26 April 2019
EMA/CHMP/208938/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Doptelet

avatrombopag

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Doptelet, intended for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure. The applicant for this medicinal product is Dova Pharmaceuticals Ireland Limited.

Doptelet will be available as 20 mg film-coated tablets. The active substance of Doptelet is avatrombopag, a thrombopoietin receptor agonist (ATC code: B02BX) that stimulates proliferation and differentiation of megakaryocytes from bone marrow progenitor cells, resulting in increased production of platelets.

The benefits with Doptelet are its ability to reduce the need for platelet transfusions before a scheduled invasive procedure or for rescue therapy for bleeding during the 7 days after the procedure. The most common side effect is fatigue.

The full indication is: "Doptelet is indicated for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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