



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

New oral treatment for rheumatoid arthritis

Olumiant to reduce inflammation and other symptoms

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Olumiant (baricitinib) for the treatment of adults with moderate to severe active rheumatoid arthritis. It is to be used to treat patients who have not responded adequately to, or who are unable to tolerate one or more disease-modifying anti-rheumatic drugs (DMARDs). Olumiant, which is taken by mouth, can be used on its own or in combination with methotrexate.

Rheumatoid arthritis is an immune system disease causing inflammation and damage in the joints. It affects between 0.5% and 1% of people in the EU. Patients with moderate to severe rheumatoid arthritis have chronic inflammation causing fatigue, pain and joint stiffness. While the symptoms are reversible with appropriate treatment, joint damage and the associated disability are permanent.

Patients with rheumatoid arthritis are treated with medicines called DMARDs, most commonly the oral treatment methotrexate on its own, or in combination with another DMARD which is given by injection or infusion. However, even with the most effective treatments available, more than half of patients do not achieve a satisfactory response. Therefore, new treatment options are needed.

Olumiant works by blocking the action of enzymes known as Janus kinases (JAKs). These enzymes play an important role in the process of immunity and inflammation that occurs in rheumatoid arthritis. By blocking these enzymes, Olumiant is expected to reduce the inflammation and other symptoms of the disease. It would be first JAK inhibitor to be used in the treatment of rheumatoid arthritis in the EU and offers a different mode of action to what is currently available.

The recommendation from EMA's Committee for Medicinal Products for Human Use (CHMP) is based on results of four randomised controlled trials in 3,100 adults with moderate to severe active rheumatoid arthritis. One trial compared Olumiant to methotrexate, another compared Olumiant to adalimumab, and two compared Olumiant to placebo. Overall, Olumiant was more effective at reducing disease activity in patients with moderate to severe rheumatoid arthritis, compared to those treated with methotrexate and adalimumab.

Maintenance of efficacy was demonstrated in 52-week-long trials. Olumiant showed efficacy in patients who had not responded to biologic DMARDs as well as in patients that had never been treated before.



The most common side effects with Olumiant in clinical trials were increased lipid (fat) levels in the blood, upper respiratory tract infections and nausea.

The opinion adopted by the CHMP at its December 2016 meeting is an intermediary step on Olumiant's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, a decision on price and reimbursement will then take place at the level of each Member State considering the potential role/use of the medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Olumiant is Eli Lilly Nederland B.V.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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