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European Medicines Agency

EMA issues advice on use of Lagevrio (molnupiravir) for the treatment of COVID-19

EMA's human medicines committee (CHMP) has issued advice on the use of Lagevrio (also known as molnupiravir or MK 4482) for the treatment of COVID-19. The medicine, which is currently not authorised in the EU, can be used to treat adults with COVID-19 who do not require supplemental oxygen and who are at increased risk of developing severe COVID-19. Lagevrio should be administered as soon as possible after diagnosis of COVID-19 and within 5 days of the start of symptoms. The medicine, which is available as capsules, should be taken twice a day for 5 days.

EMA issued this advice to support national authorities who may decide on possible early use of the medicine prior to marketing authorisation, for example in emergency use settings, in light of rising rates of infection and deaths due to COVID-19 across the EU.

The advice follows a review of data, including data on the medicine's quality and results from completed and ongoing studies. Interim results from the main study in non-hospitalised, unvaccinated patients with at least one underlying condition putting them at risk of severe COVID-19 were assessed as part of this advice. Lagevrio, when given at a dose of 800 mg twice a day, reduced the risk of hospitalisation and death when treatment started within 5 days of the start of symptoms. About one month after treatment started 7.3% of patients (28 out of 385) who took Lagevrio compared with 14.1% (53 out of 377) of patients who took placebo (a dummy treatment) had been hospitalised or had died; none of the patients in the Lagevrio group died compared with eight patients in the placebo group.

In terms of safety, the most common side effects reported during treatment and within 14 days after the last dose of Lagevrio were diarrhoea, nausea, dizziness and headache, all of which were either mild or moderate.

Lagevrio is not recommended during pregnancy and in women who can become pregnant and are not using effective contraception. Women who can become pregnant must use effective contraception during treatment and for 4 days after the last dose of Lagevrio. Breastfeeding should be interrupted during treatment and for 4 days after treatment. These recommendations are given as laboratory studies in animals have shown that high doses of Lagevrio can impact the growth and development of the foetus.

EMA's proposed conditions of use will be published shortly on the EMA website.

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EMA's advice can now be used to support national recommendations on the possible use of the medicine before marketing authorisation.

In parallel, a more comprehensive rolling review is ongoing ahead of a possible application for a marketing authorisation. EMA will further communicate on the progress of this 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.

More about the procedure

EMA's Executive Director requested the review under Article 5(3) of Regulation 726/2004 following preliminary discussions with EMA's COVID-19 pandemic task force (COVID-ETF), which brings together experts from across the European medicines regulatory network, and with the Heads of Medicines Agencies (HMA)[1].

The review has been carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), which is responsible for questions concerning medicines for human use. The Committee's scientific opinion can now be used by the EU Member States when making decisions on the use of this medicine at national level prior to marketing authorisation.

[1] The Heads of Medicines Agencies (HMA) is a network of the heads of the National Competent Authorities (NCA) whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the countries of the European Economic Area.