25 July 2024
EMA/CHMP/294331/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Otulfi

ustekinumab

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Otulfi, intended for the treatment of adults and children with plaque psoriasis and adults with psoriatic arthritis or Crohn's disease.

The applicant for this medicinal product is Fresenius Kabi Deutschland GmbH.

Otulfi will be available as 45 or 90 mg solution for injection in pre-filled syringe and 130 mg concentrate for solution for infusion. The active substance of Otulfi is ustekinumab, an immunosuppressant interleukin inhibitor (ATC code: L04AC05). Ustekinumab is a fully human IgG1κ monoclonal antibody that binds to the p40 subunit of interleukin (IL) 12 and 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 psoriasis, psoriatic arthritis and Crohn's disease.

Otulfi 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 Otulfi 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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> Otulfi 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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> Otulfi 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, and who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see section 5.1).

Psoriatic arthritis (PsA)

Otulfi, 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

Otulfi 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.

Treatment with Otulfi should be prescribed and supervised by 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 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.