23 March 2017
EMA/CHMP/153871/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dinutuximab beta Apeiron

dinutuximab beta

On 23 March 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Dinutuximab beta Apeiron, intended for the treatment of high-risk neuroblastoma in children and adults. Dinutuximab beta Apeiron was designated as an orphan medicinal product on 8 November 2012. The Committee also concluded that the active substance contained in Dinutuximab beta Apeiron (dinutuximab beta) could not be considered a new active substance.

The applicant for this medicinal product is APEIRON Biologics AG.

Dinutuximab beta Apeiron will be available as a 4.5 mg/ml concentrate for solution for infusion. The active substance of Dinutuximab beta Apeiron is dinutuximab beta, a monoclonal chimeric antibody (ATC code: L01XC) which reacts specifically with the ganglioside GD2. GD2 is highly expressed on the surface of neuroblastoma cells but in normal tissues is largely restricted to the surface of neurons, peripheral nerve fibres, and skin melanocytes.

The benefit with Dinutuximab beta Apeiron is an improvement in the survival of patients when compared with historical controls. The most common side effects are pyrexia, pain and allergic reactions.

The full indication is:

> "Dinutuximab beta Apeiron is indicated for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures.

[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] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.

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In patients with a history of relapsed/refractory disease and in patients who have not achieved a complete response after first line therapy, Dinutuximab beta Apeiron should be combined with interleukin-2 (IL-2)."

It is proposed that Dinutuximab beta Apeiron be prescribed by physician experienced in the use of oncological therapies.

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.