26 February 2015
EMA/CHMP/83846/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ristempa

pegfilgrastim

On 26 February 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ristempa, 6mg, solution for injection intended for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy.

The applicant for this medicinal product is Amgen Europe B.V. 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 Ristempa is pegfilgrastim, an immunostimulants (L03AA13) that belongs to the class of haematopoietic growth factors (granulocyte-colony stimulating factor; G-CSF) which increases the production and differentiation of mature and functionally active neutrophils from bone marrow precursor cells.

The benefits with Ristempa are its ability to reduce the duration of neutropenia and the occurrence of febrile neutropenia. The most common side effects are bone and muscle pain, headache and nausea.

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

The approved indication is: "Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)". It is proposed that Ristempa be initiated and supervised by physicians experienced in oncology and/or haematology.

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 Ristempa and therefore recommends the granting of the marketing authorisation.