24 September 2015
EMA/627858/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kyprolis

carfilzomib

On 24 September the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kyprolis, intended for the treatment of multiple myeloma. Kyprolis was designated as an orphan medicinal product on 3 June 2008. The applicant for this medicinal product is Amgen Europe B.V.

Kyprolis will be available as a 60 mg powder for solution for injection. The active substance of Kyprolis is carfilzomib, an irreversible proteasome inhibitor (ATC code: L01XX45).

The benefits with Kyprolis are its ability to delay the progression of disease when used in combination with lenalidomide and dexamethasone. The most common side effects are anaemia, fatigue, diarrhoea, thrombocytopenia, nausea, pyrexia, dyspnoea, respiratory tract infection, cough and peripheral oedema.

The full indication is: "Kyprolis in combination with lenalidomide and dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy". It is proposed that Kyprolis treatment should be supervised by a physician experienced in the use of anti-cancer therapy.

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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