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): **November 8, 2019**

ACCELERON PHARMA INC.

(Exact name of Registrant as specified in its charter)

Delaware	**001-36065**	**27-0072226**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)
128 Sidney Street		**02139**
Cambridge, **MA**		
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: **(617) 649-9200**

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))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Ticker Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 per share	XLRN	The Nasdaq Global Market

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 November 8, 2019, Acceleron Pharma Inc. (the "Company") and Celgene Corporation issued a press release announcing that the U.S. Food and Drug Administration has approved REBLOZYL® (luspatercept-aamt) for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusions. REBLOZYL will be available as a 25-mg vial and a 75-mg vial, and the wholesale acquisition cost ("WAC") price per 25-mg vial is $3,441.18, and per 75-mg vial is $10,323.53.

A copy of the press release is attached 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 Number	Description of Exhibit
99.1	Press Release of Acceleron Pharma Inc. and Celgene Corporation dated November 8, 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.

ACCELERON PHARMA INC.

By: /s/ Adam M. Veness, Esq.

Adam M. Veness, Esq.
Vice President, General Counsel and Secretary

Date: November 8, 2019

Exhibit 99.1

FDA APPROVES REBLOZYL® (LUSPATERCEPT-AAMT) FOR THE TREATMENT OF ANEMIA IN ADULTS WITH BETA THALASSEMIA WHO REQUIRE REGULAR RED BLOOD CELL TRANSFUSIONS

REBLOZYL is the first and only FDA-approved erythroid maturation agent, representing a new class of therapy for these patients

Approval of REBLOZYL marks the first FDA-approved treatment for anemia in beta thalassemia

November 8, 2019 – SUMMIT, N.J. & CAMBRIDGE, Mass. – Celgene Corporation (NASDAQ: CELG) and Acceleron Pharma Inc. (NASDAQ: XLRN) today announced the U.S. Food and Drug Administration (FDA) has approved REBLOZYL® (luspatercept-aamt) for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.[1] REBLOZYL is the first and only FDA-approved erythroid maturation agent, representing a new class of therapy which works by regulating late-stage red blood cell maturation to help patients reduce their RBC transfusion burden.[1]

"Today's approval is an important milestone and underscores our continued commitment to patients with hematology disorders," said Nadim Ahmed, President, Global Hematology and Oncology for Celgene. "There are very limited options for patients living with anemia due to beta thalassemia who are dependent on long term red blood cell transfusions. We are pleased to make REBLOZYL available as a new therapy for these patients to help address their anemia, a significant clinical complication of beta thalassemia."

"We're thrilled that Acceleron's first approved medicine is one with the potential to help patients with beta thalassemia, who have been in need of new treatments for this lifelong disease," said Habib Dable, President and Chief Executive Officer of Acceleron. "We are enormously grateful to the patients, families and caregivers who participated in and supported our research. Their contributions have been essential in helping to ensure that REBLOZYL would emerge successfully from our longstanding collaboration with Celgene."

Beta thalassemia is a rare, inherited blood disorder caused by a genetic defect in hemoglobin. The disease is associated with ineffective erythropoiesis, which results in the production of fewer and less healthy RBCs, often leading to severe anemia– a condition that can be debilitating and can lead to more severe complications for patients – as well as other serious health issues.[2,3] Treatment options for anemia associated with beta thalassemia are limited, consisting mainly of RBC transfusions, which have the potential to contribute to iron overload, which can cause serious complications such as organ damage.[4]

The approval of REBLOZYL for beta thalassemia, which received a Priority Review designation from the FDA, is based on results from the pivotal, Phase 3, randomized, double-blind, placebo-controlled, multicenter BELIEVE trial evaluating the safety and efficacy of REBLOZYL for the treatment of anemia in adult patients with beta thalassemia who require regular RBC transfusions (defined as 6-20 RBC units per 24 weeks, with no transfusion-free period greater than 35 days during that period).[1] All patients were eligible to receive best supportive care, which included RBC transfusions; iron-chelating agents; use of antibiotic, antiviral, and antifungal therapy; and/or nutritional support, as needed.[1] The trial achieved a clinically meaningful and statistically significant improvement in the primary endpoint. [1] In the

