17 January 2013
EMA/CHMP/4601/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Bosulif

Bosutinib

On 17 January 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Bosulif 100 mg and 500 mg film-coated tablets intended for the treatment of chronic myelogenous leukaemia (CML). Bosulif was designated as an orphan medicinal product on 4 August 2010. The applicant for this medicinal product is Pfizer Limited. 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 Bosulif is bosutinib, a protein kinase inhibitor (L01XE14). It acts by inhibiting the abnormal Bcr-Abl kinase that promotes CML.

The benefits with Bosulif are its haematological or cytogenetic response rates in patients with CML previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options. The most common side effects are diarrhoea, nausea, thrombocytopenia, vomiting, abdominal pain, rash, anaemia, pyrexia and alanine aminotranserase increased.

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

The approved indication is: “Bosulif is indicated for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.”

It is proposed that therapy with Bosulif be initiated by a physician experienced in the diagnosis and the treatment of patients with CML.

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

[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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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 Bosulif and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.