25 October 2021
EMA/592094/2021

COVID-19: EMA starts rolling review of molnupiravir

EMA's human medicines committee (CHMP) has started a rolling review of the oral antiviral medicine molnupiravir (also known as MK-4482 or Lagevrio), developed by Merck Sharp & Dohme in collaboration with Ridgeback Biotherapeutics for the treatment of COVID-19 in adults.

The CHMP's decision to start the rolling review is based on preliminary results from laboratory studies (non-clinical data) and clinical studies. These studies suggest that the medicine may reduce the ability of SARS-CoV-2 (the virus that causes COVID-19) to multiply in the body, thereby preventing hospitalisation or death in patients with COVID-19.

EMA will evaluate more data on the quality, safety and effectiveness of the medicine. The rolling review will continue until enough evidence is available for the company to submit a formal marketing authorisation application.

EMA will assess the compliance of molnupiravir with the usual EU standards for effectiveness, safety and quality. While EMA cannot predict the overall timelines, it should take less time than normal to evaluate an eventual application because of the work done during the rolling review.

EMA will communicate further when a marketing authorisation application for the medicine has been submitted.

How is the medicine expected to work?

This medicine is an antiviral medicine which can be taken orally (by mouth). It is a 'viral RNA polymerase inhibitor', a medicine that interferes with the production of genetic material (RNA) of viruses. By interfering with the RNA production of SARS-CoV-2, molnupiravir is expected to prevent the virus from multiplying.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What is a rolling review?

A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine or vaccine during a public health emergency. Normally, all data on a medicine or vaccine's effectiveness, safety and quality and all required documents must be ready at the start of the evaluation in a formal application for marketing authorisation. In the case of a rolling review, EMA's human medicines committee (CHMP) reviews data as they become available from ongoing studies. Once sufficient data are available, the company can submit a formal application. By reviewing the data as they become available, the CHMP can come to an opinion on the medicine's authorisation sooner.

During the rolling review, and throughout the pandemic, EMA and its scientific committees are supported by the COVID-19 EMA pandemic task force (COVID-ETF). This group brings together experts from across the European medicines regulatory network to advise on the development, authorisation and safety monitoring of medicines and vaccines for COVID-19 and facilitate quick and coordinated regulatory action.