15 September 2022
EMA/CHMP/722012/2022 Corr.[1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (initial authorisation)

Zynlonta

loncastuximab tesirine

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[3] marketing authorisation for the medicinal product Zynlonta[4], intended for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL). The applicant for this medicinal product is ADC Therapeutics (NL) B.V.

Zynlonta will be available as a 10 mg powder for concentrate for solution for infusion. The active substance of Zynlonta is loncastuximab tesirine, a monoclonal antibody and drug conjugate (ATC code: L01FX22). Zynlonta delivers SG3199, a pyrrolobenzodiazepine (PBD) dimer cytotoxin, to B-cell malignancies by targeting CD19. Upon binding to CD19, Zynlonta is internalised and SG3199 is released, resulting in the formation of highly cytotoxic DNA interstrand cross-links, which cause cell-death.

The benefits of Zynlonta are its ability to provide durable treatment responses after up to 1 year of treatment in patients with relapsed or refractory DLBCL, as shown in a phase 2, open-label, single arm study. The most common side effects are gamma-glutamyltransferase (GGT) increased, neutropenia, fatigue, anaemia, thrombocytopenia, nausea, peripheral oedema and rash.

The full indication is:

> Zynlonta as monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy.

Zynlonta should be prescribed by physicians experienced in the treatment of cancer.

Detailed recommendations for the use of this product will be described in the summary of product

[1] 19 September 2022
[2] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[3] 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.
[4] 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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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.