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Withdrawal of application for the marketing authorisation of Lagevrio (molnupiravir)

On 21 June 2023, Merck Sharp & Dohme B.V. withdrew its application for a marketing authorisation of Lagevrio for the treatment of COVID-19 in adults.

What is Lagevrio and what was it intended to be used for?

Lagevrio was developed as a medicine for the treatment of adults with COVID-19 who did not require supplemental oxygen and who were at increased risk of developing severe COVID-19.

Lagevrio contains the active substance molnupiravir and was to be available as capsules to be taken by mouth.

How does Lagevrio work?

The active substance in Lagevrio, molnupiravir, is an 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.

What did the company present to support its application?

The company submitted the results of one main study investigating Lagevrio in over 1,400 non-hospitalised, unvaccinated adults with at least one underlying condition putting them at risk of severe COVID-19. This study compared Lagevrio with placebo (a dummy treatment). The company also provided supportive data from other studies and real-world data on the use of molnupiravir in clinical practice.

How far into the evaluation was the application when it was withdrawn?

The evaluation had completed and the European Medicines Agency had recommended refusing marketing authorisation. The company had requested a re-examination of the Agency's recommendation, but it withdrew the application before this re-examination had finished.

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What did the Agency recommend at that time?

At the time of the withdrawal, the Agency's human medicines committee (CHMP) had recommended refusing marketing authorisation for Lagevrio for the treatment of adults with COVID-19.

Having evaluated the data provided by the company, the CHMP had concluded that the clinical benefit of Lagevrio in the treatment of adults with COVID-19 who are not receiving supplemental oxygen and who are at increased risk of developing severe COVID-19 had not been demonstrated.

Based on the totality of data, it was not possible to conclude that Lagevrio can reduce the risk of hospitalisation or death or shorten the duration of illness or time to recovery in adults at risk of severe disease. Furthermore, it was not possible to identify a specific group of patients in whom a clinically relevant benefit of Lagevrio had been demonstrated.

Therefore, the Agency's opinion was that the balance of benefits and risks of Lagevrio in the treatment of COVID-19 could not be established. Hence, the Agency had recommended refusing marketing authorisation.

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

In its letter notifying the Agency of the withdrawal of the application, the company stated that its decision was based on the CHMP's view that the data provided do not allow the committee to conclude on a positive benefit-risk balance for Lagevrio.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using molnupiravir. If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.