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): December 6, 2019

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 (Par Value $0.01)	BLUE	The NASDAQ Global Select 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 December 6, 2019, bluebird bio, Inc. ("bluebird") issued a joint press release with Bristol-Myers Squibb Company announcing positive topline results from KarMMa, a pivotal, open-label, single arm, multicenter, Phase 2 study of idecabtagene vicleucel (ide-cel; bb2121), the companies' lead investigational BCMA-targeted chimeric antigen receptor (CAR) T-cell therapy candidate for patients with relapsed and refractory multiple myeloma.

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 December 6, 2019.
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 thereunto duly authorized.

bluebird bio, Inc.

Date: December 6, 2019

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

Exhibit 99.1

Bristol-Myers Squibb and bluebird bio Announce Positive Top-line Results from the Pivotal Phase 2 KarMMa Study of Ide-cel in Relapsed and Refractory Multiple Myeloma

Study met its primary endpoint and key secondary endpoint, demonstrating deep and durable responses in a heavily pre-treated multiple myeloma patient population

Safety results are consistent with the data presented in CRB-401 study

PRINCETON, NJ and CAMBRIDGE, MA (December 6, 2019) — Bristol-Myers Squibb Company (NYSE: BMY) and bluebird bio, Inc. (Nasdaq: BLUE) today announced positive top-line results from KarMMa, a pivotal, open-label, single arm, multicenter, Phase 2 study of idecabtagene vicleucel (ide-cel; bb2121). KarMMa, which evaluated the efficacy and safety of the companies' lead investigational BCMA-targeted chimeric antigen receptor (CAR) T cell therapy candidate for patients with relapsed and refractory multiple myeloma, met its primary endpoint and key secondary endpoint.

KarMMa enrolled 140 patients, of whom 128 patients were treated with ide-cel across the target dose levels of 150-450 x 10^6 CAR+ T cells. All treated patients were exposed to at least three prior therapies, including an immunomodulatory (IMiD) agent, a proteasome inhibitor (PI) and an anti-CD38 antibody, and all were refractory to their last regimen. Ninety-four percent of patients were refractory to an anti-CD38 antibody and 84% percent were triple refractory (refractory to an IMiD agent, PI and anti-CD38 antibody).

Results for the primary endpoint (overall response rate [ORR]) and key secondary endpoint (complete response rate [CR]), as well as duration of response (DoR) and progression-free survival (PFS) across the target dose levels and at each of the three target doses explored in the study are presented in the table below. The median follow-up duration for all subjects was 11.3 months.

	Ide-cel Treated Population			
	150 x 10^6 CAR+ T cells (N=4)	**300 x 10^6 CAR+ T cells (N=70)**	**450 x 10^6 CAR+ T cells (N=54)**	**150-450 x 10^6 CAR+ T cells (N=128)**
ORR, n (%)	2 (50.0)	48 (68.6)	44 (81.5)	94 (73.4)
CR/sCR, n (%)	1 (25.0)	20 (28.6)	19 (35.2)	40 (31.3)
Median DoR, months	---	9.9	11.3	10.6
Median PFS, months	---	5.8	11.3	8.6

Median DOR and median PFS are not reported for the 150 x 10^6 CAR+ T cells dose group due to the small number of evaluable patients

Overall, the safety results were consistent with those observed in the phase 1 CRB-401 study, which evaluated the preliminary safety and efficacy of ide-cel. Instances of grade 3 or higher cytokine release syndrome (CRS) occurred in 5.5% (7/128) of patients, including one fatal CRS event. Investigator identified grade 3 or higher neurotoxicity events (iiNT) occurred in 3.1% (4/128) of patients and there were no Grade 4 iiNT events reported. Grade 3 or higher CRS and iiNT events were reported in <6% of subjects at each target dose. CRS of any grade occurred in 83.6% (107/128) of patients and iiNT of any grade occurred in 18% (23/128) of patients.

“For multiple myeloma patients who have relapsed and become refractory to current treatment options, there remains a high unmet need, as these patients typically experience low response rates, short response durations and poor survival,” said Kristen Hege, M.D., Senior Vice President, Hematology/Oncology and Cell Therapy, Early Clinical Development for Bristol-Myers Squibb. “The KarMMa study provides further support for ide-cel as a potential therapeutic option in this heavily pre-treated patient population, and we are encouraged by these data, especially the outcomes observed at the highest target dose of 450 x 10^6 CAR+ T cells. We are actively preparing for submission of these data to Health Authorities for proposed initial registration of ide-cel as a first-in-class BCMA-targeted CAR T cell therapy.”

“Multiple myeloma is a relentless disease and there is significant need to find new treatment options for patients who advance through the current therapies available to them,” said Joanne Smith-Farrell, Ph.D., oncology franchise lead and chief business officer, bluebird bio. “With these data in hand, bluebird bio and Bristol-Myers Squibb remain fully focused on advancing ide-cel as quickly as possible for patients in late-line myeloma, while continuing to execute our broad development program to understand the potential benefits of ide-cel across earlier lines of therapy.”

More comprehensive data from KarMMa will be submitted for presentation at a future medical meeting.

About KarMMa

KarMMa (NCT03361748) is a pivotal, open-label, single-arm, multi-center 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 and minimal residual disease evaluated by Next-Generation Sequencing (NGS) assay. 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 IMiD agent, a PI and an anti-CD38 antibody, and were refractory to their last regimen, defined as progression during or within 60 days of their last therapy.

About Ide-cel

Ide-cel is a CAR T cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The ide-cel CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta activation domain, and a 4-1BB co-stimulatory domain hypothesized to increase T-cell activation, proliferation and persistence. Ide-cel CAR T cells are proposed to recognize and bind to BCMA on the surface of multiple myeloma cells leading to apoptosis.

In November 2017, ide-cel was granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration and PRIority Medicines (PRIME) eligibility by the European Medicines Agency based on preliminary clinical data from the phase 1 CRB-401 study.

Bristol-Myers Squibb and bluebird bio's broad clinical development program for ide-cel includes clinical studies (KarMMa-2, KarMMa-3) in earlier lines of treatment for patients with 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 BMS and bluebird bio.

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

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 chimeric antigen receptor (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.

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 by researching 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 clinical trials of ide-cel or from subsequent analysis of existing data from the KarMMa study or existing or new data received from additional ongoing and future studies of ide-cel, 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 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, 2018, 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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additional clinical trials of ide-cel or from subsequent analysis of existing data from the KarMMa study or existing or new data received from additional ongoing and future studies of ide-cel, 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 such product candidate for such indication described in this release will be commercially successful, 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, 2018, 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.

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