22 February 2024
EMA/CHMP/63838/2024
Committee for Medicinal Products for Human Use (CHMP)

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

# Voydeya

## danicopan

On 22 February 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Voydeya[2], intended as add-on therapy to ravulizumab or eculizumab for the treatment of residual haemolytic anaemia in adult patients with paroxysmal nocturnal haemoglobinuria (PNH). The applicant for this medicinal product is Alexion Europe.

Voydeya will be available as 50 mg and 100 mg film-coated tablets. The active substance of Voydeya is Danicopan, a complement inhibitor (ATC code: L04AJ09) which reversibly binds to factor D to prevent alternative pathway-mediated haemolysis and deposition of complement C3 proteins on red blood cells, thereby helping to relieve the symptoms of PNH.

The benefit of Voydeya, when added to C5-inhibitor treatment, is its ability to prevent haemolysis and increase haemoglobin levels, as seen in a phase 3 randomised, placebo-controlled trial in patients with PNH and residual haemolytic anaemia. The most common side effects are pyrexia, headache, increased hepatic enzyme levels and pain in the extremities.

The full indication is:

> Voydeya is indicated as an add-on to ravulizumab or eculizumab for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have residual haemolytic anaemia

Voydeya should be prescribed by physicians experienced in the management of patients with haematological disorders.

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] 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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