30 May 2013
EMA/306855/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pomalidomide Celgene

pomalidomide

On 30 May 2013 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pomalidomide Celgene intended for the treatment of multiple myeloma. Pomalidomide Celgene was designated as an orphan medicinal product on 8 October 2009. The applicant for this medicinal product is Celgene Europe Limited. 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 Pomalidomide Celgene is pomalidomide, an immunomodulating agent (ATC Code: L04AX06). Pomalidomide has direct anti-myeloma tumouricidal activity, immunomodulatory activities and inhibits stromal cell support for multiple myeloma tumour cell growth

The benefits with Pomalidomide Celgene, in combination with low-dose dexamethasone, are its ability to prolong survival. A teratogenic effect of Pomalidomide Celgene in humans is expected. The most common side effects are anaemia, neutropenia, thrombocytopenia, fatigue and pyrexia.

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

The approved indication is: "Pomalidomide Celgene in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy."

It is proposed that Pomalidomide Celgene treatment be initiated and monitored under the supervision of physicians experienced in the management of multiple myeloma.

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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