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Merck's antiviral pill against COVID-19 is seen in an undated photograph. (Merck via AP)

HEALTH NEWS PREMIUM

Merck Says Antiviral Pill for COVID-19 Is Effective, Plans to File for Emergency Authorization

By Zachary Stieber | October 1, 2021 Updated: October 1, 2021

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Results from a clinical trial show that Merck's antiviral pill for COVID-19 is effective, the company said Friday.

The antiviral, molnupiravir, cut the risk of hospitalization or death in half for adults who were deemed at risk but not hospitalized, according to a planned interim analysis of the trial.

Compared to the 14.1 percent of patients who received placebos, 7.3 percent of trial participants who received the drug were hospitalized through day 29, the company and its partner Ridgeback Biotherapeutics said.

Eight people died in the placebo group and zero did in the group given molnupiravir.

Based on the findings, Merck plans to apply to the Food and Drug Administration (FDA) soon for emergency use authorization for its drug.

“With these compelling results, we are optimistic that molnupiravir can become an important medicine as part of the global effort to fight the pandemic,” Robert Davis, Merck’s CEO and president, said in a statement.

“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,” added Wendy Holman, the CEO of Ridgeback.

The drug works by inhibiting the replication of the virus that causes COVID-19. The virus is known as SARS-CoV-2 or the CCP (Chinese Communist Party) virus. So far, the only drugs authorized to treat COVID-19 are monoclonal antibodies, which run over $2,000 each and take more time to administer than a pill. However, clinical trials on drugs approved for other uses, including the antidepressant fluvoxamine, have shown promise against the disease.

A logo of drugs and chemicals group Merck is pictured in Darmstadt, Germany in a file photograph. (Ralph Orlowski/Reuters)

The molnupiravir trial analysis evaluated data from 775 patients who had laboratory-confirmed cases of COVID-19. None had received a COVID-19 vaccine. The phase 3 trial was meant to enroll 1,550 patients, but enrollment was stopped at the recommendation of a Data Monitoring Committee in consultation with the FDA. The trial was conducted at sites around the world, including in the United States. Full results have not yet been released. Merck did not immediately respond to emailed questions.

The company did say that the analysis found an incidence of adverse events comparable between the groups, with 35 percent of participants getting its drug experiencing an event and 40 percent of the placebo group experiencing an event. The incidence of adverse events described as being related to the drug was similar between the groups.

Merck has already been producing doses of molnupiravir in anticipation of the results from the trial and projects to produce 10 million courses by the end of the year. The United States earlier this year agreed to buy approximately 1.7 million doses upon emergency authorization or approval from U.S. drug regulators. Each course, which involves multiple pills, will cost the government $705 if the agreement kicks in.

Dr. Walid Gellad, professor of medicine at the University of Pittsburg's School of Medicine, said the antiviral would be "a game changer" and urged the FDA to prioritize granting it authorization.

Other experts noted that the data has not been peer reviewed but said the results appeared encouraging.

Two other companies are also racing to develop antiviral pills against COVID-19.

Pfizer launched two trials of its oral drug last month while Roche is also studying its version.

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