21 March 2013
EMA/CHMP/178415/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Iclusig

Ponatinib

On 21 March 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Iclusig 15 mg and 45 mg film-coated tablets intended for the treatment of chronic myeloid leukaemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL). Iclusig was designated as an orphan medicinal product on 2 February 2010. The applicant for this medicinal product is ARIAD Pharma 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 Iclusig is ponatinib, a protein kinase inhibitor (L01XE24). It acts by inhibiting the BCR-ABL kinase.

The benefits with Iclusig are its cytogenetic and haematological response rates in patients with CML and Ph+ ALL including patients bearing T315I mutation. The most common side effects are platelet count decreased, rash, dry skin, and abdominal pain.

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

The approved indication is: “Iclusig is indicated in adult patients with

- chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation
- Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

It is proposed that Iclusig be initiated by physicians experienced in the diagnosis and treatment of patients with leukaemia.

[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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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.

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