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): May 13, 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 May 13, 2020, bluebird bio, Inc. ("bluebird") and Bristol Myers Squibb Company announced updated results from the pivotal, Phase 2 KarMMa study evaluating the efficacy and safety of the companies' lead investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, idecabtagene vicleucel (ide-cel; bb2121), in patients with triple-class exposed, relapsed and refractory multiple myeloma. These data will be shared in an oral presentation at the American Society of Clinical Oncology 2020 Virtual Scientific Program on May 29, 2020.

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 May 13, 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: May 13, 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 to Present Updated Positive Results from Pivotal KarMMa Study of Ide-cel in Relapsed and Refractory Multiple Myeloma Patients at ASCO20

Ide-cel, an investigational CAR T cell therapy for multiple myeloma, met primary endpoint and key secondary endpoints

Pivotal study results demonstrated deep and durable responses in a heavily pre-treated and highly refractory patient population

PRINCETON, NJ, & CAMBRIDGE, Mass. – (BUSINESS WIRE) May 13, 2020 – Bristol Myers Squibb (NYSE: BMY) and bluebird bio, Inc. (Nasdaq: BLUE) today announced updated results from the pivotal, Phase 2 KarMMa study evaluating the efficacy and safety of the companies' investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, idecabtagene vicleucel (ide-cel; bb2121), in patients with relapsed and refractory multiple myeloma. These data will be shared in an oral presentation at the American Society of Clinical Oncology 2020 (ASCO20) Virtual Scientific Program on May 29 at 8:00 AM ET.

In the study, 128 patients with heavily pretreated relapsed and refractory multiple myeloma who were exposed to at least three prior therapies and were refractory to their last regimen per the International Myeloma Working Group (IMWG) definition (no response to therapy or disease progressed within 60 days) were treated with ide-cel across target dose levels of 150-450 x 10^6 CAR+ T cells. Patients had a median of six prior regimens; 84% were refractory to all three classes of commonly used treatments including an immunomodulatory (IMiD) agent, a proteasome inhibitor (PI) and an anti-CD38 antibody, and 94% were refractory to anti-CD38 antibodies. Median duration of follow-up was 13.3 months.

The overall response rate (ORR) was 73% across all dose levels, including 33% of patients who had a complete response (CR) or stringent CR (sCR). Median duration of response (DoR) was 10.7 months, with 19.0 month median DoR for patients who had a CR or sCR. Median progression-free survival (PFS) was 8.8 months, with 20.2 month median PFS for patients who had a CR or sCR. All patients who had CR or sCR and were evaluable for minimal residual disease (MRD), were MRD-negative. Clinically meaningful benefit was consistently observed across subgroups, and nearly all subgroups had an ORR of 50% or greater, including older and high-risk patients. The overall survival (OS) data continue to mature, with an estimated median OS of 19.4 months across all dose

levels and 78% of patients alive at 12 months.[1] Results support a favorable benefit-risk profile for ide-cel across the target dose levels of 150 to 450 × 10^6 CAR+ T cells.

Ide-cel Treated Population Across Dose Range*				
Dose, x 10^6 CAR+ T cells	150 (n=4)	300 (n=70)	450 (n=54)	150-450 (n=128)
ORR, n (%)	2 (50)	48 (69)	44 (82)	94 (73)
CR/sCR, n (%)	1 (25)	20 (29)	21 (39)	42 (33)
Median DoR, mo Median DoR by best response (CR/sCR), mo	-† -†	9.9 -††	11.3 -††	10.7 19.0
Median PFS, mo Median PFS by best response (CR/sCR), mo	2.8 -†	5.8 -††	12.1 -††	8.8 20.2

**Data have been updated following abstract publication*
†Not reported due to small n
††Data not reported

The most frequently reported adverse events (AEs) were cytopenia and cytokine release syndrome (CRS). Cytopenias were common and not dose related. Overall, CRS of any grade was reported in 84% (107/128) of patients. Grade 3 or higher CRS occurred in ≤6% (7/128) of patients, with one fatal CRS event. Investigator identified neurotoxicity events (iiNT) were reported in 18% (23/128) of patients, including Grade 3 iiNT reported in 3% (4/128) of patients. There were no Grade 4 or Grade 5 iiNT events reported.[1]

“We are very encouraged and excited by the depth and durability of responses seen with ide-cel in this first pivotal study of a CAR T cell therapy in multiple myeloma. Patients with relapsed and refractory multiple myeloma have decreased life expectancy, with no clear standard of care and limited responses to currently available treatment options, leaving them in critical need of new therapies,” said Nikhil C. Munshi, M.D., presenting author, Associate Director, The Jerome Lipper Multiple Myeloma Center at the Dana-Farber Cancer Institute, Boston, Massachusetts. “The hematology and oncology community looks forward to the potential application of ide-cel in future clinical practice.”

“These longer-term results from the KarMMa study further demonstrate the clinical benefit of ide-cel and support its role as a potentially important therapeutic option for patients with triple-class exposed, relapsed and refractory multiple myeloma,” said Kristen Hege, M.D., senior vice president, Hematology/Oncology and Cell Therapy, Early Clinical Development, Bristol Myers Squibb. “BMS and bluebird bio remain focused on improving outcomes in this population and bringing ide-cel to patients as quickly as possible.”

“Patients in the KarMMa study reflect a very advanced and highly refractory population, so it is particularly gratifying that the results announced today from the pivotal KarMMa study, demonstrating deep and durable responses, underscore the potential of ide-cel as a meaningful new treatment option for these patients,” said David Davidson, M.D., Chief Medical Officer, bluebird bio. “bluebird bio, together with our partners at Bristol Myers Squibb, understands the urgency to deliver new therapeutic options for patients living with relapsed and refractory multiple myeloma, and we are committed to bringing this potentially first-in-class BCMA-directed CAR T cell therapy to patients in need.”

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

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.

About KarMMa[3]

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 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.

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 endpoints 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

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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.

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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. Raje N, Berdeja J, Lin Y, et al. Anti-BCMA CAR T-cell therapy bb2121 in relapsed or refractory multiple myeloma. *N Engl J Med*. 2019 May 2;380(18):1726-1737.

3. ClinicalTrials.gov. Efficacy and safety study of bb2121 in subjects with relapsed and refractory multiple myeloma (KarMMA). Available at: https://clinicaltrials.gov/ct2/show/NCT03361748. Accessed May 2020.