# 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): October 5, 2018**

# 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 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 October 5, 2018, bluebird bio, Inc. (“bluebird”) issued a press release to announce that the European Medicines Agency (EMA) accepted bluebird’s marketing authorization application (MAA) for LentiGlobin, its investigational gene therapy product candidate for the treatment of adolescents and adults with transfusion-dependent β-thalassemia (TDT).

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 October 5, 2018. |

**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: October 5, 2018

**bluebird bio, Inc.**

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

**Exhibit 99.1**

# bluebird bio Announces European Medicines Agency's Acceptance of Marketing Authorization Application for LentiGlobin™ Gene Therapy for the Treatment of Transfusion-Dependent β-Thalassemia

*- European Medicines Agency Will Evaluate LentiGlobin Marketing Authorization Application Under Accelerated Assessment -*

**CAMBRIDGE, Mass. – October 5, 2018** – bluebird bio, Inc. (Nasdaq: BLUE) announced today that the European Medicines Agency (EMA) accepted the company's marketing authorization application (MAA) for its investigational LentiGlobin™ gene therapy for the treatment of adolescents and adults with transfusion-dependent β-thalassemia (TDT) and a non-$\beta^0/\beta^0$ genotype.

LentiGlobin was previously granted an accelerated assessment by the Committee for Medicinal Products for Human Use (CHMP) of the EMA in July 2018, potentially reducing the EMA's active review time of the MAA from 210 days to 150 days.

"People living with transfusion-dependent β-thalassemia require frequent blood transfusions that are life-saving but may lead to complications, including organ failure due to iron overload," said David Davidson, M.D., chief medical officer, bluebird bio. "The acceptance of our marketing authorization application for LentiGlobin is a milestone that advances us toward our goal of providing to patients the first one-time gene therapy that addresses the underlying genetic cause of TDT. We share this important milestone with the patients, families and healthcare providers who made it possible through their participation in our pioneering clinical studies of LentiGlobin."

The MAA for LentiGlobin is supported by data from the completed Phase 1/2 Northstar (HGB-204) study and the ongoing Phase 1/2 HGB-205 study as well as available data from the Phase 3 Northstar-2 (HGB-207) study and the long-term follow-up study LTF-303.

**About Transfusion-Dependent β-Thalassemia**
TDT is an inherited blood disorder caused by a mutation in the β-globin gene, which causes ineffective red blood cell production leading to severe anemia. Supportive care for people with TDT consists of a lifelong regimen of chronic blood transfusions to enable survival and suppress symptoms of the disease, and iron chelation therapy to manage iron overload that results from the transfusions.

Despite the availability of supportive care, many people with TDT experience serious complications and organ damage due to underlying disease and iron overload. By eliminating or reducing the need for blood transfusions, the long-term complications associated with TDT may be reduced.

Allogeneic hematopoietic stem cell transplantation (allo-HSCT) has been successfully used to treat TDT and is currently the only available option with the potential to correct the genetic deficiency in TDT. Complications of allo-HSCT include a risk of treatment-related mortality, graft failure, graft-versus-host disease (GvHD) and opportunistic infections, particularly in patients who undergo non-sibling matched allo-HSCT.

**About LentiGlobin**
LentiGlobin is a one-time gene therapy being studied as a potential treatment to address the underlying genetic cause of TDT, which could eliminate or reduce the need for blood transfusions.

bluebird bio's clinical development program for LentiGlobin includes ongoing studies around the world with sites in Australia, Germany, Greece, France, Italy, Thailand, the United Kingdom and the United States. For more information visit: www.northstarclinicalstudies.com or clinicaltrials.gov using identifier NCT01745120.

In addition, bluebird is conducting a long-term safety and efficacy follow-up study (LTF-303) for people who have participated in bluebird bio-sponsored clinical studies of LentiGlobin for TDT and sickle cell disease.

The EMA previously granted Priority Medicines (PRIME) eligibility and Orphan Medicinal Product designation to LentiGlobin for the treatment of TDT. LentiGlobin is also part of the EMA's Adaptive Pathways pilot program, which is part of the EMA's effort to improve timely access for patients to new medicines.

The U.S. Food and Drug Administration (FDA) also granted LentiGlobin Orphan Drug status and Breakthrough Therapy designation for the treatment of TDT.

**About bluebird bio, Inc.**
With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built a pipeline with broad potential application in severe genetic diseases and cancer.

bluebird bio's gene therapy clinical programs include investigational treatments for cerebral adrenoleukodystrophy, transfusion-dependent β-thalassemia, also known as β-thalassemia major, and severe sickle cell disease.

bluebird bio's oncology pipeline is built upon the company's 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. The company's lead oncology programs are anti-BCMA CAR T programs partnered with Celgene.

bluebird bio's discovery research programs include utilizing megaTAL/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

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

LentiGlobin is a trademark of bluebird bio, Inc.

**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 views with respect to the potential for its LentiGlobin product candidate to treat transfusion-dependent ß-thalassemia, and the Company's expectations regarding the review, potential regulatory approval and potential commercial launch of its LentiGlobin product candidate in the United States and Europe. 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 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 or planned clinical trials of LentiGlobin, the risks that the changes we have made in the LentiGlobin manufacturing will not result in improved patient outcomes, risks that the current or planned clinical trials of LentiGlobin will be insufficient to support future regulatory submissions or to support marketing approval in the US and EU, 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 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.*

**Investors & Media:**
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