15 September 2016
EMA/CHMP/603622/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ninlaro

ixazomib

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Ninlaro, intended for the treatment of multiple myeloma. Ninlaro was designated as an orphan medicinal product on 27 September 2011. The applicant for this medicinal product is Takeda Pharma A/S.

Ninlaro will be available as 2.3, 3 and 4 mg hard capsules. The active substance of Ninlaro is ixazomib, a reversible proteasome inhibitor (ATC code: L01XX50).

The benefits with Ninlaro are its ability to delay the progression of multiple myeloma when used in combination with lenalidomide and dexamethasone. The most common side effects are diarrhoea, constipation, thrombocytopenia, peripheral neuropathy, nausea, peripheral oedema, vomiting and back pain.

The full indication is: “Ninlaro 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 treatment must be initiated and monitored under the supervision of a physician 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 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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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