2seventy bio Provides Company Outlook for 2023

January 9, 2023 1:00 PM EST

Anticipate $470-$570M topline U.S. revenue Abecma *(idecabtagene vicleucel) in 2023, shared equally with Bristol Myers Squibb (BMS)*

KarMMa-3 data to be presented at EBMT-EHA 5th European CAR T-cell Meeting on February 10, 2023; 3L+ sBLA submission for Abecma *targeted completion in Q1*

Expanded translational collaboration with Regeneron to explore and fund cell therapy combinations in solid tumors

Enrollment progress across clinical-stage programs – on track for data readouts in 2023

Cash runway into 2025 and path to financial sustainability

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 9, 2023-- 2seventy bio, Inc. (Nasdaq: TSVT) announced today key corporate milestones and financial outlook for 2023.

“2022 was the launch year of 2seventy bio and we made important progress establishing the fundamentals of our business,” said Nick Leschly, chief kairos officer. “We focused on bringing *Abecma*, our first-in-class BCMA CAR T for multiple myeloma, to as many patients in need as possible. Together with BMS, we made significant progress in scaling our manufacturing capacity as well as delivering positive data from our KarMMa-3 study almost one year ahead of schedule. In 2023, our goals include expanding the *Abecma* label, launching a study of *Abecma* in newly diagnosed patients, and continuing to increase our manufacturing capacity to drive toward the potential $2-3B U.S. peak sales opportunity. In 2022, we also were able to double down on our differentiated cell therapy science and translational platform to more fully unleash the curative potential of the T cell. On this dimension, we initiated enrollment on two first of kind clinical studies in B-NHL and AML with data expected throughout 2023. We also advanced several solid tumor programs toward the clinic and expanded our translational plans with Regeneron. Importantly, we are nearing completion of our 270-MPH in-house clinical drug product manufacturing site adding to our relationship with JW Therapeutics to accelerate clinical product development in China and more effectively support our growing U.S. clinical needs. Finally, we set a strong people and culture foundation that is passionately committed to finding a way to give back priceless time to the patients and families we serve.”

***Abecma* Outlook**

Commercial Performance and Manufacturing Progress

Commercial demand for *Abecma* (idecabtagene vicleucel) remained strong throughout 2022. 2seventy bio and BMS increased manufacturing capacity and made important progress on key supply chain metrics, including delivering drug product at an average in-spec rate of 85-90% with a turnaround time (time from patient apheresis to delivery of *Abecma*) of approximately 30 days. As previously stated, 2seventy bio anticipates reaching the upper end of $250-$300M for topline U.S. revenue in 2022.

In 2023, the company anticipates continued increases in vector and drug product manufacturing capacity, including an additional adherent vector manufacturing suite, enabling topline U.S. revenue of $470-$570M. Looking out into 2024-25, 2seventy bio expects further commercial growth with an anticipated label expansion. With this growth, 2seventy bio expects *Abecma* to generate $200-300M in operating income for 2seventy bio in the 2024-25 period.

KarMMa-3 Results and Regulatory Plans

In August 2022, BMS and 2seventy bio disclosed that KarMMa-3, a Phase 3 study comparing *Abecma* to standard combination regimens in adults with multiple myeloma that is relapsed and refractory after two to four prior lines of therapy and refractory to the last regimen, had met its primary endpoint. Results of a pre-specified interim analysis showed that KarMMa-3 met its primary endpoint of demonstrating a statistically significant improvement in progression-free survival. Treatment with *Abecma* also showed an improvement in the key secondary endpoint of overall response rate compared to standard regimens. Follow-up for overall survival, a key secondary endpoint, remains ongoing.

The full data from this study will be presented at the EBMT-EHA 5th European CAR T-cell meeting in Rotterdam (Netherlands) on February 10, 2023. Abstracts for this meeting are currently available on the conference website. Based on the positive data, the companies anticipate submitting a supplemental Biologics Licensing Application (sBLA) to the U.S. FDA in Q1 2023, with potential approval also in 2023.

