13 December 2018
EMA/CHMP/862586/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lusutrombopag Shionogi

lusutrombopag

On 13 December 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lusutrombopag Shionogi, intended for the treatment of severe thrombocytopenia in adults with chronic liver disease undergoing invasive procedures. The applicant for this medicinal product is Shionogi B.V.

Lusutrombopag Shionogi will be available as 3 mg film-coated tablets. The active substance of Lusutrombopag Shionogi is lusutrombopag, a thrombopoietin (TPO) receptor agonist (ATC code: B02BX). Lusutrombopag acts on the transmembrane domain of TPO receptors, to induce proliferation and differentiation of megakaryocyte progenitor cells, thus leading to thrombocytopoiesis.

The benefit of Lusutrombopag Shionogi is that it reduces the need for platelet transfusions before the primary invasive procedure and for rescue therapy for bleeding during the 7 days after the procedure. The most common side effects are headache, nausea, portal vein thrombosis and rash.

The full indication is: "treatment of severe thrombocytopenia in adult patients with chronic liver disease undergoing invasive procedures (see section 5.1)".

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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