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): June 3, 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, $0.01 par value per share	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 June 3, 2019, bluebird bio, Inc. (“bluebird”) issued a press release announcing that the European Commission has granted conditional marketing authorization for ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-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. 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 June 3, 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: June 3, 2019

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Announces EU Conditional Marketing Authorization for ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-globin gene) Gene Therapy for Patients 12 Years and Older with Transfusion-Dependent β-Thalassemia Who Do Not Have β^0/β^0 Genotype

ZYNTEGLO is the first gene therapy approved for transfusion-dependent β-thalassemia (TDT)

European marketing authorization for ZYNTEGLO follows the fastest assessment of an advanced therapy medicinal product (ATMP) as part of the European Medicines Agency's Priority Medicines (PRIME) program

ZYNTEGLO is bluebird bio's first gene therapy to gain regulatory approval

CAMBRIDGE, Mass.--(BUSINESS WIRE)—June 3, 2019--bluebird bio, Inc. (Nasdaq: BLUE) announced today that the European Commission (EC) has granted conditional marketing authorization for ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-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. bluebird bio will continue the country-by-country reimbursement process to help ensure access to ZYNTEGLO for appropriate patients.

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. ZYNTEGLO is a one-time gene therapy that addresses the underlying genetic cause of TDT and offers patients 12 years and older who do not have a β^0/β^0 genotype the potential to become transfusion independent, which once achieved is expected to be life-long.

"EC approval of ZYNTEGLO is a milestone that represents the dedication and commitment of clinical investigators, healthcare providers, patients and their families, and our employees, all of whom have helped advance this treatment from concept to an approved therapy," said Nick Leschly, chief bluebird. "Our first product approval is a humbling moment for all of us at bluebird, and we look forward to continuing our work with the TDT community and health systems to bring this important treatment to patients."

ZYNTEGLO was reviewed as part of the European Medicines Agency's (EMA) 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. The PRIME and Adaptive Pathway programs allowed for early and enhanced dialogue and accelerated assessment of ZYNTEGLO, which was completed on the shortest timetable for an advanced therapy medicinal product (ATMP) by the EMA to date.

“As one of the investigators in the clinical studies of ZYNTEGLO, I have witnessed firsthand the hope this gene therapy can provide to patients and their families who have often been managing this disease and transfusions for years, often for decades,” 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. “This approval by the European Commission means we now have a gene therapy for certain patients with TDT that has the potential to transform lives by offering the possibility of a transfusion-free future.”

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 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 through infusion, a patient receives chemotherapy to prepare their bone marrow for the modified HSCs that now carry the $\beta^{A\text{-}T87Q}$-globin gene. 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 eliminate or significantly reduce the need for transfusions. Upon engraftment and achievement of transfusion independence, effects of ZYNTEGLO are expected to be life-long.

Due to the highly technical and specialized nature of administering gene therapy in rare diseases, bluebird bio is working with select qualified treatment centers that have expertise in stem cell transplant and treating patients with TDT to provide ZYNTEGLO.

“We welcome European Commission authorization for the first gene therapy for TDT. This achievement means the TDT community now has another treatment option that may provide new hope for people living with TDT who have been managing their disease through chronic transfusions,” said Dr. Androulla Eleftheriou, Thalassemia International Federation Executive Director. “Undoubtedly, this is not the end of the road, but merely the beginning, and TIF is ready to collaborate with all involved stakeholders to help ensure accessibility for as many appropriate patients as possible.”

The conditional marketing authorization is valid in all 28 member states of the EU as well as Iceland, Liechtenstein and Norway.

Data Supporting Clinical Profile of ZYNTEGLO
The conditional marketing authorization 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 the data cut off of December 13, 2018.
Data from Phase 1/2 HGB-205 showed that 75 percent (n=3/4) 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 or more and maintained weighted hemoglobin ≥9 g/dL. In the Phase 1/2 Northstar study, 80 percent (n=8/10) of patients who do not have a β^0/β^0 genotype achieved transfusion independence.
These 11 patients (three from HGB-205 and eight from Northstar) continued to maintain transfusion independence, which at the time of data cut off was for a duration of 21–56 months.
Five patients in Northstar-2 were evaluable for transfusion independence. Of these five, 80 percent (n=4/5) achieved transfusion independence.

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 collection and bone marrow ablation with busulfan, including SAEs of veno-occlusive disease.

For details, please see the Summary of Product Characteristics (SmPC).

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.

In addition to Priority Medicines (PRIME) designation, ZYNTEGLO received an Orphan Medicinal Product designation from the EC for the treatment of β-thalassemia intermedia and major, which includes TDT.

The U.S. Food and Drug Administration granted ZYNTEGLO Orphan Drug status and Breakthrough Therapy designation for the treatment of TDT.

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 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 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, or for additional patient populations in the EU; the risk that the production of HbA^{T87Q} 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-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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bluebird bio
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