27 June 2024
EMA/CHMP/276689/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ordspono

odronextamab

On 27 June 2024, 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 Ordspono[3], intended for the treatment of follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL). The applicant for this medicinal product is Regeneron Ireland Designated Activity Company.

Ordspono will be available as concentrate (2 mg, 80 mg and 320 mg) for solution for infusion. The active substance of Ordspono is odronextamab, an antineoplastic agent (ATC code: not yet assigned). Odronextamab is a bispecific antibody that binds to CD20-expressing B cells and CD3 expressed on T cells. Simultaneously engaging both induces T-cell activation and the generation of a polyclonal cytotoxic T-cell response, which results in the lysis of the targeted cells, including malignant B cells.

The benefits of Ordspono were evident in terms of a complete response (CR) rate and overall response rate (ORR) with a significant duration, as observed in an open-label, multicentre phase 2 trial evaluating Orspono in patients with DLBCL or FL who had relapsed after or were refractory after two or more lines of systemic therapy. The most common side effects are cytokine release syndrome, infections, neutropenia, pyrexia, anaemia, thrombocytopenia and diarrhoea.

The full indication is:

> Ordspono as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (r/r FL) after two or more lines of systemic therapy.
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> Ordspono as monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) after two or more lines of systemic therapy.

Ordspono should be prescribed by physicians experienced in the treatment of haematological

[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
[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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malignancies and who have access to appropriate medical support to manage severe reactions associated with cytokine release syndrome.

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.