KarMMa-2 Results and Planned Study in Newly Diagnosed Multiple Myeloma

At ASH 2022, BMS and 2seventy bio presented data from two arms of the KarMMa-2 study. These data suggest that *Abecma* can provide significant clinical benefit to patients with suboptimal response to transplant and support further evaluation of *Abecma* in newly diagnosed patients in the KarMMa-9 study, with planned study initiation in 2023.

The KarMMa-9 study is anticipated to enroll patients with newly diagnosed multiple myeloma who have suboptimal response to transplant, which represents a patient population with an unfavorable outcome. Of the approximately 70% of newly diagnosed multiple myeloma patients who are eligible and chose to receive transplant, up to 50% do not achieve complete response post-transplant, underscoring the high unmet need in this population.

Next-Gen Cell Therapy Product Engine and Pipeline

Pipeline Programs Update

- **bbT369**: In 2022, 2seventy bio made meaningful progress in enrolling patients with relapsed and/or refractory B cell non-Hodgkin lymphoma (B-NHL) in its Phase I CRC-403 study of

bbT369, an investigational novel CD79a/CD20 dual-targeting *CBLB* gene edited CAR T cell therapy. At the end of 2022, 2seventy bio completed the first cohort of dose-escalation. There were no dose-limiting toxicities observed to-date. The manufacturing success rate was high and turnaround time was in line with other autologous CAR Ts despite the additional complexity of this product. Patient enrollment in CRC-403 continues at the second dose level, and 2seventy bio anticipates sharing a data update in 2023.

- **SC-DARIC33:** 2seventy bio and Seattle Children's Research Institute (SCRI) is nearing completion of the mandatory adult dosing phase of a Phase 1 study evaluating our rapamycin-regulated CAR T cell therapy in patients with acute myeloid leukemia (AML); the totality of the initial data to-date suggests SC-DARIC33 activation by rapamycin. Patient enrollment in PLAT-08 continues, and, with SCRI, we expect to present initial clinical data in 2023. Additionally, a next-generation AML product concept has been selected and will enter non-clinical development in 2023. This new candidate is built off of our new RESET receptor architecture and incorporates dual targeting along with a potency enhancement while retaining the DARIC-like drug-regulation.
- **MUC16:** In collaboration with Regeneron, we anticipate an Investigational New Drug application in 2023 for our CAR T targeting MUC16 in patients with relapsed/refractory ovarian cancer. This first-in-human study will prospectively include combination agents, including those in Regeneron's pipeline, and will be the first program to utilize 2seventy bio's new in-house drug product manufacturing facility.
- **MAGE-A4:** In 2022, 2seventy bio entered into an agreement with JW Therapeutics to clinically evaluate 2seventy bio's potency enhanced MAGE-A4 TCR program in solid tumors which is being developed as part of a collaboration with Regeneron. MAGE-A4 is a member of the MAGE family of cancer-testis antigens expressed in a number of solid tumor types. JW Therapeutics plans an investigator-initiated trial in China in 2023, initially focused on esophageal carcinoma.

Regeneron Collaboration Amendment
Last week, 2seventy bio announced an expanded translational collaboration with Regeneron to facilitate the acceleration of novel cell therapy-based combinations for solid tumors. The collaboration will leverage 2seventy bio's unique cell therapy engineering and early-stage development capabilities, including the newly built in-house clinical cell therapy manufacturing facility, with Regeneron's differentiated antibodies and bispecifics.

To support this expanded clinical development plan Regeneron made a $20 million equity investment in 2seventy bio at a 50% premium and has committed to another $20 million in near-term pre-clinical and clinical milestones. The parties will continue sharing costs for these activities in a manner largely consistent with the existing agreement, with Regeneron covering 75% of certain preclinical costs necessary to study combinations and 100% of the costs for the arms of the clinical studies that include Regeneron agents through regulatory approval. For other programs, cost-sharing will follow the existing 50/50 cost sharing agreement.

