



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/CHMP/367248/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Jyseleca filgotinib

On 23 July 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jyseleca, intended for the treatment of rheumatoid arthritis. The applicant for this medicinal product is Gilead Sciences Ireland UC.

Jyseleca will be available as 100 mg and 200 mg film-coated tablets. The active substance of Jyseleca is filgotinib, an immunosuppressant (ATC code: L04AA45). Filgotinib is an adenosine triphosphate (ATP) competitive and reversible inhibitor of the Janus kinase (JAK) family.

The benefits with Jyseleca are its ability to reduce the symptoms of rheumatoid arthritis. The most common side effects are nausea, upper respiratory tract infection, urinary tract infection and dizziness. The most common serious adverse reactions are serious infections.

The full indication is:

Jyseleca 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 (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX).

It is proposed that treatment with Jyseleca should be initiated by a physician 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

