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Merck's Tamiflu-Like Covid-19 Pill Highly Successful in Key Study; Authorization Could be Granted by End of Year

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Ernice Gilbert October 01, 2021

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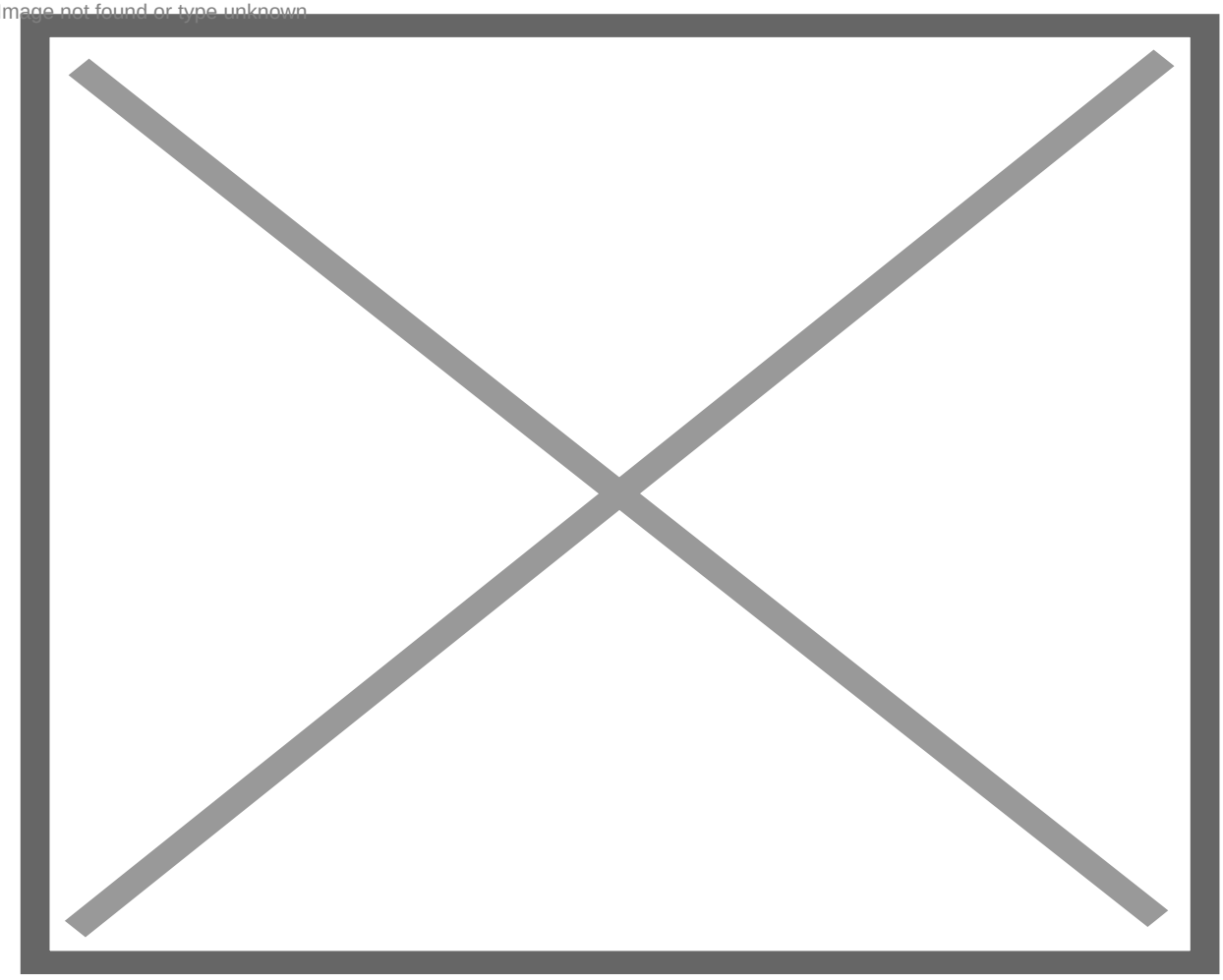

Merck and Ridgeback Biotherapeutics drug Molnupiravir. By. MERCK

Merck and Ridgeback Biotherapeutics announced Friday that their experimental Covid-19 pill significantly helped high-risk people in the early stage of infection from becoming seriously ill or dying, a major step in the battle against the pandemic. The pill is on track to become the first at-home, easy-to-use treatment for the coronavirus.

The pill, named molnupiravir, reduced the risk of hospitalization or death by approximately 50 percent. Merck said it has been so effective that the companies — at the recommendation of an independent data monitoring committee and in consultation with the U.S. Food and Drug

Administration — stopped enrollment in its late-stage trial early due to the positive results. Merck plans to submit an application for emergency use authorization to the U.S. FDA in the coming weeks based on these findings and plans to submit marketing applications to other regulatory bodies worldwide.

If approved, the drug would be the first oral antiviral drug for Covid-19, becoming a kind of Tamiflu for the virus as it would be a medication taken upon a patient's first signs of symptom development and potentially prevent individuals from becoming seriously ill.

“With these compelling results, we are optimistic that molnupiravir can become an important medicine as part of the global effort to fight the pandemic and will add to Merck’s unique legacy of bringing forward breakthroughs in infectious diseases when they are needed most," said Merck CEO Robert Davis.

“With the virus continuing to circulate widely, and because therapeutic options currently available are infused and/or require access to a healthcare facility, antiviral treatments that can be taken at home to keep people with Covid-19 out of the hospital are critically needed,” said Wendy Holman, Ridgeback Biotherapeutics CEO. “We are very encouraged by the results from the interim analysis and hope molnupiravir, if authorized for use, can make a profound impact in controlling the pandemic."

The experiment evaluated data from 775 patients who were initially enrolled in the phase 3 of the trial on or prior to Aug. 5, 2021. At the time of the decision to stop recruitment based on the compelling interim efficacy results, the trial was approaching full recruitment of the phase 3 sample size of 1,550 patients, with more than 90 percent of the intended sample size already enrolled, Merck said.

Eligibility criteria required that all patients had laboratory-confirmed mild-to-moderate Covid-19, with symptom onset within 5 days of study randomization. All patients were required to have at least one risk factor associated with poor disease outcome at study entry. Molnupiravir reduced the risk of hospitalization and/or death across all key subgroups; efficacy was not affected by timing of symptom onset or underlying risk factor.

Additionally, based on the participants with available viral sequencing data (approximately 40 percent of participants), molnupiravir demonstrated consistent efficacy across viral variants Gamma, Delta, and Mu.

Merck said it entered into a procurement agreement earlier this year with the U.S. government under which Merck will supply approximately 1.7 million courses (costing $1.2 billion) of molnupiravir to the U.S. government upon emergency use approval or approval from the FDA. Additionally, Merck has entered into supply and purchase agreements for molnupiravir with other governments worldwide, pending regulatory authorization, and is currently in discussions with other governments.

Merck expects to produce 10 million courses of treatment by the end of the year, with more doses coming next year. If authorized, Merck would begin shipping doses fairly quickly, Mr. Davis said (via WSJ).

Merck said it is committed to providing timely access to molnupiravir globally, if it is authorized or approved, and plans to implement a tiered pricing approach based on World Bank country

income criteria to reflect countries' relative ability to finance their health response to the pandemic.

As part of its commitment to widespread global access, Merck previously announced that the company has entered into non-exclusive voluntary licensing agreements for molnupiravir with established generic manufacturers to accelerate availability of molnupiravir in more than 100 low- and middle-income countries (LMICs), following approvals or emergency authorization by local regulatory agencies.