Reblozyl® (luspatercept-aamt) – Expanded indication

- On August 28, 2023, Bristol Myers Squibb announced the FDA approval of Reblozyl (luspatercept-aamt), for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions.

- Reblozyl is also approved for the treatment of anemia:

    - In adult patients with beta thalassemia who require regular RBC transfusions
    - Failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk MDS with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis.

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

- The approval of Reblozyl for the new indication was based on COMMANDS, an open-label, randomized, active-controlled study in patients with anemia due to Revised International Prognostic Scoring System (IPSS-R) very low, low, or intermediate-risk MDS or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis in ESA-naïve patients who require regular RBC transfusions. Patients received Reblozyl or an ESA (epoetin alfa). The primary endpoint was RBC transfusion independence (RBC-TI) for 12 weeks with a mean hemoglobin increase ≥ 1.5 g/dL. At the time of the interim efficacy analysis, 301 patients were included in the efficacy analysis.

    - The response rate was 58.5% with Reblozyl vs. 31.2% with epoetin alfa (common rate difference 26.6, 95% CI: 15.8, 37.4; $p < 0.0001$).

- The recommended starting dosage of Reblozyl for all uses is 1 mg/kg once every 3 weeks by subcutaneous injection.

    - Refer to the Reblozyl drug label for complete dosing and administration recommendations.