9 November 2023
EMA/492633/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Uzpruvo

ustekinumab

On 9 November 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 Uzpruvo, intended for the treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis and Crohn's disease in adults. The applicant for this medicinal product is STADA Arzneimittel AG.

Uzpruvo will be available as 45 mg and 90 mg solutions for injection. The active substance of Uzpruvo is ustekinumab, an immunosuppressant interleukin inhibitor (ATC code: L04AC05). Ustekinumab is a fully human IgG1κ monoclonal antibody that binds to the shared p40 protein subunit of interleukin (IL)-12 and IL-23, thereby preventing them from binding to the IL-12Rβ1 receptor protein expressed on the surface of immune cells. By doing so, ustekinumab may exert its clinical effects in psoriasis, psoriatic arthritis and Crohn's disease through interruption of the Th1 and Th17 cytokine pathways, which are central to the pathology of these diseases.

Uzpruvo 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 Uzpruvo has comparable quality, safety and efficacy to Stelara. More information on biosimilar medicines can be found here.

The full indications are:

Plaque psoriasis

Uzpruvo 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).

Paediatric plaque psoriasis

Uzpruvo 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 (PsA)

Uzpruvo, 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).

Crohn's Disease

Uzpruvo 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 or have medical contraindications to such therapies.

Uzpruvo is intended for use under the guidance and supervision of physicians experienced in the diagnosis and treatment of the conditions for which Uzpruvo is indicated.

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.