26 January 2017
EMA/CHMP/32752/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xeljanz

tofacitinib

On 26 January 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 Xeljanz, intended for the treatment of rheumatoid arthritis. The applicant for this medicinal product is Pfizer Limited.

Xeljanz will be available as 5-mg film-coated tablets. The active substance of Xeljanz is tofacitinib, a selective inhibitor of the Janus kinases (JAK) family (ATC code: L04AA29). Janus kinases are enzymes that transduce intracellular signals from cell surface receptors for a number of cytokines and growth factors. Tofacitinib preferentially inhibits JAK1 and JAK3 leading to an attenuation of signalling of interleukins (IL-2, -4, -6, -7, -9, -15, -21) and type I and type II interferons, which will result in modulation of the immune and inflammatory response.

The benefits with Xeljanz are its ability to reduce the signs and symptoms of rheumatoid arthritis and to improve physical function. Xeljanz has the potential to slow the progression of joint damage in patients with rheumatoid arthritis. The most common side effects are headache, upper respiratory tract infections, nasopharyngitis, diarrhoea, nausea and hypertension.

The full indication is:

"XELJANZ in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs. XELJANZ can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate (see Sections 4.4, 4.5)."

Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and 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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