30 March 2023
EMA/CHMP/138535/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Omvoh

mirikizumab

On 30 March 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 Omvoh, intended for the treatment of ulcerative colitis. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Omvoh will be available as a 300 mg concentrate for solution for infusion and a 100 mg solution for injection. The active substance of Omvoh is mirikizumab, an interleukin inhibitor (ATC code: L04AC) binding selectively to the p19 subunit of human IL-23, thereby inhibiting its interaction with the IL-23 receptor and normalising the production of effector cytokines that drive inflammatory disease.

The benefits of Omvoh in the treatment of ulcerative colitis are its ability to induce clinical remission, with both patients with no prior biologic treatment as well as those who have failed prior biologic treatment showing both clinical and endoscopic responses.

The most common side effects are upper respiratory tract infections (most frequently nasopharyngitis), headache, rash and injection site reactions (when injected subcutaneously). Hepatic enzyme elevations have been observed with and without concomitant elevations in total bilirubin.

The full indication is:

> Omvoh is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.

Omvoh is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment 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

[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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