Preliminary 2023 Financial Outlook
2seventy bio entered 2023 with approximately $268M in cash, cash equivalents and marketable securities and incurred net cash spend of approximately $260M in 2022, driven in part by upfront investments in *Abecma* manufacturing. In early January 2023, the Company received a $20M equity investment as part of its expanded Regeneron collaboration resulting in a cash balance of approximately $288M at the start of 2023. Based on its current operating plan, 2seventy bio anticipates net cash spend of $180 – 220M in 2023 and expects net cash spend to be meaningfully lower in 2024 due to the projected continued U.S. *Abecma* commercial ramp and improving profitability. The range on *Abecma* revenue guidance for 2023 and *Abecma* cash flow in 2024 and 2025 reflects the variability in timing of regulatory approvals for vector and drug product capacity increases. Our base case operating plan assumes continued success in vector and drug product scale up for *Abecma* and under this plan, the Company anticipates that its cash will be sufficient to fund current planned operations into early 2025.

"In addition to scientific innovation and patient focus, we are 2x focused on building a cell therapy company that is fit for purpose with a path to financial sustainability," said Chip Baird, chief financial officer. "Our 2022 net cash spend of approximately $260M was impacted by significant upfront investments in *Abecma* manufacturing that made the year our high-water mark in terms of our annual net cash spend. Looking forward, we see *Abecma* contributing cash back to the business in 2023, with significant growth in *Abecma* cash flow in 2024-25. Over the next three years, we plan to maximize the cash flow from the *Abecma* business, carefully manage expenses, and look to continue to be active on the corporate development front to deliver transformative medicines to the patients we serve while generating value for our shareholders."

Updated Corporate Presentation
These updates and additional information can be found in the company's updated corporate presentation, which can be found in the investor section of www.2seventybio.com.

About bbT369
bbT369 is an investigational dual-targeting CAR T cell therapy with a gene edit being evaluated for the treatment of patients with relapsed and/or refractory B-NHL. In the 3L+ relapsed and/or refractory B-NHL setting, 60-70% of patients treated with commercially available CAR T cell therapies do not achieve a long-term remission, highlighting a significant unmet clinical need.

To address this unmet need, bbT369 has been designed with three layers of innovation that aim to address several potential mechanisms of anti-CD19

CAR T cell therapy failure: dual targeting (CD79a/CD20), split co-stimulation signaling technology, and a gene edit to remove the function of CBLB.

In December 2021, the FDA cleared the Investigational New Drug (IND) application for bbT369.

The clinical development program for bbT369 includes the Phase 1/2 CRC-403 study (NCT05169489). Safety and potential efficacy of bbT369 in patients with specific subtypes of relapsed and/or refractory B-NHL will be assessed, including patients who relapsed after CD19 CAR T cell therapy as well as patients who are CAR-naïve.

bbT369 is not approved for any indication in any geography.

About SC-DARIC33
SC-DARIC33 is an investigational CD33-specific cell therapy that utilizes 2seventy bio's proprietary Dimerizing Agent Regulated Immunoreceptor Complex (DARIC) T cell platform. SC-DARIC33 is designed as a regulatable, potentially first-in-class autologous T cell therapy and is now being studied at Seattle Children's in a Phase 1 trial, PLAT-08 (NCT05105152), as a first-in-human investigation of the DARIC T cell platform in relapsed/refractory pediatric and young adult AML.

DARIC separates the antigen binding and signaling functions of a CAR, with the intent that these two components are brought together by the small molecule rapamycin (RAPA), resulting in a functional CAR construct. In preclinical studies, SC-DARIC33 has shown robust drug-dependent anti-tumor activity (similar to CD19 CAR T controls). Importantly, SC-DARIC33 has been shown to be activated by low non-immunosuppressive concentrations of RAPA in the blood and, when RAPA is removed, DARIC returns to an inactive state. SC-DARIC33 tests the hypothesis that a pharmacologically regulated CAR can enable potent AML targeting while limiting toxicities associated with normal myeloid and myeloid progenitor cell targeting.

