

Merck's experimental pill to treat covid-19 cuts risk of hospitalization and death in half, the pharmaceutical company reports

The clinical trial is being stopped early, and the drug-maker plans to apply for emergency authorization as soon as possible

By [Carolyn Y. Johnson](#)

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The United States moved a major step closer Friday to having an easy-to-take pill to treat covid-19 available in the nation's medicine cabinet, with encouraging results released about an experimental drug.

Pharmaceutical giant Merck announced that in an international clinical trial, its drug, molnupiravir, reduced the risk of hospitalization and death by nearly half among higher-risk people diagnosed with mild or moderate illness. The company said it would seek regulatory approval as soon as possible, meaning the United States could have its first anti-coronavirus pill in a matter of months.

An independent board of experts monitoring the trial recommended the Merck study be stopped early because of the positive results, a significant and telling development in a pharmaceutical study.

Merck and partner Ridgeback Biotherapeutics said in a news release they would apply for emergency use authorization for the drug.

A simple, easy-to-prescribe pill that prevents mild and moderate cases of covid-19, the illness caused by the coronavirus, from turning into dire episodes has been one of the missing pieces of the medical armamentarium to fight the virus.

Experts cautioned that even if the pill receives a regulatory green light, vaccination will remain the primary tool to fight the virus by preventing illness. But they celebrated the prospect of a treatment to help transform covid-19 from a public health crisis into a disease that can be managed if it continues to circulate long-term.

“First and foremost, preventing covid with a vaccine is always going to be preferable to treating it,” said Timothy Sheahan, a virologist at the University of North Carolina at Chapel Hill who has done research on molnupiravir. “Mistakes can be made in treating infectious disease, and people can die.”

But, Sheahan said, he is hopeful the drug will potentially reduce transmission, in addition to preventing severe bouts of illness in people who become

infected. Sheahan's work showed that the drug accelerated the clearance of infectious virus from people's noses and throats in an earlier trial — a signal that infected people may be less apt to spread the pathogen.

Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, said at a coronavirus news conference Friday that the results were “very good news.” When he was briefed by Merck officials Thursday evening on the results, Fauci said he was especially struck by one result: that there were no deaths among people who received the drug in the trial, while there were eight deaths among people who received placebo pills.

The development of a pill to combat the coronavirus would mark a significant moment in the pandemic, especially when other options have limitations and as the nation stands on the brink of recording the 700,000th coronavirus death since the start of the pandemic.

Monoclonal antibodies, treatments that have kept people out of the hospital, are expensive, tricky to manufacture and cumbersome to administer, requiring infusions or injections. Vaccines have been remarkably effective, but access is limited in much of the world.

“We always believed antivirals, especially an oral antiviral, would be an important contribution to the pandemic,” Daria Hazuda, vice president of infectious diseases and vaccine discovery at Merck, said in an interview. “Keeping people out of the hospital is incredibly important, given the emergence of variants and the continued evolution of the virus.”

The data has not yet been published or peer reviewed.

Regulators will evaluate the benefits and potential risks of the drug in detail before deciding if it is safe and effective. The drug's performance in the real world may be more complicated than in the trial, because patients could encounter delays in seeking care or receiving coronavirus test results.

Antiviral treatments for acute infections tend to have a narrow window when they can be administered and still work. Tamiflu, for example, is often given too late to help people stricken with influenza. In the trial, people had to be treated with molnupiravir within five days of their symptom onset.

There was little data about the safety of the drug, other than the fact that unspecified adverse events occurred at a similar rate among people who received the drug and those who received the placebo. More people discontinued the placebo because of an adverse event than the drug.

Merck has already begun producing the pill. The small brown capsules must be taken twice a day for five days. The company predicts it will make 10 million courses of treatment by the end of the year. The U.S. government made an advance purchase of 1.7 million treatment courses of the drug at a cost of \$1.2 billion.

The biggest impact of the medication might be in the rest of the world, where vaccine availability is low and monoclonal antibody treatments may be impractical or unavailable. Merck has licensed its drug to five Indian generic drug manufacturers to speed up availability in low- and middle-income countries, many of which have had limited access to vaccines.

The company said it would use a “tiered pricing approach,” pricing the drug to reflect countries' ability to pay for the drug.

A global trial of the pill enrolled 775 people with mild or moderate covid-19. Participants had at least one risk factor for severe covid-19, such as obesity or advanced age. They had to start the drug regimen within five days of symptom onset and be unvaccinated.

Half of study participants received the drug and half received a placebo. The rate of hospitalization and death in people who received the drug was 7.3 percent — about half the level for those who received a placebo

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Those results, showing the drug afforded significant protection, led an independent safety board to suggest halting the trial.

“It’s really a remarkable set of data, and it’s an important step,” said Kara Carter, president of the International Society for Antiviral Research and entrepreneur-in-residence at Evotec, a biotechnology company. She underscored that having multiple tools to prevent and treat infections would be essential to controlling the pandemic.

Laboratory and animal experiments suggest the pill may be effective against known variants, including delta. Unlike vaccines or antibodies that target the spike protein on the surface of the virus, molnupiravir works by introducing genetic errors that garble the coronavirus’s genetic code and stop it from making copies of itself. That could make it harder for the virus to find a way around the drug, and may mean the drug can even work on other coronaviruses or RNA viruses.

“As a virologist, that’s one of the things I find particularly exciting,” Hazuda said. “Now, we’ve demonstrated the potential to have a drug that could work across multiple coronaviruses. I don’t think this is the last pandemic in our lifetime, and having something readily available that is active would be amazing.”

[Pfizer](#) is also developing an oral antiviral drug, and announced this week it was initiating a later-stage clinical trial testing the drug’s ability to prevent illness in people exposed to the coronavirus. Atea Pharmaceuticals is also working on an [oral antiviral](#) with pharmaceutical giant Roche.

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