19 June 2025
EMA/CHMP/138479/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Usymro

ustekinumab

On 19 June 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Usymro, intended for the treatment of plaque psoriasis, psoriatic arthritis and Crohn's disease.

The applicant for this medicinal product is ELC Group s.r.o.

Usymro will be available as a 130 mg concentrate for solution for infusion, 45 mg solution for injection, and 45 mg and 90 mg solution for injection in pre-filled syringes. The active substance of Usymro is ustekinumab, an immunosuppressant interleukin inhibitor (ATC code: L04AC05). Ustekinumab is a fully human IgG1κ monoclonal antibody that binds to the shared p40 subunit of interleukin (IL)-12 and IL-23, thereby preventing them from binding to the IL-12Rβ1 receptor expressed on the surface of immune cells. By doing so, ustekinumab prevents the activation of the Th1 and Th17 cytokine pathways, which are central to the pathology of plaque psoriasis, psoriatic arthritis and Crohn's disease.

Usymro is a biosimilar medicinal product. It is highly similar to the reference product Stelara (ustekinumab), which was authorised in the EU on 15 January 2009. Data show that Usymro has comparable quality, safety and efficacy to Stelara (ustekinumab). More information on biosimilar medicines can be found here.

The full indication is:

> Plaque psoriasis
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> Usymro is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A) (see section 5.1).
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> Paediatric plaque psoriasis
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> Usymro is indicated for the treatment of moderate to severe plaque psoriasis in children and

[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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adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see section 5.1).

Psoriatic arthritis

Usymro, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate (see section 5.1).

Adult Crohn's disease

Usymro is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist.

Paediatric Crohn's disease

Usymro is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients weighting at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy.

Usymro should be used under the guidance and supervision of physicians experienced in the diagnosis and treatment of the conditions for which it is indicated.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.