16 December 2022
EMA/931846/2022
EMEA/H/C/004085/II/0028

Withdrawal of application to change the marketing authorisation for Olumiant (baricitinib)

Eli Lilly Nederland B.V. withdrew its application for the use of Olumiant in the treatment of patients hospitalised with COVID-19.

The company withdrew the application on 7 December 2022.

What is Olumiant and what is it used for?

Olumiant is a medicine used in adults for treating:

- moderate to severe rheumatoid arthritis (a disease causing inflammation of the joints) when standard treatment with disease-modifying anti-rheumatic drugs (also known as 'DMARDs') has not worked well enough or if patients cannot tolerate them. Olumiant can be used either alone or in combination with the disease-modifying drug methotrexate;
- moderate to severe atopic dermatitis (eczema) when treatments applied to the skin are not sufficient or appropriate;
- Severe alopecia areata (a disease causing hair loss of the scalp and/or other parts of the body).

Olumiant has been authorised in the EU since February 2017. It contains the active substance baricitinib and is available as tablets to be taken by mouth.

Further information on Olumiant's current uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/olumiant

What change had the company applied for?

The company applied to extend the use of Olumiant to include the treatment of adults and children aged 10 years and older hospitalised with COVID 19 requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation). During the assessment of the application, the company modified the application to the treatment of adults with COVID-19 who require low-flow oxygen or non-invasive ventilation/high-flow oxygen.

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How does Olumiant work?

The active substance in Olumiant, baricitinib, is an immunosuppressant (a medicine that reduces the activity of the immune system). It works by blocking the action of enzymes known as Janus kinases. These enzymes play an important role in the processes of inflammation and damage that occur in rheumatoid arthritis, atopic dermatitis and alopecia areata. By blocking these enzymes, baricitinib reduces joint, skin and hair follicle inflammation and other symptoms of these diseases.

In patients hospitalised with COVID-19, Olumiant was expected to work in the same way as it does in its existing indication(s), but also by directly keeping the SARS-CoV-2 virus from entering the body's cells.

What did the company present to support its application?

The company presented the results from three studies in patients hospitalised with COVID-19.

In one study, around 1,000 patients were given Olumiant or placebo (a dummy treatment), in combination with remdesivir (an antiviral medicine used to treat COVID-19). The main measure of effectiveness was the time it took patients to recover. In another study, about 1,500 patients received Olumiant or placebo. This study investigated if the medicine prevented worsening of disease or death. A third study in over 8,000 patients compared treatment with Olumiant and placebo and looked at prevention of death.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's responses to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Olumiant could not have been authorised for the treatment of COVID-19. The Agency considered that the evidence submitted by the company did not conclusively demonstrate that the medicine provides meaningful benefits to patients. Therefore, at the time of the withdrawal, the Agency's opinion was that the benefit/risk balance of Olumiant was negative.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that its withdrawal is based on the Agency's opinion that available data were not sufficient to conclude on a positive benefit-risk balance for the proposed indication.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Olumiant.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Olumiant for the treatment of other diseases?

There are no consequences on the use of Olumiant in its authorised uses.