EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/CHMP/494372/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ivozall

clofarabine

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ivozall, intended for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients. The applicant for this medicinal product is ORPHELIA Pharma SAS.

Ivozall will be available as a 1 mg/ml concentrate for solution for infusion. The active substance of Ivozall is clofarabine, an antineoplastic agent (ATC code: L01BB06). Its anti-tumour activity is believed to be due to the inhibition of DNA polymerase and of ribonucleotide reductase and the disruption of mitochondrial membrane integrity.

Ivozall is a generic of Evoltra, which has been authorised in the EU since 29 May 2006. Since Ivozall and Evoltra are administered intravenously, both are fully bioavailable and a bioequivalence study was not required. A question-and-answer document on generic medicines can be found here.

The full indication is:

> "Treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients who have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response. Safety and efficacy have been assessed in studies of patients ≤ 21 years old at initial diagnosis."

It is proposed that Ivozall be prescribed by physicians experienced in the treatment of patients with acute leukaemias.

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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