

**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): November 27, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 November 27, 2018, bluebird bio, Inc. (“bluebird”) announced the completion of enrollment in the pivotal study (KarMMA) of bb2121, the anti-BCMA CAR T product candidate to treat patients with relapsed-refractory multiple myeloma, being developed in collaboration with Celgene Corporation.

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	<u>Press release issued by bluebird bio, Inc. on November 27, 2018.</u>

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: November 27, 2018

bluebird bio, Inc.

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



Exhibit 99.1

CELGENE CORPORATION AND BLUEBIRD BIO COMPLETE ENROLLMENT OF PIVOTAL KARMMMA STUDY OF ANTI-BCMA CAR T CELL THERAPY BB2121 IN PATIENTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA

SUMMIT, NJ and CAMBRIDGE, MA (November 27, 2018)— Celgene Corporation (Nasdaq: CELG) and bluebird bio, Inc. (Nasdaq: BLUE) today announced the completion of enrollment for the KarMMa pivotal study of bb2121, the companies' lead investigational anti-BCMA CAR T cell therapy candidate for patients with relapsed and refractory multiple myeloma. bb2121 is being developed as part of a Co-Development, Co-Promote and Profit Share Agreement between Celgene and bluebird bio.

“We continue to be excited about bb2121 as a potential first-in-class BCMA-targeted therapy for patients with multiple myeloma,” said Alise Reicin, M.D., President, Global Clinical Development for Celgene. “We would like to thank everyone who enabled this achievement, especially the patients and caregivers, and we congratulate the physicians and others involved in the KarMMa study, including our dedicated partners at bluebird bio. We look forward to seeing the data from this study and are progressing our broader bb2121 development program as we advance closer toward delivering this important new option to appropriate patients in need.”

“We are committed to developing new treatment options to improve the care of patients with multiple myeloma, and completing enrollment of the KarMMa study moves us closer to this goal,” said David Davidson, M.D., chief medical officer, bluebird bio. “As we advance our clinical studies of bb2121 in earlier lines of therapy in collaboration with our partners at Celgene, we remain very grateful to the patients, families and healthcare providers who have made this program possible.”

KarMMa is a pivotal, open-label, single-arm, multi-center phase 2 study evaluating the efficacy and safety of bb2121 in patients with relapsed and refractory multiple myeloma. In November 2017, bb2121 was granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration and PRiority Medicines (PRIME) eligibility by the European Medicines Agency. The BTD designation and PRIME eligibility were based on preliminary clinical data from the phase 1 CRB-401 study.

The FDA action date for the bb2121 NDA is anticipated in 2020. bb2121 is currently an investigational therapy; safety and efficacy have not yet been established. bb2121 has not been approved for use by any health authority.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com.

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About bluebird bio, Inc.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, Durham, North Carolina and Zug, Switzerland.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between bluebird bio and Celgene in the development of bb2121; the potential of bb2121 as a therapeutic drug; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue, or that marketing approval will be granted. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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

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For Celgene:

Investors:

Patrick Flanigan, 908-673-9969

pflanigan@celgene.com

or

Media:

Greg Geissman, 908-673-9854

ggeissman@celgene.com

For bluebird bio

Investors:

Elizabeth Pingpank, 617-914-8736

epingpank@bluebirdbio.com

or

Media:

Stephanie Fagan, 201-572-9581

sfagan@bluebirdbio.com