14 December 2021
EMA/746468/2021
European Medicines Agency

EMA reviewing new data on effectiveness of Lagevrio (molnupiravir) for the treatment of COVID-19

Following EMA's interim recommendations to support national authorities who may decide on early use of Lagevrio (molnupiravir) prior to marketing authorisation, the Agency will review more data from the main study of Lagevrio (MK-4482-002).

The above recommendations issued by EMA in November 2021 in the context of an Article 5(3) review were based on an assessment of interim data from this study which were available at the time of the review. These data, based on 762 subjects, showed that Lagevrio reduced the risk of hospitalisation or death in people with COVID-19 who were at higher risk of severe disease from 14.1% in the placebo (dummy treatment) group to 7.3% in the Lagevrio group. The study did not include people who had been vaccinated.

The updated results, based on 1,408 subjects, show that Lagevrio reduced the risk of hospitalisation or death in people with COVID-19 who were at higher risk of severe disease from 9.7% in the placebo group to 6.8% in the Lagevrio group. EMA will assess these data as part of a more comprehensive marketing authorisation application.

The earlier recommendations remain unchanged. EMA will communicate further on the outcome of the marketing authorisation application that is currently under review.

More about the medicine

Lagevrio is an oral antiviral medicine that reduces the ability of SARS-CoV-2 (the virus that causes COVID-19) to multiply in the body. It does this by increasing the number of alterations (mutations) in the virus' genetic material (known as RNA) in a way that impairs the ability of SARS-CoV-2 to multiply.

Lagevrio is being developed by Merck Sharp & Dohme in collaboration with Ridgeback Biotherapeutics.

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