated a favorable benefit/risk profile for patients with triple-class exposed relapsed or refractory multiple myeloma based on results from the pivotal Phase 3 KarMMa-3 study, including the key secondary endpoint of overall survival. The recommendation from the ODAC will be considered by the FDA during its ongoing review of the supplemental Biologics License Application (sBLA) for *Abecma* for this patient population. The FDA has not yet assigned a new target action date for review of the sBLA.

"We are extremely pleased with the positive outcome of the ODAC meeting, which recognizes the favorable benefit/risk profile of *Abecma,* and based on results from the KarMMa-3 study, we are confident in the significant clinical benefit that *Abecma* delivers for patients with triple-class exposed relapsed or refractory multiple myeloma, an incurable disease with no clear effective standard of care in earlier lines of therapy," said Anne Kerber, senior vice president, head of Late Clinical Development, Hematology, Oncology and Cell Therapy, Bristol Myers Squibb. "We look forward to working with the FDA as it completes review of our sBLA in order to bring this potentially transformative therapy to more patients in need."

"The favorable and supportive outcome of the ODAC meeting brings us another step closer to expanding the benefits of *Abecma* to myeloma patients earlier in their treatment course," said Anna Truppel-Hartmann, senior vice president, Clinical Research and Development, 2seventy bio. "We believe in the strength of the KarMMa-3 data and remain committed to increasing treatment options and improving outcomes for patients living with multiple myeloma."

The positive vote from the ODAC followed discussion of the interim overall survival data from the KarMMa-3 study which was presented at the 2023 American Society of Hematology (ASH) Annual Meeting and Exposition in December 2023.

"With patients becoming triple-class exposed earlier in the multiple myeloma treatment paradigm, it is critical that new treatment options with the potential to improve long-term outcomes are available as early as possible," said Sagar Lonial, MD, FACP, professor and chair, Department of Hematology & Medical Oncology, Emory University School of Medicine, chief medical officer, Winship Cancer Institute of Emory University. "We are thankful that today's ODAC vote recognizes this unmet need and helps to advance ide-cel, a novel treatment option with demonstrated clinically meaningful benefit, for patients with triple-class exposed relapsed or refractory multiple myeloma."

Abecma was recently approved in Japan and Switzerland for patients with relapsed and/or refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody based on the KarMMa-3 study, making it the first CAR T cell therapy to receive regulatory approval for use in earlier lines of therapy for patients with relapsed or refractory multiple myeloma. *Abecma* also received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the extension of indication to include the treatment of patients with triple-class exposed relapsed and refractory multiple myeloma after at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

About *Abecma*

Abecma is a CAR T cell therapy that recognizes and binds to the B-cell maturation antigen (BCMA) on the surface of multiple myeloma cells leading to CAR T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells. *Abecma* is the first-in-class BCMA-directed CAR T cell immunotherapy approved by the U.S. FDA for the treatment of adult patients with relapsed or

refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Please see the Important Safety Information section below, including Boxed WARNINGS for *Abecma* regarding CRS, neurologic toxicities, Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome and Prolonged Cytopenia. *Abecma* is being jointly developed and commercialized in the U.S. as part of a Co-Development, Co-Promotion, and Profit Share Agreement between Bristol Myers Squibb and 2seventy bio.

Abecma is also approved in the European Union, Switzerland, Japan, the United Kingdom and Israel for adult patients with triple-class exposed relapsed or refractory multiple myeloma after three to four or more prior lines of therapy. Bristol Myers Squibb assumes sole responsibility for *Abecma* drug product manufacturing and commercialization outside of the U.S.

The companies' broad clinical development program for *Abecma* includes ongoing and planned clinical studies (KarMMa-2, KarMMa-9) for patients with multiple myeloma. For more information visit clinicaltrials.gov.

U.S. Important Safety Information

BOXED WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, AND PROLONGED CYTOPENIA

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with ABECMA. Do not administer ABECMA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurologic Toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with ABECMA. Provide supportive care and/or corticosteroids as needed.
- Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS) including fatal and life-threatening reactions, occurred in patients following treatment with ABECMA. HLH/MAS can occur with CRS or neurologic toxicities.
- Prolonged Cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with ABECMA.
- ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.

