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 22, 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 (Par Value $0.01)	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 October 22, 2019, bluebird bio, Inc. ("bluebird") issued a press release announcing that it received approval from the European Medicines Agency (EMA) of the refined commercial drug product manufacturing specifications for ZYNTEGLO (autologous CD34+ cells encoding βA-T87Q-globin gene), for patients 12 years and older with transfusion-dependent β-thalassemia (TDT) who do not have a β0/β0 genotype.

The full text of bluebird's press release is being furnished 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 22, 2019.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

bluebird bio, Inc.

Date: October 22, 2019

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

Exhibit 99.1

European Medicines Agency Approves Refined Commercial Manufacturing Specifications for ZYNTEGLO™

First gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia who do not have a β^0/β^0 genotype now available to be manufactured in the European Union

CAMBRIDGE, Mass. – October 22, 2019 – bluebird bio, Inc. (Nasdaq: BLUE) announced today that the European Medicines Agency (EMA) approved the refined commercial drug product manufacturing specifications for ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-globin gene), a one-time 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.

"We look forward to serving TDT patients with ZYNTEGLO and providing a treatment option that offers the possibility of a transfusion-free future," said Alison Finger, Chief Commercial Officer at bluebird bio. "This is one step along the commercial journey as we advance our ongoing launch and market access activities on a country-by-country basis, with the goal of enrolling our first commercial patient in 2019."

The refined commercial drug product specifications support the efficacy and safety profile of ZYNTEGLO and will give patients the best opportunity for clinically meaningful outcomes consistent with the results that were foundational to the conditional marketing authorization in the European Union. ZYNTEGLO addresses the underlying genetic cause of TDT and offers patients the potential to become transfusion independent, which once achieved is expected to be life-long.

"These are exciting times also for apceth, as we are now in the final stages of preparing to manufacture a cell-based gene therapy for commercial use," commented Dr. Christine Guenther, CEO of apceth Biopharma. "We are proud to be the commercial manufacturing partner of bluebird bio and to be part of bringing this potentially life-changing therapy to TDT patients in Europe."

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.

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. At last follow up all patients treated with ZYNTEGLO in the clinical trial program remain alive.

For details, please see the Summary of Product Characteristics (SmPC). ZYNTEGLO has received a conditional marketing authorization in the European Union and is not approved in the United States.

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, LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

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 the company's commercialization plans and expectations for ZYNTEGLO. 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 we will encounter challenges in the commercial launch of ZYNTEGLO in the European Union, including in managing our complex supply chain for the delivery of drug product, in the adoption of value-based payment models or in obtaining sufficient coverage or reimbursement for our product. 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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