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): July 29, 2020

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bluebird bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

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)

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 July 29, 2020, bluebird bio, Inc. (“bluebird”) and Bristol Myers Squibb Company issued a press release announcing the resubmission 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. This submission provides further details on the Chemistry, Manufacturing and Controls (CMC) module to address the outstanding regulatory requests from the FDA in May 2020 following the original BLA submission in March 2020.

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 July 29, 2020.
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: July 29, 2020

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

Exhibit 99.1

Bristol Myers Squibb and bluebird bio Announce Submission of Biologics License Application (BLA) to FDA for Idecabtagene Vicleucel (Ide-cel, bb2121) for Adults with Relapsed and Refractory Multiple Myeloma

BLA submission based on results from pivotal Phase 2 KarMMa study evaluating ide-cel in heavily pre-treated patient population

Companies are committed to working with the FDA to rapidly advance ide-cel through the regulatory review process

PRINCETON, NJ, & CAMBRIDGE, Mass. – (BUSINESS WIRE) July 29, 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' investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, for the treatment of adult patients with relapsed and refractory multiple myeloma. This submission provides further details on the Chemistry, Manufacturing and Controls (CMC) module to address the outstanding regulatory requests from the FDA in May 2020 following the original BLA submission from March 2020.

The submission is based on results from the pivotal Phase 2 KarMMa study evaluating the efficacy and safety of ide-cel in relapsed and refractory multiple myeloma patients exposed to an immunomodulatory (IMiD) agent, a proteasome inhibitor (PI) and an anti-CD38 antibody. Results from the study were shared during an oral presentation as part of the American Society of Clinical Oncology 2020 (ASCO20) Virtual Scientific Program.[1]

Multiple myeloma is a cancer of plasma cells.[2] The cause of multiple myeloma is not known and currently there is no cure; however, there are a number of treatment options available that can lead to response.[2] Patients who have already been treated with some available therapies but continue to have progression of their disease have "relapsed" and "refractory" multiple myeloma, meaning their cancer has returned after they have received initial treatments. Patients with relapsed and refractory multiple myeloma that have been exposed to all three major drug classes, including an IMiD agent, a PI and an anti-CD38 antibody, have fewer treatment options and poor outcomes, including shorter response durations and lower overall survival.[3]

Ide-cel was granted Breakthrough Therapy Designation (BTD) by the FDA, and PRIority MEdicines (PRIME) designation and validation of its Marketing Authorization Application (MAA) by the European Medicines Agency for relapsed and refractory multiple myeloma.

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

For Holders of Contingent Value Rights (CVR), Ticker BMY-RT

U.S. FDA approval of ide-cel by March 31, 2021 is one of the required remaining milestones of the Contingent Value Rights issued upon the close of the Celgene acquisition in the fourth quarter of 2019. The other is U.S. FDA approval of liso-cel by December 31, 2020. The company is committed to working with FDA to progress both applications and achieve the remaining regulatory milestones required by the CVR.

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.

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 was granted accelerated assessment by the European Medicines Agency (EMA) on March 26, 2020, and the MAA was validated by the EMA on May 20, 2020.

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 adults 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 10^6 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 patients' quality of life, 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 potential 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 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, that future study results will be consistent with the results to date, that ide-cel, or bb2121, may not achieve its primary study endpoint or 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.

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 the BLA submission may not be accepted for filing by the FDA without the provision of further information or responses to additional requests, if at all, that ide-cel may not receive regulatory approval for the indication described in this release in the currently anticipated timeline or at all, and, if approved, whether ide-cel will be commercially successful, that the positive results for ide-cel may not continue in additional clinical 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 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, 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

1. Munshi NC, et al. Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): initial KarMMa results. ASCO 2020 Virtual Scientific Program. Abstract #8503.
2. American Cancer Society. What is Multiple Myeloma? Available at: https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html. Accessed June 2020.
3. Jagannath S, et al. KarMMa-RW: a study of real world treatment patterns in heavily pretreated patients with relapsed and refractory multiple myeloma (RRMM) and comparison of outcomes to KarMMa. ASCO 2020 Virtual Scientific Program. Abstract #8525.

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