IN MDS

Reblozyl®
(luspatercept-aamt)
for injection 25mg • 75mg

REBLOZYL limits transfusions[1,2]

Rapidly advance to REBLOZYL when ESAs fail

In the MEDALIST study, REBLOZYL's primary endpoint was RBC transfusion independence ≥8 weeks during weeks 1-24.[1] Additional information can be found within this video.
ESA=erythropoiesis stimulating agents; RBC=red blood cell.

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.

Please see additional Important Safety Information throughout and full Prescribing Information for REBLOZYL at this booth.

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommends luspatercept-aamt (REBLOZYL) as a treatment option after 6-8 weeks of no response to ESAs +/- G-CSF[2]*

*For symptomatic anemia in very low- to intermediate-risk MDS with ring sideroblasts (≥15% or ≥5% with an *SF3B1* mutation) and with serum EPO ≤500 mU/mL and no del(5q) with or without other cytogenetic abnormalities.

EPO=erythropoietin; G-CSF=granulocyte colony-stimulating factor; MDS=myelodysplastic syndromes; NCCN=National Comprehensive Cancer Network® (NCCN®).

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.

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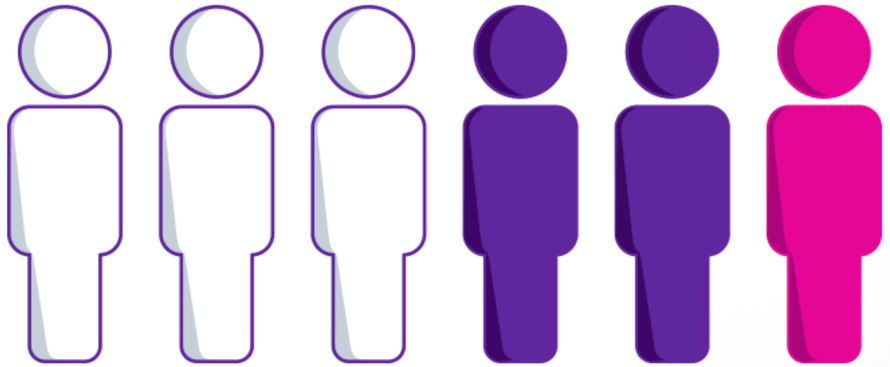
ESAs may fail in up to **50% of patients,** leading to a dependence on transfusions[3-7]



1 in 3 of those patients may experience signs and symptoms of ESA failure within **8 weeks**[5-7]

Lower-risk MDS patients need an alternative treatment option after ESA failure

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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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The NCCN Guidelines® defines lack of response to ESAs as[2]:

<1.5 g/dL rise in hemoglobin (Hgb) by **6-8 weeks** of treatment

OR

No decrease in RBC transfusion requirement by **6-8 weeks** of treatment

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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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In patients with MDS-RS,

Treat anemia with REBLOZYL after ESA failure

Consider REBLOZYL for adult patients who[1,9]:

- Are failing, intolerant to, or ineligible for an **ESA**
- Have anemia, requiring 2 or more **RBC units** over 8 weeks
- Have been classified as:

  Very low- to intermediate-risk **MDS with ring sideroblasts (RS)**, defined as MDS with:

  - **≥15%** bone marrow (BM) RS
  - **≥5%** BM RS with an *SF3B1* mutation

  OR

  Myelodysplastic syndromes/ Myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

IMPORTANT SAFETY INFORMATION

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.

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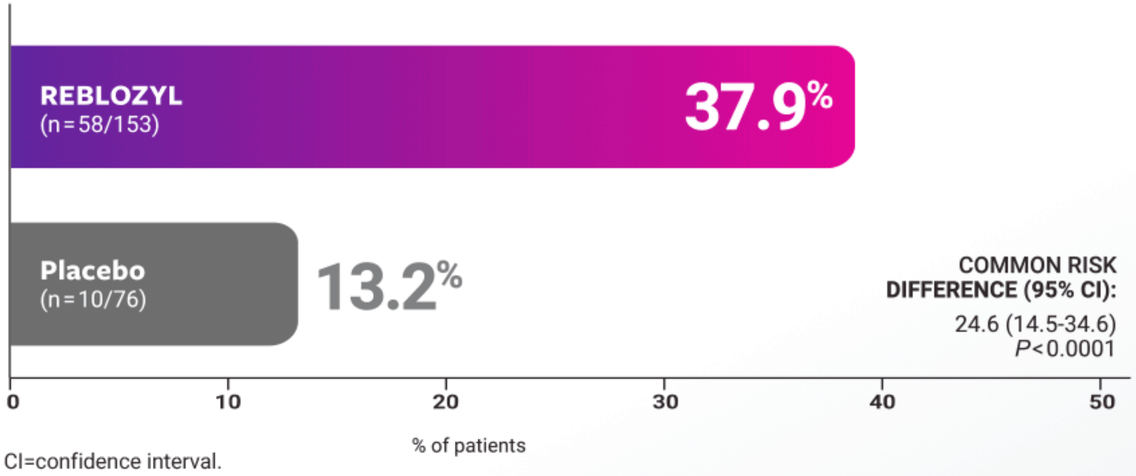
With REBLOZYL, you can now achieve transfusion independence[1]