WARNINGS AND PRECAUTIONS:

Cytokine Release Syndrome (CRS): CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA in 85% (108/127) of patients. Grade 3 or higher CRS occurred in 9% (12/127) of patients, with Grade 5 CRS reported in one (0.8%) patient. The median time to onset of CRS, any grade, was 1 day (range: 1 - 23 days) and the median duration of CRS was 7 days (range: 1 - 63 days). The most common manifestations included pyrexia, hypotension, tachycardia, chills, hypoxia, fatigue, and headache. Grade 3 or higher events that may be associated with CRS include hypotension, hypoxia, hyperbilirubinemia, hypofibrinogenemia, acute respiratory distress syndrome (ARDS), atrial fibrillation, hepatocellular injury, metabolic acidosis, pulmonary edema, multiple organ dysfunction syndrome, and HLH/MAS.
Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Fifty four percent (68/127) of patients received tocilizumab (single dose: 35%; more than 1 dose: 18%). Overall, 15% (19/127) of patients received at least 1 dose of corticosteroids for treatment of CRS. All patients that received corticosteroids for CRS received tocilizumab. Ensure that a minimum of 2 doses of tocilizumab are available prior to infusion of ABECMA.
Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of CRS and monitor patients for signs or symptoms of CRS for at least 4 weeks after ABECMA infusion. At the first sign of CRS, institute treatment with supportive care, tocilizumab and/or corticosteroids as indicated.
Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.
Neurologic Toxicities: Neurologic toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA in 28% (36/127) of patients receiving ABECMA, including Grade 3 in 4% (5/127) of patients. One patient had ongoing Grade 2 neurotoxicity at the time of death. Two patients had ongoing Grade 1 tremor at the time of data cutoff. The median time to onset of neurotoxicity was 2 days (range: 1 - 42 days). CAR T cell-associated neurotoxicity resolved in 92% (33/36) of patients with a median time to resolution of 5 days (range: 1 - 61 days). The median duration of neurotoxicity was 6 days (range: 1 - 578) in all patients including 3 patients with ongoing neurotoxicity. Thirty-four patients with neurotoxicity had CRS with onset in 3 patients before, 29 patients during, and 2 patients after CRS. The most frequently reported manifestations of CAR T cell-associated neurotoxicity include encephalopathy, tremor, aphasia, and delirium. Grade 4 neurotoxicity and cerebral edema in 1 patient, Grade 3 myelitis, and Grade 3 parkinsonism have been reported with ABECMA in another study in multiple myeloma.
Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of neurologic toxicities and monitor patients for signs or symptoms of neurologic toxicities for at least 4 weeks after ABECMA infusion and treat promptly. Rule out other causes of neurologic symptoms. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Counsel patients to seek immediate medical attention should signs or symptoms occur at any time.
Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS): HLH/MAS occurred in 4% (5/127) of patients receiving ABECMA. One patient developed fatal multi-organ HLH/MAS with CRS and another patient developed fatal bronchopulmonary aspergillosis with contributory HLH/MAS. Three cases of Grade 2 HLH/MAS resolved. All events of HLH/MAS had onset within 10 days of receiving ABECMA with a median onset of 7 days (range: 4 - 9 days) and occurred in the setting of ongoing or worsening CRS. Two patients with HLH/MAS had overlapping neurotoxicity. The manifestations of HLH/MAS include hypotension, hypoxia, multiple organ dysfunction, renal dysfunction, and cytopenia. HLH/MAS is a potentially life-threatening condition with a high mortality rate if not recognized early and treated. Treatment of HLH/MAS should be administered per institutional guidelines.
ABECMA REMS: Due to the risk of CRS and neurologic toxicities, ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS. Further information is available at www.AbecmaREMS.com or 1-888-423-5436.
Hypersensitivity Reactions: Allergic reactions may occur with the infusion of ABECMA. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) in ABECMA.
Infections: ABECMA should not be administered to patients with active infections or inflammatory disorders. Severe, life-threatening, or fatal infections occurred in patients after ABECMA infusion. Infections (all grades) occurred in 70% of patients. Grade 3 or 4 infections occurred in 23% of patients. Overall, 4 patients had Grade 5 infections (3%); 2 patients (1.6%) had Grade 5 events of pneumonia, 1 patient (0.8%) had Grade 5 bronchopulmonary aspergillosis, and 1 patient (0.8%) had cytomegalovirus (CMV) pneumonia associated with Pneumocystis jirovecii. Monitor patients for signs and symptoms of infection before and after ABECMA infusion and treat appropriately. Administer prophylactic, pre-emptive, and/or therapeutic antimicrobials according to standard institutional guidelines.
Febrile neutropenia was observed in 16% (20/127) of patients after ABECMA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care.
Viral Reactivation: CMV infection resulting in pneumonia and death has occurred following ABECMA administration. Monitor and treat for CMV reactivation in accordance with clinical guidelines. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against plasma cells. Perform screening for CMV, HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines before collection of cells for manufacturing.
Prolonged Cytopenias: In the clinical study, 41% of patients (52/127) experienced prolonged Grade 3 or 4 neutropenia and 49% (62/127) experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Month 1 following ABECMA infusion. In 83% (43/52) of patients who recovered from Grade 3 or 4 neutropenia after Month 1, the median time to recovery from ABECMA infusion was 1.9 months. In 65% (40/62) of

