



## **Abecma (idecabtagene vicleucel) Reduced the Risk of Disease Progression or Death by 51% Versus Standard Regimens in Earlier Lines of Therapy for Relapsed and Refractory Multiple Myeloma Based on Results from Phase 3 KarMMa-3 Study**

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***Abecma more than tripled progression-free survival (13.3 months vs. 4.4 months) compared with standard regimens for triple-class exposed multiple myeloma***

***Safety results were consistent with the well-established and predictable safety profile of Abecma***

***Abecma is the first and only CAR T cell therapy to demonstrate superiority over standard regimens in triple-class exposed relapsed and refractory multiple myeloma in a randomized, controlled Phase 3 trial***

***Data published in The New England Journal of Medicine and presented at the EBMT and the European Hematology Association's 5<sup>th</sup> European CAR T-cell Meeting***

PRINCETON, N.J., & CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Bristol Myers Squibb](#) (NYSE: BMY) and [2seventy bio, Inc.](#) (Nasdaq: TSVT) today announced the first [publication](#) and presentation of positive results from KarMMa-3, a pivotal Phase 3, open-label, global, randomized, controlled study evaluating *Abecma* (idecabtagene vicleucel) compared with standard combination regimens in adults with relapsed and refractory multiple myeloma after two to four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody, and who were refractory to their last regimen. Data from KarMMa-3 are being published in *The New England Journal of Medicine* and simultaneously presented at the EBMT and the European Hematology Association's (EHA) 5<sup>th</sup> European CAR T-cell Meeting on Friday, February 10 in an oral presentation during the Best Abstract Session.

At a median follow up of 18.6 months, treatment with *Abecma* (n=254) demonstrated a clinically meaningful and statistically significant improvement in the primary endpoint of progression-free survival (PFS) compared with standard regimens (n=132), with a median PFS of 13.3 months (95% CI: 11.8-16.1) vs. 4.4 months (95% CI: 3.4-5.9), respectively (HR:0.49; p<0.0001). This represents a 51% reduction in risk of disease progression or death with *Abecma*. Based on results from KarMMa-3, *Abecma* is the first and only chimeric antigen receptor (CAR) T cell therapy to demonstrate superiority over standard regimens in triple-class exposed relapsed and refractory multiple myeloma in a randomized, controlled Phase 3 trial.

"In earlier lines of treatment for multiple myeloma, regimens consisting of immunomodulatory agents, proteasome inhibitors, and anti-CD38 monoclonal antibodies are often used to help manage the disease. This shift in the treatment paradigm leaves many patients who are triple-class exposed with relapsed and refractory disease and in need of new treatment options sooner," said Paula Rodriguez-Otero, M.D., Ph.D., Department of Hematology, Clinica Universidad de Navarra, Pamplona, Spain. "Results from the KarMMa-3 study with *Abecma* clearly demonstrate the benefit of earlier use of a CAR T cell therapy in providing the longest progression-free survival for patients with relapsed and refractory multiple myeloma compared to current standard regimens for these patients."

"With *Abecma*, our first-in-class anti-BCMA CAR T cell therapy, we sought to deliver a personalized therapy that provides durable outcomes with a single infusion to advance the multiple myeloma treatment paradigm for patients," said Anne Kerber, senior vice president, Cell Therapy Development, Bristol Myers Squibb. "This represents the third *New England Journal of Medicine* publication for *Abecma*, showing the clear clinical benefit of using *Abecma* across lines of therapy for patients with triple-class exposed relapsed and refractory multiple myeloma to provide the best chance for lasting disease control."

Results for the key secondary endpoint of overall response rate also met statistical significance with the majority of patients (71%) treated with *Abecma* achieving a response, and 39% achieving a complete response or stringent complete response. In comparison, less than half of patients (41%) who received standard regimens achieved a response, with 5% experiencing a complete response or stringent complete response (p<0.0001). Responses with *Abecma* were durable with a median duration of 14.8 months (95% CI: 12.0-18.6) compared with 9.7 months (95% CI: 5.4-16.3) for standard regimens. Clinical benefit with *Abecma* was consistently observed across difficult-to-treat subgroups.

"For relapsing triple-class exposed multiple myeloma patients, median progression-free survival is just 4.6 months and there is no established standard treatment approach that provides durable responses," said Sergio Giral, M.D., Division of Hematologic Malignancies, Memorial Sloan Kettering Cancer Center. "In this study, we are seeing efficacy among a population with historically difficult-to-treat disease, with a significant improvement in progression-free survival and deep and lasting responses. These results from KarMMa-3 introduce the potential for this anti-BCMA CAR T cell therapy to become a standard of care earlier in the treatment course for relapsed and refractory multiple myeloma."

*Abecma* exhibited a consistent and generally predictable safety profile, including no new safety signals, with mostly low-grade occurrences of cytokine release syndrome (CRS) and neurotoxicity. In patients treated with *Abecma*, 88% experienced any grade CRS, with Grade 3/4 events occurring in 4% of patients. Two patients (1%) experienced a Grade 5 CRS event. Median time to onset of CRS was 1 day (range: 1-14) and median duration of CRS was 3.5 days (range: 1-51). Any grade neurotoxicity occurred in 15% of patients, with Grade 3/4 neurotoxicity occurring in 3% of patients, and no Grade 5 events reported. Median time to onset of neurotoxicity was 3 days (range: 1-317) and median duration of neurotoxicity was 2 days (range: 1-37).

"The KarMMa-3 study is the first with a BCMA-directed CAR T therapy to demonstrate superiority versus standard regimens for patients with relapsed and refractory multiple myeloma, illustrating the potential of *Abecma* to change the standard of care of triple-class exposed multiple myeloma in early lines," said Steve Bernstein, M.D., chief medical officer, 2seventy bio. "We are pleased to present and have these data published to build on the compelling efficacy profile of *Abecma* demonstrating significant improvement in progression-free survival and we look forward to working with regulatory authorities to make *Abecma* available to more myeloma patients who could benefit from this important treatment option."

Bristol Myers Squibb and 2seventy bio intend to include these data in a planned supplemental Biologics License Application submission to the U.S. Food and Drug Administration (FDA) in 2023. *Abecma* is the first-in-class B-cell maturation antigen (BCMA)-directed CAR T cell immunotherapy approved by the 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 also approved in the European Union, Switzerland, Japan, Canada, 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.

*Memorial Sloan Kettering Cancer Center disclosures: Dr. Giralt and Memorial Sloan Kettering Cancer Center have financial interests associated with the research described in this release.*

### About KarMma-3

KarMma-3 (NCT03651128) is a pivotal, Phase 3, open-label, global, randomized, controlled trial evaluating *Abecma* compared to standard regimens in patients with relapsed and refractory multiple myeloma who have received two to four prior lines of treatment, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody, and were refractory to the last treatment regimen. Patients were randomized to receive *Abecma* or standard regimens that consisted of combinations that included daratumumab, pomalidomide, and dexamethasone (DPd), daratumumab, bortezomib, and dexamethasone (DvD), ixazomib, lenalidomide, and dexamethasone (IRd), carfilzomib and dexamethasone (Kd) or elotuzumab, pomalidomide and dexamethasone (EPd) chosen based on their most recent treatment regimen and investigator discretion. 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* 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* 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-9) in earlier lines of treatment for patients with multiple myeloma. For more information visit [clinicaltrials.gov](https://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

#### **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](http://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 scientific expertise, cutting-edge capabilities and discovery platforms enable the company to look at 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. Because 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](https://www.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. 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](https://www.2seventybio.com).

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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. 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, 2021, 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 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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