REBLOZYL arm, 21.4% of patients (n=48) achieved a ≥33% reduction from baseline in RBC transfusion burden (with a reduction of at least 2 units) during weeks 13–24 after randomization, compared to 4.5% (n=5) in the placebo arm (risk difference [95% CI]: 17.0 [10.4, 23.6], P<0.0001).[1]

The study also met key secondary endpoints, including transfusion burden reduction of at least 33% (with a reduction of at least 2 units), during weeks 37 to week 48, which was achieved in 19.6% (n=44) of patients in the REBLOZYL arm and 3.6% (n=4) in the placebo arm (risk difference [95% CI]: 16.1 [9.8, 22.4], P<0.0001).[1]

Other efficacy endpoints included transfusion burden reduction of ≥50% (with a reduction of at least 2 units) during weeks 13-24 and weeks 37-48.[1] A ≥50% reduction in transfusion burden was observed in 7.6% of patients (n=17) receiving REBLOZYL vs. 1.8% of patients (n=2) in the placebo arm at weeks 13-24 (risk difference [95% CI]: 5.8 [1.6, 10.1], P=0.0303), and 10.3% of patients (n=23) vs. 0.9% of patients (n=1) at weeks 37-48 (risk difference [95% CI]: 9.4 [5, 13.7], P=0.0017), respectively.[1]

In the BELIEVE trial, thromboembolic events, including deep vein thromboses, pulmonary embolus, portal vein thrombosis, and ischemic stroke, were experienced in 3.6% (8/223) of REBLOZYL treated patients.[1] Hypertension was reported in 10.7% (61/571) of REBLOZYL-treated patients across the clinical development program.[1] REBLOZYL may cause fetal harm when administered to a pregnant woman. Serious adverse reactions occurred in 3.6% of patients receiving REBLOZYL.[1] Serious adverse reactions reported in 1% of patients were cerebrovascular accident and deep vein thrombosis.[1] One patient died due to an unconfirmed case of AML.[1] The most common adverse reactions (at least 10% for REBLOZYL, and 1% more than placebo) were headache (26% vs 24%), bone pain (20% vs 8%), arthralgia (19% vs 12%), fatigue (14% vs 13%), cough (14% vs 11%), abdominal pain (14% vs 12%), diarrhea (12% vs 10%) and dizziness (11% vs 5%).[1]

Permanent discontinuation due to an adverse reaction (Grades 1-4) occurred in 5.4% of patients who received REBLOZYL.[1] The most frequent adverse reactions requiring permanent discontinuation in patients who received REBLOZYL included arthralgia (1%), back pain (1%), bone pain (<1%), and headache (<1%).[1] Dosage reductions due to an adverse reaction occurred in 2.7% of patients who received REBLOZYL.[1] The most frequent adverse reactions requiring a dosage reduction in >0.5% of patients who received REBLOZYL included hypertension and headache.[1] Dosage interruptions due to an adverse reaction occurred in 15.2% of patients who received REBLOZYL.[1] The most frequent adverse reactions requiring a dosage interruption in >1% of patients who received REBLOZYL included upper respiratory tract infection, ALT increase, and cough.[1]

REBLOZYL is anticipated to be available 1 week following the FDA approval.

About BELIEVE
BELIEVE is a Phase 3, randomized, double-blind, placebo-controlled multicenter study comparing REBLOZYL + best supportive care (BSC) versus placebo + BSC in adults who require regular RBC transfusions (6-20 RBC units per 24 weeks with no transfusion-free period greater than 35 days during that period) due to beta thalassemia.[1] Best supportive care included RBC transfusions; iron-chelating agents; use of antibiotic, antiviral, and antifungal therapy; and/or nutritional support as needed. The median age of patients was 30 years in both treatment arms.[1] 336 patients were randomized 2:1 to receive either REBLOZYL (224 patients) or placebo (112 patients) at a starting dose of 1.0 mg/kg by subcutaneous injection every 21 days for up to 48 weeks.[1] Patients had the option to cross over to the luspatercept-aamt treatment groups only after all patients completed the treatment period, and after unblinding based on the recommendation of an independent Data Safety Monitoring Committee. Patients

treated with luspatercept-aamt will be followed for up to 5 years. The study was conducted at 65 sites in 15 countries. [1]

About REBLOZYL®
REBLOZYL is a first-in-class erythroid maturation agent that promotes late-stage red blood cell maturation in animal models. [1] Celgene and Acceleron are jointly developing REBLOZYL as part of a global collaboration.

