HEALTH AND SCIENCE

Merck’s Covid pill shows lower efficacy in updated data

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KEY POINTS

The drugmaker released interim data in October showing a roughly 50% reduction in hospitalizations and deaths in 775 patients.

The updated rate on Friday is based on data from over 1,400 patients.

In this article

MRK -3.76 (-4.57%)

Merck's experimental Covid-19 treatment pill, called molnupiravir

MERCK & CO INC | via Reuters

Merck said on Friday updated data from the study of its experimental COVID-19 pill showed lower efficacy in reducing the risk of hospitalization and deaths than an earlier interim analysis, cutting them by 30% in the study.

The drugmaker released interim data in October showing a roughly 50% reduction in hospitalizations and deaths in 775 patients. The updated rate on Friday is based on data from over 1,400 patients.

Merck's shares fell 3% in premarket trading, amid a fall in the broader markets.

The company said the data on the drug molnupiravir, developed with Ridgeback Biotherapeutics, had been submitted to the U.S. Food and Drug Administration ahead of a meeting of its expert advisers on Tuesday.

A planned interim analysis of the data last month showed that 7.3% of those given molnupiravir twice a day for five days were hospitalized and none had died by 29 days after the treatment. That compared with a hospitalization rate of 14.1% for placebo patients.

In the updated data, 6.8% of those given molnupiravir were hospitalized and one person died, while the other placebo group had a hospitalization rate of 9.7%.

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MRK -3.76 (-4.57%)

HEALTH AND SCIENCE

Merck to seek emergency authorization for oral Covid treatment after 'compelling results' in trials

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Chloe Taylor
@CHLOETAYLOR141

KEY POINTS

A phase 3 trial of Merck and Ridgeback Biotherapeutics' oral antiviral treatment molnupiravir showed it reduced the risk of hospitalization or death by around 50% in Covid patients.

Merck plans to seek emergency use authorization in the U.S. and submit marketing applications to other global drug regulators.

If authorized by regulatory bodies, molnupiravir could be the first oral antiviral medicine for Covid.

In this article

Merck and Ridgeback Biotherapeutics plan to seek emergency authorization for their oral antiviral treatment for Covid, after the medicine showed "compelling results" in clinical trials.

The drug, molnupiravir, reduced the risk of hospitalization or death by around 50% for patients with mild or moderate cases of Covid, the companies announced Friday. Molnupiravir is administered orally and works by inhibiting the replication of the coronavirus inside the body.

An interim analysis of a phase 3 study found that 7.3% of patients treated with molnupiravir were hospitalized within 29 days. Of the patients who received a placebo, 14.1% were hospitalized or died by day 29. No deaths were reported in patients who were given molnupiravir within the 29-day period, while eight deaths were reported in placebo-treated patients.

All 775 trial participants had laboratory-confirmed symptomatic Covid-19 and were BREAKING NEWS piravir or a placebo within five days of symptoms.

Every participant was unvaccinated and had at least one underlying factor that put them at greater risk of developing a more severe case of the virus. The most common risk factors included obesity, being over age 60 and having diabetes or heart disease.

VIDEO 02:58

Merck CEO Davis provides update on highly anticipated Covid-19 pill

The phase 3 part of the trial was conducted at more than 170 sites, in countries including the U.S., Brazil, Italy, Japan, South Africa, Taiwan and Guatemala.

Molnupiravir's efficacy was not affected by the timing of symptom onset or patients' underlying risk factors, the study showed. It also proved to be consistently effective in treating all variants of Covid, including the widely dominant and highly transmissible delta strain.

Adverse events were comparable in the molnupiravir and placebo groups, with around 10% reporting adverse events. Just 1.3% of the molnupiravir group discontinued therapy due to an adverse event — less than the 3.4% of the placebo group who did so.

Recruitment into the study is being stopped early due to the positive results, at the
BREAKING NEWS
ı independent Data Monitoring Committee and in consultation
l Drug Administration.

Merck is also testing molnupiravir in a separate global phase 3 study to evaluate its efficacy in preventing the spread of Covid within households.

Robert M. Davis, CEO and president of Merck, said in a press release Friday that the company would do everything it can to bring molnupiravir to patients as quickly as possible.

"With these compelling results, we are optimistic that molnupiravir can become an important medicine as part of the global efforts to fight the pandemic," he said.

VIDEO 05:20

Dr. Gottlieb on when the FDA will authorize a COVID vaccine for kids

Ridgeback Biotherapeutics CEO Wendy Holman added: "With the virus continuing to circulate widely, and because therapeutic options currently available are infused 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."

"We are very encouraged by the results from the interim analysis and hope

ized for use, can make a profound impact in controlling the pandemic," she said.

Emergency use authorization

Merck said Friday it plans to seek emergency use authorization for the drug in the U.S.

international drug regulators.

If authorized by regulatory bodies, molnupiravir could be the first oral antiviral medicine for Covid. Antiviral treatments now in use, such as remdesivir, are administered intravenously.

Merck has already begun producing molnupiravir. The pharmaceutical giant expects to produce 10 million courses of treatment by the end of 2021, and more doses in 2022.

The company agreed earlier this year to supply the U.S. with around 1.7 million courses of molnupiravir if it receives emergency use authorization or full approval from the FDA.

Merck has also entered supply and purchase agreements for the drug with other governments — pending regulatory authorization — and is in discussions with other governments about the supply of molnupiravir.

The company said it plans to implement a tiered pricing approach based on World Bank country income criteria to ensure molnupiravir can be accessed globally. Merck previously announced that it had entered into nonexclusive voluntary licensing agreements for molnupiravir with generic manufacturers, a move intended to assist low and middle-income countries in gaining access to the treatment. Those agreements are also pending approvals or emergency authorization by local regulators.

Profit share

Ridgeback received an upfront payment from Merck as part of the companies' development of molnupiravir. The company is also eligible to receive contingent payments depending on developmental and regulatory approval milestones.

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Profits arising from the collaboration will be split between Merck and Ridgeback equally.