patients who recovered from Grade 3 or 4 thrombocytopenia, the median time to recovery was 2.1 months. Three patients underwent stem cell therapy for hematopoietic reconstitution due to prolonged cytopenia. Two of the three patients died from complications of prolonged cytopenia. Monitor blood counts prior to and after ABECMA infusion. Manage cytopenia with myeloid growth factor and blood product transfusion support.
Hypogammaglobulinemia: Hypogammaglobulinemia was reported as an adverse event in 21% (27/127) of patients; laboratory IgG levels fell below 500 mg/dl after infusion in 25% (32/127) of patients treated with ABECMA. Monitor immunoglobulin levels after treatment with ABECMA and administer IVIG for IgG <400 mg/dl. Manage appropriately per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.
The safety of immunization with live viral vaccines during or after ABECMA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during ABECMA treatment, and until immune recovery following treatment with ABECMA.
Secondary Malignancies: Patients treated with ABECMA may develop secondary malignancies. Monitor life-long for secondary malignancies. If a secondary malignancy occurs, contact Bristol-Myers Squibb at 1-888-805-4555 to obtain instructions on patient samples to collect for testing of secondary malignancy of T cell origin.
Effects on Ability to Drive and Operate Machinery: Due to the potential for neurologic events, patients receiving ABECMA are at risk for altered or decreased consciousness or coordination in the 8 weeks following ABECMA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.
Adverse Reactions: The most common nonlaboratory adverse reactions include CRS, infections – pathogen unspecified, fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite.
Please see full Prescribing Information, including **Boxed WARNINGS** and Medication Guide.

Bristol Myers Squibb: Creating a Better Future for People with Cancer
Bristol Myers Squibb is inspired by a single vision — transforming patients' lives through science. The goal of the company's cancer research is to deliver medicines that offer each patient a better, healthier life and to make cure a possibility. Building on a legacy across a broad range of cancers that have changed survival expectations for many, Bristol Myers Squibb researchers are exploring new frontiers in personalized medicine and, through innovative digital platforms, are turning data into insights that sharpen their focus. Deep understanding of causal human biology, cutting-edge capabilities and differentiated research platforms uniquely position the company to approach cancer from every angle.

Cancer can have a relentless grasp on many parts of a patient's life, and Bristol Myers Squibb is committed to taking actions to address all aspects of care, from diagnosis to

survivorship. As a leader in cancer care, Bristol Myers Squibb is working to empower all people with cancer to have a better future.

Learn more about the science behind cell therapy and ongoing research at Bristol Myers Squibb here.

About Bristol Myers Squibb
Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube, Facebook and Instagram.

About 2seventy bio
Our name, 2seventy bio, reflects why we do what we do - TIME. Cancer rips time away, and our goal is to work at the maximum speed of translating human thought into action – 270 miles per hour – to give the people we serve more time. With a deep understanding of the human body's immune response to tumor cells and how to translate cell therapies into practice, we're applying this knowledge to deliver the first FDA-approved CAR T cell therapy for multiple myeloma. We are focused on delivering therapies that are designed with the goal to "think" smarter and faster than the disease. Importantly, we remain focused on accomplishing these goals by staying genuine and authentic to our "why" and keeping our people and culture top of mind every day.

For more information, visit www.2seventybio.com.

Follow 2seventy bio on social media: Twitter and LinkedIn.

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Bristol Myers Squibb Cautionary Statement Regarding Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that future study results may not be consistent with the results to date, that Abecma® (idecabtagene vicleucel) may not receive regulatory approval for the additional indication described in this release in the currently anticipated timeline or at all, that any marketing approvals, if granted, may have significant limitations on their use, and, if approved, whether such product candidate for such additional indication described in this release will be commercially successful. No forward-looking statement can be guaranteed. It should also be noted that acceptance of the sBLA does not change the standards for FDA approval, that validation by the EMA of the application does not change the standards for EMA approval, and that acceptance of the sNDA does not change the

standards for Japan's Ministry of Health, Labour and Welfare approval. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb's business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2023, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

2seventy bio Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of Abecma® (idecabtagene vicleucel). All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, the possibility that Abecma may not receive FDA approval for the indication described in this release in the currently anticipated timeline or at all, that any marketing approvals, if granted, may have significant limitations on their use, that future study results may not be consistent with the results to date, that Abecma may not be commercially successful and that collaboration with Bristol Myers Squibb may not continue or be successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect 2seventy bio's business, particularly those identified in the risk factors discussion in 2seventy bio's Annual Report on Form 10-K, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, 2seventy bio undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

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