14 December 2023
EMA/CHMP/552342/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Velsipity

etrasimod

On 14 December 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Velsipity, intended for the treatment of ulcerative colitis. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Velsipity will be available as a 2 mg film-coated tablet. The active substance of Velsipity is etrasimod, a selective immunosuppressant (ATC code: L04AE05). The mechanism by which etrasimod exerts therapeutic effects in ulcerative colitis is unknown, but it may involve the reduction of lymphocyte migration into sites of inflammation, as selective binding of etrasimod to S1P receptors 1,4 and 5 partially and reversibly blocks the capacity of lymphocytes to egress from lymphoid organs.

The benefits of Velsipity are the achievement of remission of ulcerative colitis in patients with moderate to severe disease, normalizing stool frequency and rectal bleeding and inducing endoscopic healing. Efficacy was demonstrated in two phase 3 randomised, double-blind, and placebo-controlled studies. The most common side effects are lymphopenia and headache.

The full indication is:

> Velsipity is indicated for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

Treatment with Velsipity should be initiated under the supervision of a physician experienced in the management of ulcerative colitis.

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

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