13 December 2018
EMA/CHMP/867687/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Besremi

ropeginterferon alfa-2b

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 Besremi, intended for the treatment of polycythaemia vera without symptomatic splenomegaly. Besremi was designated as an orphan medicinal product on 9 December 2011. The applicant for this medicinal product is AOP Orphan Pharmaceuticals AG.

Besremi will be available as a solution for injection (250 microgram/0.5 ml and 500 microgram /0.5 ml). The active substance of Besremi is ropeginterferon alfa-2b (ATC code: L03AB15), which inhibits the proliferation of hematopoietic and bone marrow fibroblast progenitor cells and antagonises the action of growth factors and other cytokines involved in the development of myelofibrosis.

The benefits with Besremi are its ability to achieve complete haematological responses in patients with polycythaemia vera. The most common side effects are leucopenia, thrombocytopenia, arthralgia, fatigue, flu-like illness and myalgia.

The full indication is: "Besremi is indicated as monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly." It is proposed that Besremi is prescribed by physicians experienced in the management of the disease.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact