15 December 2011
EMA/CHMP/926998/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zelboraf

vemurafenib

On 15 December 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zelboraf, 240mg, Film-coated tablet intended for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma (see section 5.1). The applicant for this medicinal product is Roche Registration 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 Zelboraf is vemurafenib, a protein kinase inhibitors (LO1XE15) that inhibits the BRAF serine-threonine kinase which has a mutation at position 600 (BRAF V600E). This mutation results in constitutively activated BRAF proteins, which can cause cell proliferation in the absence of growth factors that would normally be required for proliferation.

The benefits with Zelboraf are its ability to improve overall survival in melanoma patients that have tumours that are positive for BRAFV600E. The most common side effects are rash, arthralgia, fatigue, photosensitivity reaction, nausea, alopecia and pruritis.

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

The approved indication is: "Vemurafenib is indicated in monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma (see section 5.1)." It is proposed that Zelboraf be initiated and supervised by a qualified physician experienced in the use of anticancer medicinal products.

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 Zelboraf and therefore recommends the granting of the marketing authorisation.

[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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