The investigation of SC-DARIC33 in the Phase 1 PLAT-08 study of pediatric and young adult AML patients and the scientific translation of these data are intended to establish the safety profile of SC-DARIC33 and evaluate feasibility of the reversable modulation (OFF-ON-OFF) of SC-DARIC33.

About KarMMa-3
KarMMa-3 (NCT03651128) is a pivotal, Phase 3, global, randomized, multicenter trial evaluating *Abecma* compared to standard regimens in patients with multiple myeloma that is relapsed and refractory after two to four prior lines of treatment and refractory to the last treatment regimen. Patients were randomized to receive *Abecma* or standard regimens that consisted of combinations that included daratumumab, pomalidomide, dexamethasone, bortezomib, ixazomib, lenalidomide, carfilzomib or elotuzumab. The primary endpoint evaluated in this study is progression-free survival, defined as time from randomization to the first documentation of progressive disease or death due to any cause, whichever occurs first. Key secondary endpoints include overall response rate and overall survival.

About *Abecma*
Abecma is the first-in-class B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy approved in the U.S. 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. *Abecma* recognizes and binds to 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 was approved by the U.S. Food and Drug Administration (FDA) in March 2021 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 cytokine release syndrome, 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.

The companies' broad clinical development program for *Abecma* includes clinical studies (KarMMa-2, KarMMa-3, KarMMa-7, KarMMa-9) in earlier lines of treatment for patients with multiple myeloma. For more information visit clinicaltrials.gov.

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.

Cytokine Release Syndrome (CRS): CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA. CRS occurred in 85% (108/127) of patients receiving ABECMA. Grade 3 or higher CRS (Lee grading system) 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) in all patients including the patient who died. The most common manifestations of CRS included pyrexia (98%), hypotension

(41%), tachycardia (35%), chills (31%), hypoxia (20%), fatigue (12%), and headache (10%). 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. HLH/MAS is a potentially life-threatening condition. 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; 35% (45/127) received a single dose while 18% (23/127) received more than 1 dose of tocilizumab. Overall, across the dose levels, 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.

Overall rate of CRS was 79% and rate of Grade 2 CRS was 23% in patients treated in the 300 x 10^6 CAR+ T cell dose cohort. For patients treated in the 450 x 10^6 CAR+ T cell dose cohort, the overall rate of CRS was 96% and rate of Grade 2 CRS was 40%. Rate of Grade 3 or higher CRS was similar across the dose range. The median duration of CRS for the 450 x 10^6 CAR+ T cell dose cohort was 7 days (range: 1-63 days) and for the 300 x 10^6 CAR+ T cell dose cohort was 6 days (range: 2-28 days). In the 450 x 10^6 CAR+ T cell dose cohort, 68% (36/53) of patients received tocilizumab and 23% (12/53) received at least 1 dose of corticosteroids for treatment of CRS. In the 300 x 10^6 CAR+ T cell dose cohort, 44% (31/70) of patients received tocilizumab and 10% (7/70) received corticosteroids. All patients that received corticosteroids for CRS also 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 and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 4 weeks after 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, including concurrently with CRS, after CRS resolution, or in the absence of CRS. CAR T cell-associated neurotoxicity occurred 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 duration of neurotoxicity was 5 days (range: 1 - 61 days). The median duration of neurotoxicity was 6 days (range: 1 - 578) in all patients including those with ongoing neurotoxicity at the time of death or data cut off. Thirty-four patients with neurotoxicity had CRS. Neurotoxicity had onset in 3 patients before, 29 patients during, and 2 patients after CRS. The rate of Grade 3 neurotoxicity was 8% in the 450 x 10^6 CAR+ T cell dose cohort and 1.4% in the 300 x 10^6 CAR+ T cell dose cohort. The most frequently reported (greater than or equal to 5%) manifestations of CAR T cell-associated neurotoxicity include encephalopathy (20%), tremor (9%), aphasia (7%), and delirium (6%). Grade 4 neurotoxicity and cerebral edema in 1 patient has been reported with ABECMA in another study in multiple myeloma. Grade 3 myelitis and Grade 3 parkinsonism have been reported after treatment 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 and symptoms of neurologic toxicities. Rule out other causes of neurologic symptoms. Monitor patients for signs or symptoms of neurologic toxicities for at least 4 weeks after infusion and treat promptly. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Counsel patients to seek immediate medical attention should signs or symptoms of neurologic toxicity occur at any time.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS): HLH/MAS occurred in 4% (5/127) of patients receiving ABECMA. One patient treated in the 300 x 10^6 CAR+ T cell dose cohort developed fatal multi-organ HLH/MAS with CRS. In another patient with fatal bronchopulmonary aspergillosis, HLH/MAS was contributory to the fatal outcome. Three cases of Grade 2 HLH/MAS resolved. The rate of HLH/MAS was 8% in the 450 x 10^6 CAR+ T cell dose cohort and 1% in the 300 x 10^6 CAR+ T cell dose cohort. 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 standards.

