20 May 2021
EMA/CHMP/212648/2021 corr.
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Klisyri

tirbanibulin

On 20 May 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Klisyri, intended for the treatment of actinic keratosis.

The applicant for this medicinal product is Almirall, S.A.

Klisyri will be available as 10 mg/g ointment. The active substance of Klisyri is tirbanibulin and belongs to the pharmacotherapeutic group of antibiotics and chemotherapeutics for dermatological use (ATC code: D06BX03). It works by disrupting microtubules by direct binding to tubulin, which induces cell cycle arrest and apoptotic death of proliferating cells.

The benefits of Klisyri are higher complete and partial clearance rates of lesions on the face and scalp in patients treated with Klisyri compared with vehicle, as observed in two pivotal randomised, double-blind, vehicle-controlled Phase III studies. The most common side effects are local skin reactions at the application site including erythema, flaking/scaling, crusting, swelling and erosion/ulceration.

The full indication is:

> Klisyri is indicated for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.

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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