



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Tafinlar dabrafenib

On 27 June 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 Tafinlar, 50 and 75 mg capsules, hard, intended for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. The applicant for this medicinal product is GlaxoSmithKline Trading Services 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 Tafinlar is dabrafenib, a protein kinase inhibitor (L01XE23) that inhibits BRAF kinases with activating codon 600 mutations.

The benefits with Tafinlar are its ability to delay the progression of disease and to improve the response rate. The most common side effects are hyperkeratosis, headache, pyrexia, arthralgia, fatigue, nausea, papilloma, alopecia, rash and vomiting.

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

The approved indication is: "Dabrafenib is indicated in monotherapy for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation (see section 5.1). It is proposed that Tafinlar 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 Tafinlar 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.

