20 November 2014
EMA/CHMP/490023/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Otezla

apremilast

On 20 November 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Otezla, 10 mg, 20 mg, 30 mg, film-coated tabled intended for the treatment , alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy and the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA). The applicant for this medicinal product is Celgene Europe Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Otezla is apremilast, an immunosuppressant (ATC Code: L04AA32). Apremilast, an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4), works intracellularly to modulate a network of pro-inflammatory and anti-inflammatory mediators. PDE4 is a cyclic adenosine monophosphate (cAMP)-specific PDE and the dominant PDE in inflammatory cells. PDE4 inhibition elevates intracellular cAMP levels, which in turn down-regulates the inflammatory response by modulating the expression of TNF-α, IL-23, IL-17 and other inflammatory cytokines. Cyclic AMP also modulates levels of anti-inflammatory cytokines such as IL-10.

The benefits with Otezla in psoriatic arthritis are its ability to significantly improve the signs and symptoms of psoriatic arthritis, as assessed by the American college of rheumatology (ACR) 20 response criteria compared to placebo at Weeks 16. This ACR 20 response was maintained at Week 24.

The benefits with Otezla in plaque psoriasis are its ability to significantly improve moderate to severe plaque psoriasis as demonstrated by the proportion of patients with Psoriasis Area and Severity Index score (PASI)-75 and sPGA responses at Week 16, compared to placebo.

[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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The most common side effects are gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache, and tension headache.

A pharmacovigilance plan for Otezla will be implemented as part of the marketing authorisation.

The approved indications are:

Psoriatic arthritis

Otezla, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy (see section 5.1).

Psoriasis

Otezla is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA).

Treatment with Otezla should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Otezla and therefore recommends the granting of the marketing authorisation.