19 July 2012
EMA/461407/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dacogen

decitabine

On 19 July 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dacogen, 50 mg, powder for concentrate for solution for infusion, intended for the treatment of acute myeloid leukaemia. Dacogen was designated as an orphan medicinal product on 8 June 2006. The applicant for this medicinal product is Janssen-Cilag International NV. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Dacogen is decitabine, a Pyrimidine analogue (L01BC08). It is a cytosine nucleoside analogue which inhibits DNA methyltransferase.

The benefits with Dacogen are its ability to show an increase in overall survival. The most common side effects are pyrexia, pneumonia, thrombocytopenia, anaemia, febrile neutropenia, neutropenia, nausea and diarrhoea.

A pharmacovigilance plan for Dacogen will be implemented as part of the marketing authorisation.

The approved indication is: “Dacogen is indicated for the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy”. It is proposed that Dacogen be prescribed by physicians experienced in the use of chemotherapeutic agents.

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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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Dacogen and therefore recommends the granting of the marketing authorisation.