# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

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# FORM 8-K

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**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 26, 2021**

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# bluebird bio, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

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| **Delaware** | **001-35966** | **13-3680878** |
|---|---|---|
| **(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)**

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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, $0.01 par value per share | BLUE | 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 8.01 Other Events.**

On March 26, 2021, bluebird bio, Inc. ("bluebird") and Bristol Myers Squibb Company issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved *Abecma* (idecabtagene vicleucel; ide-cel) as the first B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy for the treatment of adults with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody. *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 bluebird.

The full text of bluebird's press release regarding this announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by bluebird bio, Inc. on March 26, 2021. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

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

Date: March 29, 2021

**bluebird bio, Inc.**

By: /s/ Jason F. Cole
Jason F. Cole
*Chief Operating and Legal Officer*

**Exhibit 99.1**

# U.S. Food and Drug Administration Approves Bristol Myers Squibb's and bluebird bio's *Abecma* (idecabtagene vicleucel), the First Anti-BCMA CAR T Cell Therapy for Relapsed or Refractory Multiple Myeloma

*Abecma is a first-in-class BCMA-directed personalized immune cell therapy delivered as a one-time infusion for triple-class exposed patients with multiple myeloma[1]*

*In the pivotal KarMMa trial, the majority (72%) of patients achieved rapid, deep and durable responses[1]*

*Safety profile of Abecma is well-established and predictable including cytokine release syndrome and neurologic toxicities that are mostly low-grade with early onset and resolution[1]*

PRINCETON, N.J., & CAMBRIDGE, Mass., March 26, 2021--(BUSINESS WIRE)--**Bristol Myers Squibb** (NYSE: BMY) and **bluebird bio, Inc.** (Nasdaq: BLUE) today announced that the U.S. Food and Drug Administration (FDA) has approved *Abecma* (idecabtagene vicleucel; ide-cel) as the first B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy 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* is a personalized immune cell therapy approved as a one-time infusion with a recommended dose range of 300 to 460 x $10^6$ CAR-positive T cells.[1] As an anti-BCMA CAR T cell therapy, *Abecma* recognizes and binds to BCMA, a protein that is nearly universally expressed on cancer cells in multiple myeloma, leading to the death of BCMA-expressing cells.[2] Please see the Important Safety Information section below, including **Boxed WARNINGS** for *Abecma* regarding Cytokine Release Syndrome (CRS), Neurologic Toxicities (NT), Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), and Prolonged Cytopenia.

"CAR T cell therapies have shown transformational potential for the treatment of hematologic malignancies, and we, with our partners at bluebird bio, are proud to bring the first CAR T cell therapy to appropriate triple-class exposed patients with relapsed or refractory multiple myeloma, offering the chance for durable response," said Samit Hirawat, M.D., chief medical officer, Bristol Myers Squibb. "Bristol Myers Squibb is now the only company with two approved CAR T cell therapies with distinct targets of CD19 and BCMA. As our second FDA-approved CAR T cell therapy, *Abecma* underscores our commitment to deliver on the promise of cell therapies for patients who are battling aggressive and advanced blood cancers with limited effective treatment options."

"Our journey to today's approval of *Abecma* started nearly a decade ago with pioneering research at bluebird bio and has been driven ever since by our mission to provide patients with multiple myeloma a new approach to fight this relentless disease. This achievement would not have been possible without all of the patients, caregivers, investigators and healthcare staff who participated in our clinical studies, as well as the tremendous collaboration with the FDA," said Nick Leschly, chief bluebird, bluebird bio. "Today's announcement represents an important milestone for bluebird bio, marking both our first approved treatment in oncology and our first approved treatment in the United States."

Despite advances in treatment, multiple myeloma remains an incurable disease characterized by periods of remission and relapse.[3] Most patients experience relapse following initial therapies, and depth and duration of response as well as survival outcomes decrease with each successive treatment.[4-9] Patients with relapsed or refractory multiple myeloma that have been exposed to all three major drug classes (triple-class exposed), including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, tend to demonstrate poor clinical outcomes with very low response rates (20% to 30%), short duration of response (2 to 4 months) and poor survival.[5,10,11,12]

“In the KarMMa study, ide-cel elicited rapid responses in the majority of patients, and these deep and durable responses were observed in patients with triple-class exposed and refractory multiple myeloma,” said Nikhil C. Munshi, M.D., Associate Director, Jerome Lipper Multiple Myeloma Center at the Dana-Farber Cancer Institute, Boston, Massachusetts. “As a treating physician, I often work with patients with relapsed or refractory multiple myeloma who are in critical need of new therapies. Now, with the approval of ide-cel as the first anti-BCMA CAR T cell therapy, we are excited to finally be able to offer patients a new, effective personalized treatment option that is delivered through a single infusion.”

A network has been created to support rapid and dependable manufacturing of *Abecma* and ensure capacity to accommodate patient demand. *Abecma* will be manufactured for each individual patient using the patient’s own T cells at Bristol Myers Squibb’s state-of-the-art cellular immunotherapy manufacturing facility in Summit, New Jersey. The lentiviral vector, which is used to engineer the CAR T cells, was developed by bluebird bio. *Abecma* patients, caregivers and physician teams can access relevant information, manufacturing updates and patient and caregiver support through Cell Therapy 360, a digital service platform provided to optimize the *Abecma* patient and physician treatment experience. Various programs and resources will also be offered to help address the needs of patients and caregivers and provide support that allows for access to therapies, including *Abecma.* Due to the specialized nature of administering cell therapy, *Abecma* will be available at certified treatment centers throughout the country. A Risk Evaluation and Mitigation Strategy (REMS) program will be implemented at certified centers to support appropriate use of *Abecma* including training on the management of cytokine release syndrome and neurologic toxicities.

