25 April 2013
EMA/CHMP/263262/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Erivedge

vismodegib

On 25 April 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 Erivedge 150 mg, hard capsule, intended for the treatment of adult patients with symptomatic metastatic basal cell carcinoma or locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy.

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 Erivedge is vismodegib, an antineoplastic agent (ATC Code: L01XX43), an orally available small-molecule which acts by blocking specific genes involved in proliferation, survival, and differentiation of cells.

The benefits with Erivedge are its ability to reduce lesion size or sum of the longest diameter of lesions more than 30 % or to provide complete resolution of ulceration in all target lesions in 48% of the patients with locally advanced BCC and in 33% of the patients with metastatic BCC. The most common side effects are muscle spasms, alopecia, dysgeusia, weight decreased, fatigue and nausea. There is a high risk that Erivedge can cause embryo-foetal death or severe birth defects.

A pregnancy prevention plan and a pharmacovigilance plan for Erivedge will be implemented as part of the marketing authorisation.

The approved indication is: “treatment of adult patients with symptomatic metastatic basal cell carcinoma, or locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy ". It is proposed that Erivedge be prescribed by physicians experienced in the treatment of advanced basal cell carcinoma.

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 Erivedge 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.