



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2023
EMA/CHMP/25569/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Reblozyl luspatercept

On 26 January 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Reblozyl. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted an extension to an existing indication to include treatment of anaemia associated with non-transfusion-dependent beta thalassaemia.

For information, the full indications will be as follows:²

Reblozyl is indicated for the treatment of adult patients with transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS) with ring sideroblasts, who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy (see section 5.1).

Reblozyl is indicated in adults for the treatment of anaemia associated with transfusion-dependent **and non-transfusion-dependent beta-thalassaemia** (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold

