EU medicines agency starts review of Merck oral COVID drug

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The EU's medicines watchdog said on Monday it had started reviewing an oral COVID medication from the US pharmaceutical firm Merck, raising hopes for an easy-to-administer treatment to reduce serious or

deadly cases.

The move, which could eventually lead to authorisation on the European market, comes two weeks after Merck applied for emergency use in the US of the anti-coronavirus drug.

"EMA's human medicines committee (CHMP) has started a rolling review of the oral antiviral medicine molnupiravir... developed by Merck Sharp & Dohme in collaboration with Ridgeback Biotherapeutics for the treatment of COVID-19 in adults," the European Medicines Agency said in a statement.

Preliminary results "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," the Amsterdam-based EMA said.

Antivirals like molnupiravir work by decreasing the ability of a virus to replicate, thereby slowing down the disease. It is taken orally.

Given to patients within days of a positive test, the treatment halves the risk of hospitalisation, according to a clinical trial conducted by Merck, also called MSD outside the United States.

If approved, molnupiravir would represent a major breakthrough in reducing severe forms of the disease, which Merck also said prevented 100 percent of deaths compared to a placebo. The sample size however, was relatively small and the figure couldn't yet be reliably extrapolated.

The EMA will now assess whether molnupiravir complies with European standards of efficacy, safety and quality.

It can take several months between the start of a rolling review by the

EMA and any eventual green light, but the review is conducted as soon as data becomes available, thereby speeding up the process.

Once sufficient data has been gathered, a company can then submit a formal application to have the medicine authorised by the European Commission, based on the scientific evaluation by the EMA.

Simple pill

A simple pill to treat the coronavirus has been sought since the start of the pandemic and Merck's announcement was hailed as a major step towards that goal.

Until now, COVID therapeutics such as monoclonal antibodies and Gilead's remdesivir—authorised for use in the EU under the name Veklury—have been administered intravenously.

But experts have said it is not a miracle cure and should complement vaccines, not replace them.

They have also cautioned it would be critical to administer the drug early for it to be effective.

Since it isn't always clear who is at risk for developing severe disease, it would have the greatest impact if it were cheap enough and safe enough to distribute widely.

Molnupiravir was initially developed as an inhibitor of influenza and respiratory syncytial virus, two other important acute respiratory infections, by a team at Emory University.