25 February 2021
EMA/CHMP/86405/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Orladeyo

berotralstat

On 25 February 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Orladeyo[2], intended for the prevention of recurrent attacks of hereditary angioedema (HAE).

The applicant for this medicinal product is BioCryst Ireland Limited.

Orladeyo will be available as 150-mg hard capsules. The active substance of Orladeyo is berotralstat, an inhibitor of plasma kallikrein (ATC code: B06AC) which acts by reducing the release of bradykinin, a potent vasodilator involved in HAE attacks.

The benefit of Orladeyo is its ability to significantly reduce the hereditary angioedema attack rate. In patients receiving Orladeyo 150 mg orally, HAE attacks were 44% less frequent than with placebo. The most common adverse reactions are headache, abdominal pain and diarrhoea.

The full indication is:

> Orladeyo is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older.

Orladeyo should be prescribed by physicians experienced in the treatment of hereditary angioedema.

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 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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