10 December 2020
EMA/CHMP/652159/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lumoxiti

moxetumomab pasudotox

On 10 December 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Lumoxiti[3], intended for the treatment of relapsed or refractory hairy cell leukaemia.

The applicant for this medicinal product is AstraZeneca AB.

Lumoxiti will be available as 1-mg powder (with stabiliser solution) for concentrate for solution for infusion. The active substance of Lumoxiti is moxetumomab pasudotox, an antineoplastic agent (ATC code: L01XC34). Moxetumomab pasudotox is a CD22-targeted immunotoxin designed to direct the cytotoxic action of the truncated Pseudomonas exotoxin to cells which express the CD22 receptor.

The benefit with Lumoxiti is its ability to provide a durable response in patients with relapsed or refractory hairy cell leukaemia. The most common side effects are peripheral oedema, nausea, fatigue, headache, and pyrexia. Important identified risks are haemolytic uraemic syndrome and capillary leak syndrome.

The full indication is:

> Lumoxiti as monotherapy is indicated for the treatment of adult patients with relapsed or refractory hairy cell leukaemia (HCL) after receiving at least two prior systemic therapies, including treatment with a purine nucleoside analogue (PNA).

Lumoxiti should be prescribed by physicians experienced in the use of anticancer 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

[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
[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.
[3] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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