21 April 2017
EMA/243800/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kevzara

sarilumab

On 21 April 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kevzara, intended for the treatment of rheumatoid arthritis. The applicant for this medicinal product is Sanofi-Aventis groupe.

Kevzara will be available as a solution for subcutaneous injection in pre-filled syringes and pre-filled pens.

The active substance of Kevzara is sarilumab, an interleukin inhibitor (ATC code: L04AC14). Sarilumab is a human monoclonal antibody (IgG1 subtype) that specifically binds to IL-6 receptors (IL-6Rα), and inhibits IL-6-mediated signalling.

The benefits with Kevzara are its ability to reduce the signs and symptoms of rheumatoid arthritis and to improve physical function. Kevzara has been shown to inhibit the progression of joint damage in patients with rheumatoid arthritis. The most common side effects are neutropenia, increased ALT, injection site erythema, upper respiratory-tract infections, and urinary tract infections.

The full indication is:

"Kevzara in combination with methotrexate (MTX) is indicated for the treatment of moderately to severely active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDs). Kevzara can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate (see section 5.1)."

It is proposed that Kevzara be prescribed by physicians experienced in the treatment of rheumatoid 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.

[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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