REBLOZYL provided substantial clinical benefit through RBC transfusion independence (RBC-TI) vs placebo

Primary endpoint: RBC-TI ≥8 weeks during Weeks 1 to 24



CI=confidence interval.

APPROXIMATELY

3X greater percentage of patients receiving REBLOZYL achieved RBC transfusion independence (primary endpoint) than placebo

Study design: REBLOZYL was studied in the pivotal phase 3 MEDALIST trial of 229 patients with IPSS-R very low-, low-, or intermediate-risk MDS who have ring sideroblasts and require RBC transfusions (≥2 RBC units/8 weeks) who were randomized 2:1 to REBLOZYL (n=153) or placebo (n=76). Patients were required to have had an inadequate response to prior treatment with an ESA, be intolerant of ESAs, or be ineligible for ESAs (serum EPO ≥200 U/L). MEDALIST excluded patients with del(5q) MDS, white blood cell count >13 Gi/L, neutrophils <0.5 Gi/L, platelets <50 Gi/L, or with prior use of a disease-modifying agent for treatment of MDS. REBLOZYL was administered 1 mg/kg subcutaneously every 3 weeks.

IPSS-R=Revised International Prognostic Scoring System.

IMPORTANT SAFETY INFORMATION

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.

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Adverse reactions with REBLOZYL

- Among the 242 patients treated with REBLOZYL, **5 (2.1%) had a fatal adverse reaction**[1]
- **Selected laboratory abnormalities** that changed from Grade 0 to 1 at baseline to Grade ≥2 at any time during the studies in at least 10% of patients included creatinine clearance decreased, total billirubin increased, and alanine aminotransferase increased[1]
- **Other clinically relevant adverse reactions** reported in <5% of patients included bronchitis, urinary tract infection, and hypertension[1]

The majority of adverse reactions with REBLOZYL were Grade 1 or 2 (mild to moderate)[1]

- **The most common (≥10%) all-grade adverse reactions** included fatigue, musculoskeletal pain, dizziness, diarrhea, nausea, hypersensitivity reactions, hypertension, headache, upper respiratory tract infection, bronchitis, and urinary tract infection
- **The most common (≥2%) Grade ≥3 adverse reactions** included fatigue, hypertension, syncope, and musculoskeletal pain

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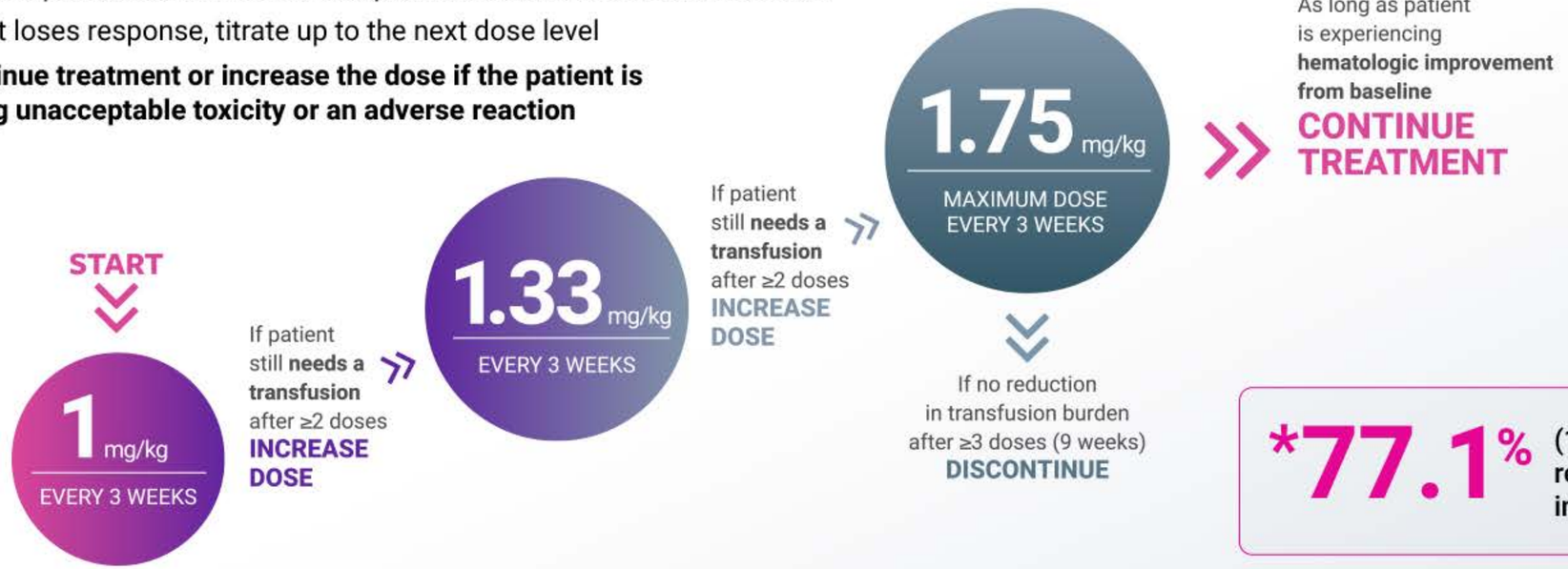
Optimize your patients' response to REBLOZYL