Additional Clinical Investigation
The FDA is also evaluating luspatercept-aamt for the treatment of anemia in adults with very low- to intermediate-risk myelodysplastic syndromes (MDS) who have ring sideroblasts and require RBC transfusions. The FDA has set a Prescription Drug User Fee Act (PDUFA), or target action, date of April 4, 2020 for this indication. In Europe, Celgene's Marketing Authorization Application for the treatment of anemia in adults with beta thalassemia or MDS is currently under review.

A Phase 2 trial (BEYOND) in adult patients with non-transfusion-dependent beta thalassemia [5]; a Phase 3 trial (COMMANDS) in ESA-naïve, lower-risk MDS patients[6]; and a Phase 2 trial in myelofibrosis patients are ongoing. [7] For more information, please visit www.clinicaltrials.gov.

REBLOZYL has not been approved as safe and effective for use in patients with MDS or myelofibrosis in any country.

Indication
REBLOZYL is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions

REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia

Important Safety Information

WARNINGS AND PRECAUTIONS
Thrombosis/Thromboembolism
Thromboembolic events (TEE) were reported in 8/223 (3.6%) REBLOZYL-treated patients. TEEs included deep vein thrombosis, pulmonary embolus, portal vein thrombosis, and ischemic stroke. Patients with known risk factors for thromboembolism, (splenectomy or concomitant use of hormone replacement therapy), may be at further increased risk of thromboembolic conditions. Consider thromboprophylaxis in patients at increased risk of TEE. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly.

Hypertension
Hypertension was reported in 10.7% (61/571) of REBLOZYL-treated patients. Across clinical studies, the incidence of grade 3-4 hypertension ranged from 1.8% to 8.6%. In patients with beta thalassemia with normal baseline blood pressure, 13 (6.2%) patients developed systolic blood pressure (SBP) >130 mm Hg and 33 (16.6%) patients developed diastolic blood pressure (DBP) >80 mm Hg. Monitor blood pressure prior to each administration. Manage new or exacerbations of preexisting hypertension using anti-hypertensive agents.

Embryo-Fetal Toxicity

REBLOZYL may cause fetal harm when administered to a pregnant woman. REBLOZYL caused increased post-implantation loss, decreased litter size, and an increased incidence of skeletal variations in pregnant rat and rabbit studies. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurring in 1% of patients included cerebrovascular accident and deep vein thrombosis. A fatal adverse reaction occurred in one patient treated with REBLOZYL who died due to an unconfirmed case of AML.

Most common adverse reactions (at least 10% for REBLOZYL, and 1% more than placebo) were headache (26% vs 24%), bone pain (20% vs 8%), arthralgia (19% vs 12%), fatigue (14% vs 13%), cough (14% vs 11%), abdominal pain (14% vs 12%), diarrhea (12% vs 10%) and dizziness (11% vs 5%).[1]

LACTATION

It is not known whether REBLOZYL is excreted into human milk or absorbed systemically after ingestion by a nursing infant. REBLOZYL was detected in milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because many drugs are excreted in human milk, and because of the unknown effects of REBLOZYL in infants, a decision should be made whether to discontinue nursing or to discontinue treatment. Because of the potential for serious adverse reactions in the breastfed child, breastfeeding is not recommended during treatment and for 3 months after the last dose.

Please see full Prescribing Information for REBLOZYL

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com.

Follow Celgene on Social Media: Twitter, Pinterest, LinkedIn, Facebook and YouTube.

