
**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): February 3, 2017

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

(I.R.S. Employer
Identification No.)

**150 Second Street
Cambridge, MA**

(Address of principal executive offices)

02141

(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:

- 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))
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Item 8.01 Other Events

On February 3, 2017, bluebird bio, Inc. issued a press release announcing the treatment of the first patient under the amended study protocol for its HGB-206 study, a Phase I clinical study of its LentiGlobin product candidate in patients with severe sickle cell disease. The full text of the 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on February 3, 2017.

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: February 3, 2017

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Legal Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on February 3, 2017.



bluebird bio Announces First Patient Treated with LentiGlobin™ Drug Product Under Amended Study Protocol in HGB-206 Phase 1 Study of Patients with Severe Sickle Cell Disease

-LentiGlobin™ drug product had a vector copy number (DP VCN) of 3.3 copies/diploid genome, with 83% of cells lentiviral vector sequence positive (LVV+) –

Cambridge, Mass., February 3, 2017 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic diseases and T cell-based immunotherapies for cancer, announced treatment of the first patient under the amended study protocol in HGB-206, the company’s Phase 1 study of its LentiGlobin Drug Product in patients with severe sickle cell disease (SCD). This study now incorporates several changes to the study protocol with the goal of increasing production of therapeutic anti-sickling hemoglobin (HbA^{T87Q}).

“Our early clinical experience with LentiGlobin drug product in sickle cell disease has given us a deeper understanding of the biology of this complex disease,” said David Davidson, M.D., chief medical officer. “This research has informed numerous changes we have implemented in the HGB-206 study protocol that, in addition to the introduction of the transduction enhancers into our manufacturing process, we hope will improve *in vivo* VCN and HbA^{T87Q} expression. The impressive drug product VCN achieved in the first patient under this amended protocol highlights the success of the changes to our drug product manufacturing process, and we are hopeful that these modifications will improve patient outcomes.”

Changes to the study protocol for HGB-206 include increasing the percentage of transduced cells through manufacturing improvements, improving myeloablation (and subsequent engraftment) by increasing the target busulfan area under the curve, introducing a minimum period of regular blood transfusions prior to stem cell collection, improved cell processing and exploring an alternate hematopoietic stem cell (HSC) procurement method. To accommodate these changes to the protocol, the study enrollment has been expanded for a total enrollment of up to 29 patients.

About the HGB-206 Study

HGB-206 is an ongoing, open-label Phase 1 study designed to evaluate the safety and efficacy of LentiGlobin BB305 Drug Product in the treatment of subjects with SCD. The study is designed to enroll up to 29 subjects. Subjects will be followed to evaluate safety and efficacy, which will be measured based on changes in red cell function tests, hemolysis markers, and frequency of clinical events secondary to SCD (e.g., vaso-occlusive crises or acute chest syndrome events).



For more information on the HGB-206 Study, please visit <http://www.clinicaltrials.gov> using identifier NCT02140554.

About SCD

SCD is an inherited disease caused by a mutation in the beta-globin gene that results in sickle-shaped red blood cells. The disease is characterized by anemia, vaso-occlusive crisis, infections, stroke, overall poor quality of life and sometimes, early death. Where adequate medical care is available, common treatments for patients with SCD largely revolve around management and prevention of acute sickling episodes. Chronic management may include hydroxyurea and, in certain cases, chronic transfusions. Given the limitations of these treatments, there is no effective long-term treatment. The only advanced treatment for SCD is allogeneic hematopoietic stem cell transplant (HSCT). Complications of allogeneic HSCT include a significant risk of treatment-related mortality, graft failure, graft-versus-host disease and opportunistic infections, particularly in patients who undergo non-sibling-matched allogeneic HSCT.

About bluebird bio, Inc.

With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and cancer. bluebird bio's gene therapy clinical programs include its Lenti-D™ product candidate, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin™ BB305 product candidate, currently in four clinical studies for the treatment of transfusion-dependent β -thalassemia and severe sickle cell disease. bluebird bio's oncology pipeline is built upon the company's leadership in lentiviral gene delivery and T cell engineering, with a focus on developing novel T cell-based immunotherapies, including chimeric antigen receptor (CAR T) and T cell receptor (TCR) therapies. bluebird bio's lead oncology program, bb2121, is an anti-BCMA CAR T program partnered with Celgene. bb2121 is currently being studied in a Phase 1 trial for the treatment of relapsed/refractory multiple myeloma. bluebird bio also has discovery research programs utilizing megaTAL/homing endonuclease gene editing technologies with the potential for use across the company's pipeline. bluebird bio has operations in Cambridge, Massachusetts and Seattle, Washington.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the Company's research, development, manufacturing and regulatory approval plans for its LentiGlobin product candidate to treat severe sickle cell disease, including statements whether the manufacturing process changes for LentiGlobin will improve outcomes of patients with



severe sickle cell disease and whether the planned changes to the HGB-206 clinical trial protocol will improve outcomes in patients with severe sickle cell disease. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks that the preliminary positive efficacy and safety results from our prior and ongoing clinical trials of LentiGlobin will not continue or be repeated in our ongoing, planned or expanded clinical trials of LentiGlobin, the risks that the changes we have made in the LentiGlobin manufacturing process or the HGB-206 clinical trial protocol will not result in improved patient outcomes, the risk of a delay in the enrollment of patients in our clinical studies, and the risk that any one or more of our product candidates will not be successfully developed, approved or commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and bluebird bio undertakes no duty to update this information unless required by law.

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