19 April 2012
EMA/CHMP/231626/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jakavi
ruxolitinib

On 19 April 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jakavi, 5, 15, 20mg, tablet intended for the treatment of chronic idiopathic myelofibrosis and treatment of myelofibrosis secondary to polycythaemia vera or essential thrombocythaemia. Jakavi was designated as an orphan medicinal product on 07 November 2008 and 03 April 2009. The applicant for this medicinal product is Novartis Europharm Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Jakavi is ruxolitinib, a protein kinase inhibitor, ATC code: L01XE18, the antineoplastic activity of which is linked to the selective inhibition of the Janus Associated Kinases (JAKs) involved in the signalling mediation of a number of cytokines and growth factors that are important for haematopoiesis and immune function.

The benefits with Jakavi are its ability to reduce the size of the spleen by at least 35 % and to treat other symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. The most common side effects are thrombocytopenia, anaemia and bleeding.

A pharmacovigilance plan for Jakavi will be implemented as part of the marketing authorisation.

The approved indication is: " Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis." It is proposed that ruxolitinib be prescribed by physicians experienced in the administration of anti-cancer agents.

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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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Jakavi and therefore recommends the granting of the marketing authorisation.