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): March 29, 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 (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 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 March 29, 2019, bluebird bio, Inc. (“bluebird”) issued a press release to announce that it received a positive opinion recommending conditional marketing authorization from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for ZYNTEGLO (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-globin gene) for patients 12 years and older with transfusion-dependent β-thalassemia who do not have a β^0/β^0 genotype.

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 March 29, 2019.

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: March 29, 2019

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Receives Positive Opinion from CHMP for ZYNTEGLO™ (autologous CD34+ cells encoding β $^{A\text{-}T87Q}$-globin gene) Gene Therapy for Patients 12 Years and Older with Transfusion-Dependent β-Thalassemia (TDT) Who Do Not Have β^0/β^0 Genotype

First gene therapy recommended for approval in the EU for TDT

Treatment with ZYNTEGLO has been shown to help eliminate the need for chronic blood transfusions in patients with TDT

ZYNTEGLO is bluebird bio's first gene therapy submitted for regulatory approval

CAMBRIDGE, Mass.--(BUSINESS WIRE)--March 29, 2019--bluebird bio, Inc. (Nasdaq: BLUE) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending conditional marketing authorization for ZYNTEGLO™ (autologous CD34+ cells encoding β $^{A\text{-}T87Q}$-globin gene), a gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia (TDT) who do not have a β^0/β^0 genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available. If approved, ZYNTEGLO, formerly referred to as LentiGlobin™ for TDT, will be the first gene therapy to treat TDT.

The CHMP's positive opinion will now be reviewed by the European Commission (EC), which has the authority to grant marketing authorization for ZYNTEGLO in the European Union (EU). A CHMP positive opinion is one of the final steps before the EC decides on whether to authorize a new medicine. A final decision by the EC for ZYNTEGLO is anticipated in the second quarter of 2019.

TDT is a severe genetic disease caused by mutations in the β-globin gene that result in reduced or absent hemoglobin. In order to survive, people with TDT maintain hemoglobin levels through lifelong chronic blood transfusions. These transfusions carry the risk of progressive multi-organ damage due to unavoidable iron overload.

"The goal of treatment with ZYNTEGLO is to enable patients with transfusion-dependent β-thalassemia to produce hemoglobin at sufficient levels to allow lifelong independence from blood transfusions," said David Davidson, M.D., chief medical officer, bluebird bio. "The positive CHMP opinion for ZYNTEGLO is a crucial step toward providing what would be the first one-time gene therapy for people living with TDT. We share this achievement with the TDT community, patients and clinical investigators whose dedication made it possible. We look forward to the upcoming decision from the European Commission."

"For many of my patients, living with TDT means a lifetime of chronic blood transfusions, iron chelation therapy and supportive treatments to manage anemia and other serious complications of this disease," said Professor Franco Locatelli, M.D., Ph.D., Professor of Pediatrics, Sapienza University of Rome, Italy

and Director, Department of Pediatric Hematology/Oncology and Cell and Gene Therapy, IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy. “The burden placed on these patients and their families is significant. It extends beyond immediate health implications to their daily lives, which are affected by the symptoms, hospitalizations and necessary chronic care required for TDT.”

“The present management of TDT, including regular blood transfusions every two to four weeks and daily iron chelation therapy has many psychological and social consequences, including marginalization and isolation. And in many patients TDT-related morbidities can lead to a shortened life span. Therefore, it is with great anticipation and eagerness that the international patient community has closely followed the dynamic rejuvenation of scientific interest and research of gene therapy in TDT over the last few years,” said Dr. Androulla Eleftheriou, Thalassaemia International Federation Executive Director. “Thus, the potential approval of a gene therapy brings hope that we can dramatically change the course of this disease and the health and quality of lives of patients with TDT.”

ZYNTEGLO adds functional copies of a modified form of the β-globin gene ($\beta^{A\text{-}T87Q}$-globin gene) into a patient’s own hematopoietic (blood) stem cells (HSCs). This means there is no need for donor HSCs from another person as is required for allogeneic HSC transplantation (allo-HSCT). A patient’s HSCs are collected and removed from the body through a process called apheresis. These HSCs are taken to a lab where a lentiviral vector is used to insert the $\beta^{A\text{-}T87Q}$-globin gene into the patient’s HSCs. This step is called transduction. Before their modified HSCs are returned, the patient receives chemotherapy to prepare their bone marrow for the modified HSCs, which are returned through an infusion. Once a patient has the $\beta^{A\text{-}T87Q}$-globin gene they have the potential to produce HbA^{T87Q}, which is gene therapy- derived-hemoglobin, at levels that significantly reduce or eliminate the need for transfusions.

“The EMA’s collaborative approach and innovative programs have been instrumental in improving timely access of new medicines to patients with significant unmet needs, like those who are living with TDT,” said Anne-Virginie Eggimann, senior vice president of regulatory science at bluebird bio.

ZYNTEGLO was reviewed under an accelerated assessment timeline as part of the EMA’s Priority Medicines (PRIME) and Adaptive Pathways programs, which support medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options.

Data Supporting Clinical Profile of ZYNTEGLO
The positive CHMP opinion is supported by efficacy, safety and durability data from the Phase 1/2 HGB-205 study and the completed Phase 1/2 Northstar (HGB-204) study as well as available data from the ongoing Phase 3 Northstar-2 (HGB-207) and Northstar-3 (HGB-212) studies, and the long-term follow-up study LTF-303.
As of September 14, 2018, data from Phase 1/2 Northstar showed that 80 percent (n=8/10) of patients who do not have a β^0/β^0 genotype achieved transfusion independence, meaning they had not received a transfusion for at least 12 months and maintained hemoglobin ≥9 g/dL. These eight patients had maintained transfusion independence for a median duration of 38 months (21 – 44 months) at the time of data cut off.

In the Phase 3 Northstar-2 and Northstar-3 studies, a refined manufacturing process was used to produce ZYNTEGLO and was intended to further improve the clinical results observed in the Northstar study. As of September 14, 2018, the median (min – max) total hemoglobin for patients six months after ZYNTEGLO infusion in the Northstar-2 study (n=10) was 11.9 (8.4, 13.3) g/dL.
Non-serious adverse events (AEs) observed during clinical trials that were attributed to ZYNTEGLO were hot flush, dyspnoea, abdominal pain, pain in extremities and non-cardiac chest pain. One serious adverse event (SAE) of thrombocytopenia was considered possibly related to ZYNTEGLO.

Additional AEs observed in clinical studies were consistent with the known side effects of HSC and bone marrow ablation with busulfan including SAEs of veno-occlusive disease.

ZYNTEGLO continues to be evaluated in the ongoing Phase 3 Northstar-2 and Northstar-3 studies and the long-term follow-up study LTF-303.

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, transfusion-dependent 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.

ZYNTEGLO and LentiGlobin are trademarks of bluebird bio.

The full common name for ZYNTEGLO: A genetically modified autologous CD34+ cell enriched population that contains hematopoietic stem cells transduced with lentiviral vector encoding the $\beta^{A\text{-}T87Q}$-globin gene.

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 plans and expectations for the regulatory approval, and commercialization for ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-globin gene, formerly LentiGlobin™ in TDT) to treat TDT, and the potential implications of clinical data for patients. 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: the risk that our MAA submitted for ZYNTEGLO may not be approved by the European Commission when expected, or at all; the risk that the efficacy and safety results from our prior and ongoing clinical trials of ZYNTEGLO will not continue or be repeated in our ongoing or planned clinical trials of ZYNTEGLO; the risk that the current or planned clinical trials of ZYNTEGLO will be insufficient to support regulatory submissions or marketing approval in the US and EU; the risk that the production of HbAT87Q may not be sustained over extended periods of time; and the risk that we may not secure adequate pricing or reimbursement to support continued development or commercialization of ZYNTEGLO following regulatory approval. 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 Form 10-K, 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.

bluebird bio
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