EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2014
EMA/CHMP/601448/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Scenesse

afamelanotide

On 23 October 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 Scenesse, 16 mg, implant, intended for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). Scenesse was designated as an orphan medicinal product on 8 May 2008. The applicant for this medicinal product is Clinuvel UK 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 Scenesse is afamelanotide, a synthetic analogue of the physiologically occurring α-melanocyte stimulating hormone that acts as a melanocortin-1 receptor agonist thereby stimulating melanogenesis and emollients and protectives (D02BB02). The increased melanogenesis results in increased pigmentation of the skin.

The benefits with Scenesse are a decrease in light sensitivity, which translates into a limited increase in time EPP patients may spend in daylight or sunlight. Patients report an improved quality of life with increased time spent outside (commuting, work, leisure/sport, social). The most common side effects are headache, nausea, nasopharyngitis, migraine, abdominal pain, fatigue, lethargy and somnolence.

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

The approved indication is: “indicated for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP)". It is proposed that Scenesse be prescribed by physicians experienced in the treatment of erythropoietic protoporphyria.

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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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Scenesse and therefore recommends the granting of the marketing authorisation under exceptional circumstances[2].

[2] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.