EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: clofarabine

Procedure No. EMEA/H/C/PSUSA/00000805/201412

Period covered by the PSUR: 29 December 2013 – 28 December 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for clofarabine, the scientific conclusions of CHMP are as follows:

A search in the Marketing Authorisation Holder safety database retrieved 25 cases reporting acute hepatic failure/hepatic failure (including 24 fatal cases) and 13 cases reporting hepatitis (including 1 fatal case). Although the majority of cases were confounded by concurrent conditions (especially sepsis and multiorgane failure) and/or concomitant medications, the PRAC concurs with the MAH that safety analysis provides sufficient evidence to support a causal relationship between hepatic failure/hepatitis and clofarabine. In support of this position, a potential risk for hepatocellular injury in association with clofarabine was evidenced in a multi-cycle 6 months toxicity study in rats.

Therefore, in view of available data regarding hepatitis and hepatic failure, the PRAC considers that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for clofarabine the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing clofarabine is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation should be varied.