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, preemptive, 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 as medically indicated.

Viral Reactivation: Cytomegalovirus (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: Patients may exhibit prolonged cytopenias following lymphodepleting chemotherapy and ABECMA infusion. In the KarMMa 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. Rate of prolonged neutropenia was 49% in the 450 x 10^6 CAR+ T cell dose cohort and 34% in the 300 x 10^6 CAR+ T cell dose cohort. 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. Median time to cytopenia recovery was similar across the 300 and 450 x 10^6 dose cohort.

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 according to institutional guidelines.

Hypogammaglobulinemia: Plasma cell aplasia and hypogammaglobulinemia can occur in patients receiving treatment with ABECMA. 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 per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

The safety of immunization with live viral vaccines during or following 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, including altered mental status or seizures, 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 (incidence greater than or equal to 20%) 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.

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. We are building the leading immuno-oncology cell therapy company, focused on discovering and developing new therapies that truly disrupt the cancer treatment landscape 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 next generation cellular therapies that focus on a broad range of hematologic malignancies, including the first FDA-approved CAR T cell therapy for multiple myeloma, as well as solid tumors. Our research and development is 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.

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. 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 statements include, but are not limited to, statements about: the research, development, and commercialization of Abecma; our plans, strategies, timelines and expectations with respect to the development, manufacture or sale of our product candidates, including the initiation and completion of pre-clinical and clinical studies; ; anticipated revenues and operating income resulting from sales of Abecma and related financial contribution and cash flow; the potential expansion of the Abecma label; launching a study in newly diagnosed patents; expected increases in vector and drug product manufacturing; the potential U.S. peak sales opportunity for Abecma; the timing or likelihood of regulatory filings and acceptances and approvals thereof; timelines for the initiation and results of ongoing and planned clinical trials for our product candidates; expectations regarding Abecma financial expectations regarding our use of capital, expenses and other future financial results, including our net cash spend in 2023 and 2024 and cash runway. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation,; the risk that interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data; the risk that we may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities; the risk that the market opportunities for our approved product or any future approved product are smaller than we believe they are; the risk that BMS, upon whom we rely for the successful development and commercialization of Abecma does not devote sufficient resources thereto, is unsuccessful in its efforts, or chooses to terminate its agreements with us; the risk that we and/or BMS will be unable to increase manufacturing and supply capacity for Abecma; the risk that our BLAs and INDs will not be accepted for filing by the FDA on the timeline that we expect, or at all; the risk that our plans with respect to the preclinical and clinical development and regulatory approval of our product candidates may not be successfully achieved on the planned timeline, or at all; the risk that Abecma will not be as commercially successful as we may anticipate; and the risk that we are unable to manage our operating expenses or cash use for operations. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230109005455/en/

2seventy contacts:
Investors:
Elizabeth Pingpank
860-463-0469
elizabeth.pingpank@2seventybio.com

Media:
Morgan Adams
774.313.9852
morgan.adams@2seventybio.com

Jenn Snyder
617-448-0281
jenn.snyder@2seventybio.com

Source: 2seventy bio, Inc.