25 June 2015
EMA/CHMP/400811/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Odomzo

sonidegib

On 25 June 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Odomzo, intended for the treatment of adults with locally advanced basal cell carcinoma (BCC). The applicant for this medicinal product is Novartis Europharm Ltd.

Odomzo will be available as 200 mg hard capsules. The active substance of Odomzo is sonidegib, an antineoplastic agent (ATC code: L01XX48). Sonidegib inhibits the Hedgehog pathway, a key regulator of development and morphogenesis in mammals, which is linked to the pathogenesis of several cancers including BCC.

The benefits with Odomzo are its ability to reduce locally advanced BCC lesions, with a response rate of about 54% and a progression-free survival of approximately 22 months. The most common side effects of Odomzo treatment are muscle cramps, muscle pain, hair loss, alteration or loss of taste, nausea, diarrhoea, blood creatine phosphokinase increased weight decrease and fatigue.

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

The full indication is: "Odomzo is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) who are not amenable to curative surgery or radiation therapy." It is proposed that Odomzo should only be prescribed by or under the supervision of a specialist physician experienced in the management of the approved indication.

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

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