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EMA receives application for marketing authorisation for Lagevrio (molnupiravir) for treating patients with COVID-19

EMA has started evaluating an application for marketing authorisation for the oral antiviral medicine Lagevrio (molnupiravir). Lagevrio, which is being developed by Merck Sharp & Dohme in collaboration with Ridgeback Biotherapeutics, is intended for the treatment of COVID-19 in adults.

EMA will assess the benefits and risks of Lagevrio under a reduced timeline and could issue an opinion within weeks if the data submitted are sufficiently robust and complete to show the efficacy, safety and quality of the medicine.

Such a short timeframe is only possible because EMA has already reviewed a substantial portion of the data on the medicine during a rolling review. During this phase, EMA's human medicines committee (CHMP) assessed data from laboratory and animal studies (non-clinical data), information on the quality of the medicine and the way it will be produced, and data on its efficacy and safety. In addition, CHMP assessed data from completed and ongoing clinical studies. These include interim results from the main study on the effects of Lagevrio in non-hospitalised, unvaccinated patients with at least one underlying condition putting them at risk of severe COVID-19.[1]

Furthermore, EMA's committee for medicines for children (PDCO) has issued its opinion on the company's paediatric investigation plan (PIP), which describes how the medicine should be developed and studied for use in children, in accordance with the accelerated timelines for COVID-19 products.

If EMA concludes that the benefits of Lagevrio outweigh its risks in treating COVID-19, it will recommend granting a marketing authorisation. The European Commission will then fast-track its decision-making process with a view to granting a marketing authorisation valid in all EU and EEA Member States within days.

EMA will communicate at the time of CHMP's opinion.

How is the medicine expected to work?

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 so by introducing alterations (mutations) in the genetic material (known as RNA) of SARS-CoV-2 during replication in a way that impairs the ability of the virus to multiply. This is expected to reduce the need for hospitalising patients with COVID-19.

[1] Based on an interim analysis of this study EMA issued advice on use of Lagevrio prior to marketing authorisation to support Member States on 19 November 2021.

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