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# Merck Approaches FDA for Approval of its Covid-19 Pill for At-Home Use

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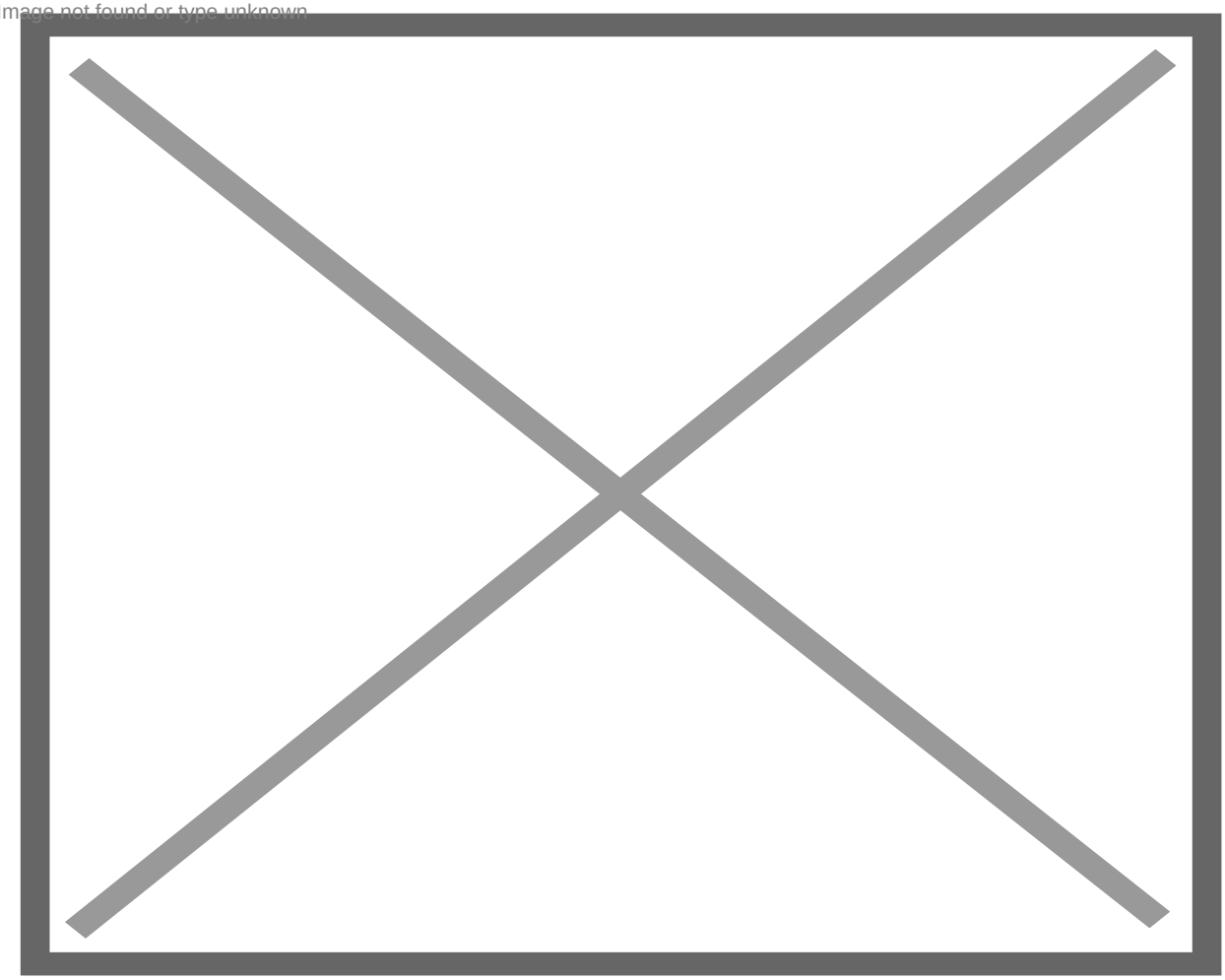

**The U.S. Food and Drug Administration could approve Merck's Covid-19 drug for at-home use in the coming weeks.** By. MERCK

U.S. drug company Merck and its Canada-headquartered partner Ridgeback Biotherapeutics on Monday filed an application asking the U.S. Food and Drug Administration to approve their Covid-19 pill, a move that pushes the U.S. closer to what many believe will be a turning point in the battle against the pandemic: an effective drug for use at home.

The filing comes approximately two weeks after the companies announced that their experimental Covid-19 pill significantly helped high-risk people in the early stage of infection from becoming seriously ill or dying.

The FDA could approve the drug in the coming weeks, ahead of what some health experts predict could be another deadly winter, especially among the unvaccinated.

“The extraordinary impact of this pandemic demands that we move with unprecedented urgency, and that is what our teams have done by submitting this application for molnupiravir to the FDA within 10 days of receiving the data,” said Merck Chief Executive Robert Davis.

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.

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.