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Public statement

Lumoxiti

Withdrawal of the marketing authorisation in the European Union

On 23 July 2021 the European Commission withdrew the marketing authorisation for Lumoxiti (moxetumomab pasudotox) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, AstraZeneca AB, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Lumoxiti was granted marketing authorisation in the EU on 8 February 2021 for treatment of adult patients with relapsed or refractory hairy cell leukaemia (HCL) after receiving at least two prior systemic therapies. The marketing authorisation was initially valid for a 5-year period. The product had not been marketed in the EU.

The European Public Assessment Report (EPAR) for Lumoxiti will be updated to indicate that the marketing authorisation is no longer valid.

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