FDA APPROVED FOR ANEMIA

IN MDS

Reblozyl®

(luspatercept-aamt)

for injection 25mg • 75mg

for patients with ring sideroblasts who are failing an ESA and require ≥2 RBC units/8 weeks[1]

HOW TO DOSE REBLOZYL

INDICATION

REBLOZYL is indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

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

In adult patients with beta thalassemia, thromboembolic events (TEE) were reported in 8/223 (3.6%) of 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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for REBLOZYL.

ESA=erythropoiesis-stimulating agent; RBC=red blood cell.

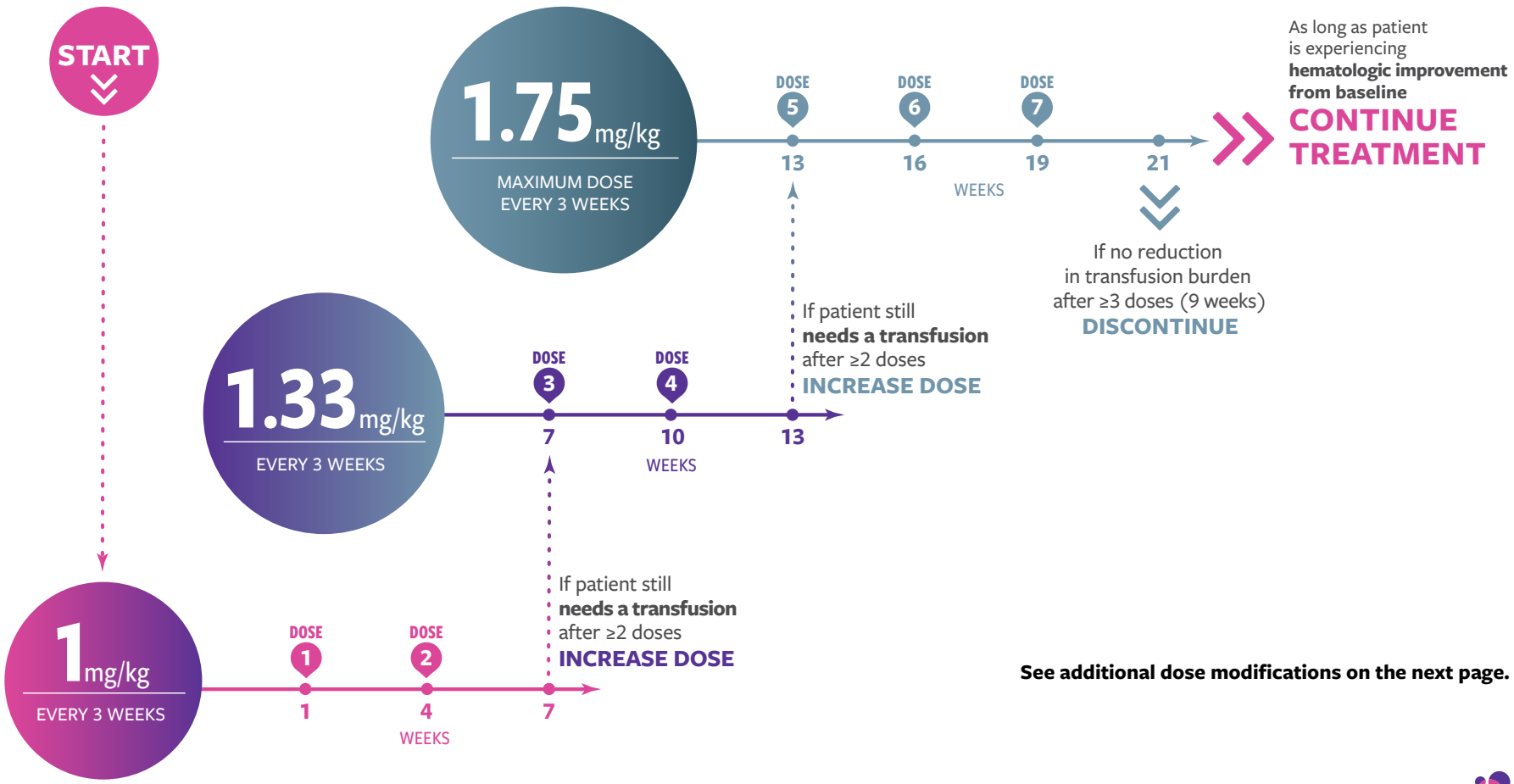
PLAN TO TREAT FOR A MINIMUM OF 7 CYCLES (21 WEEKS) TO ACHIEVE TREATMENT GOAL

Adjust dosing to optimize patient response[1]

