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FDA approves REBLOZYL® to treat anemia

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REBLOZYL is the first and only FDA-approved erythroid maturation agent, representing a new class of therapy for adults with beta thalassemia who require regular red blood cell transfusions

Celgene Corporation and Acceleron Pharma Inc. have 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. 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.

“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.”

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).

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