



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2014
EMA/CHMP/197424/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Mekinist trametinib

On 25 April 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mekinist, 0.5, 1 and 2 mg, film-coated tablet intended for the treatment of unresectable or metastatic melanoma with a BRAF V600 mutation. The applicant for this medicinal product is Glaxo Group 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 Mekinist is trametinib, a protein kinase inhibitor (L01XE25) that inhibits mitogen-activated extracellular signal regulated kinase 1 (MEK1) and MEK2 activation and kinase activity.

The benefits with Mekinist are its ability to improve overall survival and progression free survival in melanoma patients with a BRAF V600 mutation compared to chemotherapy. The most common side effects are rash, diarrhoea, fatigue, oedema peripheral, nausea, and dermatitis acneiform.

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

The approved indication is: "Trametinib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Trametinib has not demonstrated clinical activity in patients who have progressed on a prior BRAF inhibitor therapy (see section 5.1)." It is proposed that Mekinist be initiated and supervised by a physician experienced in the administration of anti-cancer 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.

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.



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