*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 bluebird bio.

**KarMMa Pivotal Trial Results**

The FDA approval of *Abecma* is based on data from the pivotal Phase II KarMMa trial of 127 patients with relapsed or refractory multiple myeloma who had received at least three prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody. The efficacy evaluable population consists of 100 patients who received *Abecma* within the dose range of 300 to 460 x $10^6$ CAR-positive T cells. Of these patients, 88% of patients received four or more prior lines of therapy and 85% were triple-class refractory.[1]

In the study, the overall response rate (ORR) for the efficacy evaluable population (n=100) was 72% (95% CI: 62-81), and 28% of patients achieved a stringent complete response (sCR; 95% CI: 19-38).[1] Responses were rapid and durable, with a median time to response of 30 days (range: 15 to 88 days)

and median duration of response of 11 months (95% CI: 10.3 – 11.4) for all responders and 19 months (95% CI: 11.4 – NE) for those who achieved a sCR. Of the 28 patients who achieved a sCR, an estimated 65% (95% CI: 42% - 81%) had remission lasting at least 12 months.[1]

In patients treated with *Abecma* in the KarMMa study, the safety profile was well-established with mostly low-grade occurrence of cytokine release syndrome (CRS) and neurotoxicity (NT), and predictable early onset and resolution. CRS of any grade occurred in 85% (108/127) of patients using the Lee grading system.[1,13] Grade ≥3 CRS occurred in 9% (12/127) of patients, with Grade 5 CRS reported in one patient (0.8%). The median time to onset of CRS was one day (range: 1-23 days) and the median duration of CRS was seven days (range: 1-63 days). The most common manifestations of any grade CRS included pyrexia (98%), hypotension (41%), tachycardia (35%), chills (31%), hypoxia (20%), fatigue (12%), and headache (10%). NT of any grade occurred in 28% (36/127) of patients, including Grade ≥3 events in 4% (5/127) of patients. One patient had ongoing Grade 2 NT at the time of death. The median time to onset of NT was two days (range: 1-42 days). NT resolved in 33 of 36 patients (92%) with a median time to resolution of five days (range: 1-61 days). Hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS), potential complications related to excessive immune activation associated with CAR T cell therapies, occurred in 4% (5/127) of patients, including one patient who developed fatal multi-organ HLH/MAS with CRS and one patient with fatal bronchopulmonary aspergillosis, with HLH/MAS contributing to the fatal outcome. Three cases of Grade 2 HLH/MAS resolved. In the study, 41% (52/127) of patients experienced prolonged Grade 3 or 4 neutropenia and 49% (62/127) of patients experienced prolonged Grade 3 or 4 thrombocytopenia. Three patients underwent stem cell transplant for hematopoietic reconstitution due to prolonged cytopenia. Two of the three patients died from complications of prolonged cytopenia, which occurred in the setting of ongoing or prior severe CRS or HLH/MAS.[1]

The most common (≥20%) types of nonlaboratory adverse reactions included CRS, infections, fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite. Serious adverse reactions occurred in 67% of patients, with the most common (≥5%) being CRS (18%), general physical health deterioration (10%), pneumonia (12%), infections (19%), viral infections (9%), sepsis (7%), and febrile neutropenia (6%). The most common Grade 3 or 4 nonlaboratory adverse reactions were febrile neutropenia (16%) and infections (14%). Fatal adverse reactions occurred in 6% of patients.[1]

**Indication**

ABECMA (idecabtagene vicleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated 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.

**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**.

**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** or follow us on **LinkedIn**, **Twitter**, **YouTube**, **Facebook** and **Instagram**.

Celgene and Juno Therapeutics are wholly owned subsidiaries of Bristol-Myers Squibb Company. In certain countries outside the U.S., due to local laws, Celgene and Juno Therapeutics are referred to as, Celgene, a Bristol Myers Squibb company and Juno Therapeutics, a Bristol Myers Squibb company.

**About bluebird bio, Inc.**

bluebird bio is pioneering gene therapy with purpose. From our Cambridge, Mass., headquarters, we're developing gene and cell therapies for severe genetic diseases and cancer, with the goal that people facing potentially fatal conditions with limited treatment options can live their lives fully. Beyond our labs, we're working to positively disrupt the healthcare system to create access, transparency and education so that gene therapy can become available to all those who can benefit.

bluebird bio is a human company powered by human stories. We're putting our care and expertise to work across a spectrum of disorders including cerebral adrenoleukodystrophy, sickle cell disease, β-thalassemia and multiple myeloma using three gene therapy technologies: gene addition, cell therapy and (megaTAL-enabled) gene editing.

bluebird bio has additional nests in Seattle, Wash.; Durham, N.C.; and Zug, Switzerland. For more information, visit **bluebirdbio.com**.

Follow bluebird bio on social media: @**bluebirdbio**, **LinkedIn**, **Instagram** and **YouTube**.

bluebird bio is a trademark of bluebird bio, Inc.

**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 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, whether Abecma (idecabtagene vicleucel; ide-cel) for the indication described in this release will be commercially successful and that continued approval of such product candidate for such indication described in this release may be contingent upon verification and description of clinical benefit in confirmatory trials. 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, 2020, 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.*

**bluebird bio 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 ide-cel. 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 be commercially successful, that continued approval of such product candidate for such indication described in this release may be contingent upon verification and description of clinical benefit in confirmatory trials, and that the 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 bluebird bio's business, particularly those identified in the risk factors discussion in bluebird 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, bluebird 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.*

*Hyperlinks are provided as a convenience and for informational purposes only. Neither Bristol Myers Squibb nor bluebird bio bears responsibility for the security or content of external websites or websites outside of their respective control.*

## References


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