Generic Name:
Luspatercept?aamt
Trade Name:
Reblozyl
Company:
Celgene
Notes:

FDA has approved luspatercept?aamt to treat anemia in adult patients with beta thalassemia who require regular red blood cell transfusions.

Beta thalassemia, also called ?Cooley?s anemia,? is an inherited blood disorder that reduces the production of hemoglobin. In people with beta thalassemia, low levels of hemoglobin lead to a lack of oxygen in many parts of the body and anemia, which can cause pale skin, weakness, fatigue, and more serious complications. Supportive treatment for people with beta thalassemia often consists of lifelong regimens of chronic blood transfusions for survival and treatment for iron overload due to the transfusions. People with beta thalassemia are also at an increased risk of developing abnormal blood clots.

Approval of the new drug was based on results of a clinical trial of 336 patients with beta thalassemia who required red blood cell transfusions, of which 112 received a placebo. Twenty-one percent of the patients who received luspatercept?aamt achieved at least a 33% reduction in transfusions, compared with 4.5% of the patients who received a placebo. The transfusion reduction meant that the patient needed fewer transfusions over 12 consecutive weeks while taking luspatercept?aamt.

Common adverse effects were headache, bone pain, arthralgia, fatigue, cough, abdominal pain, diarrhea, and dizziness. Patients may experience hypertension while using luspatercept?aamt. Health professionals are advised to monitor a patient?s blood pressure during treatment and to initiate antihypertensive treatment if necessary. Patients who receive the drug should be monitored for thrombosis.

FDA advises health professionals to tell females of reproductive age to use effective contraception during treatment. Women who are pregnant or breastfeeding should not take luspatercept?aamt because it may cause harm to a developing fetus or newborn baby.

Medication Monitor Categories:
New Drug Approvals