30 April 2020
EMA/CHMP/222209/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Daurismo

glasdegib

On 30 April 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Daurismo[2], intended for the treatment of acute myeloid leukaemia (AML). The applicant for this medicinal product is Pfizer Europe MA EEIG.

Daurismo will be available as 25 mg and 100 mg film-coated tablets. The active substance of Daurismo is glasdegib, an antineoplastic agent (ATC code: L01XX63). Glasdegib is an inhibitor of the Hedgehog (Hh) signal transduction pathway. It binds to a transmembrane protein (Smoothened, SMO), leading to decreased glioma-associated oncogene (GLI) transcription factor activity and downstream pathway signalling, thus reducing GLI1 levels in AML cells and the leukaemic initiating potential of AML cells.

The benefits of Daurismo are its ability to improve the overall survival when combined with low-dose cytarabine. The most common side effects are nausea, decreased appetite, fatigue, muscle spasms, diarrhoea, dysgeusia, constipation, abdominal pain, rash and vomiting. The most frequent severe adverse reaction reported was fatigue.

The full indication is:

> Daurismo is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed de novo or secondary acute myeloid leukaemia (AML) in adult patients who are not candidates for standard induction chemotherapy.

It is proposed that Daurismo be prescribed by physicians experienced in the use of anticancer 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 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

[2] 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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