26 April 2023
EMA/167799/2023
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Jaypirca

pirtobrutinib

On 26 April 2023, 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 Jaypirca[3], intended for the treatment of relapsed or refractory mantle cell lymphoma (MCL). The applicant for this medicinal product is Eli Lilly Nederland B.V.

Jaypirca will be available as 50 mg and 100 mg film-coated tablets. The active substance of Jaypirca is pirtobrutinib, a protein kinase inhibitor (ATC code: not yet assigned). Pirtobrutinib is a reversible, noncovalent inhibitor of Bruton's tyrosine kinase, which is involved in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion.

The benefit of Jaypirca is its ability to bring about a response in patients with relapsed and refractory mantle cell lymphoma. The most common side effects are fatigue, neutropenia, diarrhoea and contusion.

The full indication is:

> Jaypirca as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor.

Jaypirca should be prescribed by physicians experienced in the treatment of mantle cell lymphoma.

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 expected to provide comprehensive clinical data at a later stage.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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