Plan to treat for a *minimum* of **7 cycles** (21 weeks) to achieve treatment goal

Most patients will likely require at least one dose increase*

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



***77.1%** (118/153) of all MEDALIST patients receiving REBLOZYL had their dose increased at least once[10]

INDICATION

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Dose modifications for predose Hgb levels or rapid Hgb rise[1]

SCENARIO	REBLOZYL Dosing recommendation
Predose Hgb is ≥**11 g/dL** in the absence of transfusions	• 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 transfusions 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

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Other dose modifications

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

- If, upon 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

Discountinue treatment if no reduction in transfusion burden is observed at maximum dose[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

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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 previously displayed table.

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Help your patients with MDS-associated anemia live with fewer transfusions

Learn more about REBLOZYL today

Speak with a Bristol Myers Squibb Hematology Consultant at this booth or visit REBLOZYLpro.com

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References: 1. REBLOZYL [US Prescribing Information]. Summit, NJ: Celgene Corporation; 2022. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes V.1.2023. National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed September 20, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **3.** Park S, Hamel J-F, Toma A, et al. Outcome of lower-risk patients with myelodysplastic syndromes without 5q deletion after failure of erythropoiesis-stimulating agents. *J Clin Oncol.* 2017;35(14):1591-1597. **4.** Fenaux P, Santini V, Spiriti MAA, et al. A phase 3 randomized, placebo-controlled study assessing the efficacy and safety of epoetin-α in anemic patients with low-risk MDS. *Leukemia.* 2018;32(12):2648-2658. **5.** Greenberg PL, Sun Z, Miller KB, et al. Treatment of myelodysplastic syndrome patients with erythropoietin with or without granulocyte colony-stimulating factor: results of a prospective randomized phase 3 trial by the Eastern Cooperative Oncology Group (E1996). *Blood.* 2009;114(12):2393-2400. **6.** Giraldo P, Nomdedeu B, Loscertales J, et al. Darbepoetin ˚ for the treatment of anemia in patients with myelodysplastic syndromes. *Cancer.* 2006;107(12):2807-2816. **7.** Kelaidi C, Park S, Sapena R, et al. Long-term outcome of anemic lower-risk myelodysplastic syndromes without 5q deletion refractory to or relapsing after erythropoiesis-stimulating agents. *Leukemia.* 2013;27(6):1283-1290. **8.** Kelaidi C, Beyne-Rauzy O, Braun T, et al. High response rate and improved exercise capacity and quality of life with a new regimen of darbepoetin alfa with or without filgrastim in lower-risk myelodysplastic syndromes: a phase II study by the GFM. *Ann Hematol.* 2013;92(5):621-631. **9.** Arber DA, Orazi A, Hasserjian R, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood.* 2016;127(20):2391-2405. **10.** Platzbecker U, Fenaux P, Mufti GJ, et al. Assessment of dose-dependent response to luspatercept in patients with lower-risk myelodysplastic syndromes with ring sideroblasts in the phase 3 MEDALIST trial [abstract EP812]. Presented at: 25th Congress of the European Hematology Association (EHA); June 11-14, 2020.

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