About Acceleron

Acceleron is a biopharmaceutical company dedicated to the discovery, development, and commercialization of therapeutics to treat serious and rare diseases. The Company's leadership in the understanding of TGF-beta superfamily biology and protein engineering generates innovative compounds that engage the body's ability to regulate cellular growth and repair.

Acceleron focuses its research and development efforts in hematologic, neuromuscular, and pulmonary diseases. In hematology, the Company and its global collaboration partner, Celgene, are co-promoting newly approved REBLOZYL® (luspatercept-aamt) in North America for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusions and developing luspatercept for the treatment of chronic anemia in myelodysplastic syndromes and myelofibrosis. Acceleron is also advancing its neuromuscular program with ACE-083, a locally-acting Myostatin+ agent in Phase 2 development in Charcot-Marie-Tooth disease and is conducting a Phase 2 pulmonary program with sotatercept in pulmonary arterial hypertension.

For more information, please visit www.acceleronpharma.com. Follow Acceleron on Social Media: @AcceleronPharma and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between Acceleron and Celgene; the potential of REBLOZYL ® (luspatercept-aamt) as a therapeutic drug; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that REBLOZYL will be successfully commercialized, or continue to be developed or complete necessary clinical phases. Forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in ongoing or planned clinical trials; the ability to obtain, maintain and enforce patent and other intellectual property protection for REBLOZYL; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission and with respect to Celgene includes risk factors related to the proposed transaction between Bristol-Myers Squibb and Celgene, such as, but not limited to, the risks that: management's time and attention is diverted on transaction related issues; disruption from the transaction makes it more difficult to maintain business, contractual and operational relationships; and Bristol-Myers Squibb, Celgene or the combined company is unable to retain key personnel. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Hyperlinks are provided as a convenience and for informational purposes only. Neither Celgene nor Acceleron bears responsibility for the security or content of external websites or websites outside of their respective control.

Celgene Corporation
Investors:
(908) 673-9628
ir@celgene.com
or
Media:
(908) 673-2275
media@celgene.com

Acceleron Pharma Inc.
Investors:

Todd James, IRC, (617) 649-9393
Vice President, Investor Relations and Corporate Communications

Ed Joyce, (617) 649-9242
Director, Investor Relations

or
Media:
Matt Fearer, (617) 301-9557
Director, Corporate Communications

---

[1]REBLOZYL U.S. Prescribing Information. Accessed November 2019.

[2]National Center for Advancing Translational Sciences, Genetic and Rare Diseases Information Center. Beta-thalassemia. Available at: http://rarediseases.info.nih.gov/gard/871/beta-thalassemia/resources/1. Accessed October 2019.

[3]National Institutes of Health: Genetics Home Reference. Beta-thalassemia. Available at: https://ghr.nlm.nih.gov/condition/beta-thalassemia#inheritance. Accessed October 2019.

[4]Galanello R and Origa R. Beta-thalassemia. *Orphanet J Rare Dis.* 2010 May 21;5:11. Available at: https://ojrd.biomedcentral.com/articles/10.1186/1750-1172-5-11. Accessed October 2019.

[5]ClinicalTrials.gov. A Study to Determine the Efficacy and Safety of Luspatercept in Adults With Non Transfusion Dependent Beta (â)-Thalassemia (BEYOND). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03342404?term=BEYOND&cond=Beta-Thalassemia&rank=2. Accessed October 2019.

[6]ClinicalTrials.gov. Efficacy and Safety Study of Luspatercept (ACE-536) Versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low or Intermediate Risk Myelodysplastic Syndromes (MDS) in ESA Naïve Subjects Who Require Red Blood Cell Transfusions (COMMANDS). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03682536?term=COMMANDS+luspatercept&rank=1. Accessed October 2019.

[7]ClinicalTrials.gov. A Safety and Efficacy Study to Evaluate Luspatercept in Subjects With Myeloproliferative Neoplasm-associated Myelofibrosis Who Have Anemia With and Without Red Blood Cell-transfusion Dependence. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03194542?term=luspatercept&cond=Myelofibrosis&rank=1. Accessed October 2019.