

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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): March 31, 2020

bluebird bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-35966

(Commission File Number)

13-3680878

(IRS Employer
Identification No.)

**60 Binney Street,
Cambridge, MA**

(Address of Principal Executive Offices)

02142

(Zip Code)

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

Not Applicable

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$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 31, 2020, bluebird bio, Inc. (“bluebird”) and Bristol Myers Squibb Company issued a press release announcing the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the product candidate idecabtagene vicleucel (ide-cel; bb2121) for the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody.

The full text of bluebird’s press release regarding the 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 31, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Bristol Myers Squibb and bluebird bio Announce Submission of Biologics License Application (BLA) for Anti-BCMA CAR T Cell Therapy Idecabtagene Vicleucel (Ide-cel, bb2121) to FDA

BLA submission includes results from pivotal Phase 2 KarMMa study evaluating ide-cel in a heavily pre-treated patient population with relapsed and refractory multiple myeloma

PRINCETON, NJ. & CAMBRIDGE, Mass. – (BUSINESS WIRE) -- March 31, 2020 -- Bristol Myers Squibb (NYSE: BMY) and bluebird bio, Inc. (Nasdaq: BLUE) today announced the submission of their Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for idecabtagene vicleucel (ide-cel; bb2121), the companies' lead investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, for the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody.

The submission is based on results from the pivotal Phase 2 KarMMa study. The KarMMa study evaluated the efficacy and safety of ide-cel in heavily pre-treated patients with relapsed and refractory multiple myeloma. Topline data from KarMMa, reported in December 2019, indicated the study met its primary endpoint of overall response rate, and the key secondary endpoint of complete response rate in this patient population treated with ide-cel. The safety results were consistent with those observed in the supportive Phase 1 CRB-401 study, which evaluated the preliminary safety and efficacy of ide-cel. Comprehensive results of the KarMMa study will be presented at a future medical meeting.

BCMA is a protein that is nearly universally expressed on cancer cells in multiple myeloma, making it an important potential target for the treatment of this aggressive blood cancer. Ide-cel is the first CAR T cell therapy submitted for regulatory approval to target this antigen and for multiple myeloma.

Ide-cel was granted Breakthrough Therapy Designation (BTD) by the FDA and PRiority MEDicines (PRIME) designation by the European Medicines Agency for relapsed and refractory multiple myeloma.

About Ide-cel

Ide-cel is a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T cell immunotherapy. The ide-cel CAR is comprised of a murine extracellular single-chain variable fragment (scFv) specific for recognizing BCMA, attached to a human CD8 α hinge and transmembrane domain fused to the T cell cytoplasmic signaling domains of CD137 4-1BB and CD3- ζ chain, in tandem. Ide-cel 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.

Bristol Myers Squibb and bluebird bio's broad clinical development program for ide-cel includes clinical studies (KarMMa-2, KarMMa-3, KarMMa-4) in earlier lines of treatment for patients with multiple myeloma, including newly diagnosed multiple myeloma. For more information visit clinicaltrials.gov.

Ide-cel is being developed as part of a Co-Development, Co-Promotion and Profit Share Agreement between Bristol Myers Squibb and bluebird bio.

Ide-cel is not approved for any indication in any geography.

About KarMMa

KarMMa (NCT03361748) is a pivotal, open-label, single-arm, multicenter, multinational, Phase 2 study evaluating the efficacy and safety of ide-cel in adult patients with relapsed and refractory multiple myeloma in North America and Europe. The primary endpoint of the study is overall response rate as assessed by an independent review committee (IRC) according to the International Myeloma Working Group (IMWG) criteria. Complete response rate is a key secondary endpoint. Other efficacy endpoints include time to response, duration of response, progression-free survival, overall survival, minimal residual disease evaluated by Next-Generation Sequencing (NGS) assay and safety. The study enrolled 140 patients, of whom 128 received ide-cel across the target dose levels of 150-450 x 10⁶ CAR+ T cells after receiving lymphodepleting chemotherapy. All enrolled patients had received at least three prior treatment regimens, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and were refractory to their last regimen, defined as progression during or within 60 days of their last therapy.

Bristol Myers Squibb: Advancing Cancer Research

At Bristol Myers Squibb, patients are at the center of everything we do. The goal of our cancer research is to increase quality, long-term survival and make cure a possibility. We harness our deep scientific experience, cutting-edge technologies and discovery platforms to discover, develop and deliver novel treatments for patients.

Building upon our transformative work and legacy in hematology and Immuno-Oncology that has changed survival expectations for many cancers, our researchers are advancing a deep and diverse pipeline across multiple modalities. In the field of immune cell therapy, this includes registrational CAR T cell agents for numerous diseases, and a growing early-stage pipeline that expands cell and gene therapy targets, and technologies. We are developing cancer treatments directed at key biological pathways using our protein homeostasis platform, a research capability that has been the basis of our approved therapies for multiple myeloma and several promising compounds in early- to mid-stage development. Our scientists are targeting different immune

system pathways to address interactions between tumors, the microenvironment and the immune system to further expand upon the progress we have made and help more patients respond to treatment. Combining these approaches is key to delivering new options for the treatment of cancer and addressing the growing issue of resistance to immunotherapy. We source innovation internally, and in collaboration with academia, government, advocacy groups and biotechnology companies, to help make the promise of transformational medicines a reality for patients.

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 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](#).

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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 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 of unfavorable results from additional studies involving ide-cel, or bb2121, that such product candidate may not receive regulatory approval for the indication described in this release in the currently anticipated timeline or at all and, if approved, whether such product candidate for such 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, 2019, 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.

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