Merck asks EU regulator to authorize its COVID-19 pill

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This undated file image provided by Merck & Co. shows their new antiviral medication. The European Medicines Agency said it has received a request from Merck to authorize its coronavirus antiviral, the first pill shown to treat COVID-19. In a statement on Tuesday, Nov. 23, 2021, the EU drug regulator said it had started evaluating molnupiravir, made by Merck and Ridgeback Biotherapeutics and that a decision could be made within weeks on whether it might be cleared. Credit: Merck & Co. via AP, File

The European Medicines Agency said it has received a request from Merck to authorize its coronavirus antiviral, the first pill shown to treat COVID-19.

In a statement Tuesday, the EU drug regulator said it had started evaluating molnupiravir, made by Merck and Ridgeback Biotherapeutics, and that a decision could be made within weeks on whether it might be cleared.

Last week, the EMA issued emergency advice saying that molnupiravir could be used to treat adults infected with the coronavirus who don't yet need extra oxygen and are at increased risk of developing severe disease.

The agency said the drug should be given as soon as possible after COVID-19 has been diagnosed and within five days of symptoms starting. It is intended to be taken twice a day for five days.

Earlier this month, Britain became the first country in the world to OK the drug. The U.K. licensed molnupiravir for adults diagnosed with COVID-19 and with at least one risk factor for severe disease.

An antiviral pill that reduces symptoms and speeds recovery could prove groundbreaking, easing caseloads on hospitals and helping to curb explosive outbreaks in conjunction with vaccination campaigns.

Europe is now at the epicenter of the pandemic and the World Health Organization has warned that without urgent measures, Europe could see 700,000 more COVID-19 deaths by the spring.

Molnupiravir is also pending review with regulators in the U.S., which is expected to convene an expert panel later this month to consider authorization.

Even if the pill is licensed, initial supplies will be limited. Merck has said it can produce 10 million treatment courses this year, but much of that supply has already been purchased by governments worldwide.

In October, Merck agreed to let other drugmakers produce molnupiravir and signed a licensing agreement with the U.N.-backed Medicines Patent Pool allowing its pill to be made by companies in dozens of countries.