- **If patient experiences transfusion independence, continue current dose**
- If patient loses response, titrate up to next dose level
- Do not continue treatment or increase the dose if the patient is experiencing unacceptable toxicity or an adverse reaction

Most patients will likely require at least 1 dose increase

77.1% of all MEDALIST patients receiving REBLOZYL had their dose increased at least once



See additional dose modifications on the next page.

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Dose modifications for predose Hgb levels or rapid Hgb rise

SCENARIO	REBLOZYL Dosing recommendation
Predose Hgb is ≥11.5 g/dL in the absence of transfusion	• Interrupt treatment • Restart when the Hgb is no more than **11 g/dL**
Increase in Hgb >2 g/dL within 3 weeks in the absence of transfusion and:	
Current dose is **1.75 mg/kg**	• Reduce dose to **1.33 mg/kg**
Current dose is **1.33 mg/kg**	• Reduce dose to **1 mg/kg**
Current dose is **1 mg/kg**	• Reduce dose to **0.8 mg/kg**
Current dose is **0.8 mg/kg**	• Reduce dose to **0.6 mg/kg**
Current dose is **0.6 mg/kg**	• Discontinue treatment

Dose increase in the event of loss of response[1]

- If, upon dose reduction, the patient loses response (ie, requires a transfusion) or Hgb concentration drops by 1 g/dL or more in 3 weeks in the absence of transfusion, increase the dose by 1 dose level
- Wait a minimum of 6 weeks between dose increases
- Dose increases to 1.33 mg/kg and subsequently to 1.75 mg/kg may occur at any time during treatment after patients have received at least 2 consecutive doses at the prior lower dose level
- Do not increase the dose more frequently than every 2 consecutive doses (6 weeks) or beyond the maximum dose of 1.75 mg/kg

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Hypertension

Hypertension was reported in 10.7% (61/571) of REBLOZYL-treated patients. Across clinical studies, the incidence of Grade 3 to 4 hypertension ranged from 1.8% to 8.6%. In adult patients with MDS with normal baseline blood pressure, 26 (29.9%) patients developed SBP ≥130 mm Hg and 23 (16.4%) patients developed DBP ≥80 mm Hg. Monitor blood pressure prior to each administration. Manage new or exacerbations of preexisting hypertension using anti-hypertensive agents.

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Discontinue treatment if no reduction in transfusion burden is observed[1]

- Discontinue REBLOZYL if a patient does not experience a decrease in transfusion burden after 3 doses (9 weeks of treatment) at the maximum dose level or if unacceptable toxicity occurs at any time

If a planned administration of REBLOZYL is delayed or missed[1]

- Administer REBLOZYL as soon as possible and continue dosing as prescribed, with at least 3 weeks between doses

REBLOZYL dosing modifications for adverse reactions[1]

SCENARIO	REBLOZYL Dosing recommendation
Grade 3 or 4 hypersensitivity reactions*	• Discontinue treatment
Other Grade 3 or 4 adverse reactions*	• Interrupt treatment • When the adverse reaction resolves to no more than Grade 1, restart treatment at the next lower dose level† • If the lower dose delay is >12 consecutive weeks, discontinue treatment

*Grade 1 is mild, Grade 2 is moderate. Grade 3 is severe, and Grade 4 is life-threatening.
†Per dose reductions in table above.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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 final dose.

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IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

Grade ≥3 (≥2%) adverse reactions included fatigue, hypertension, syncope and musculoskeletal pain. A fatal adverse reaction occurred in 5 (2.1%) patients.

The most common (≥10%) adverse reactions included fatigue, musculoskeletal pain, dizziness, diarrhea, nausea, hypersensitivity reactions, hypertension, headache, upper respiratory tract infection, bronchitis, and urinary tract infection.

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 click here for full Prescribing Information for REBLOZYL.

Click here to access a quick and easy interactive dosing calculator.

References: 1. REBLOZYL [Prescribing Information]. Summit, NJ: Celgene Corporation; 2020.
2. Data on file. Celgene Corporation. Summit, New Jersey.

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