Merck to ask FDA for emergency approval of its new antiviral pill for COVID

October 1 2021, by Robin Foster

(HealthDay)—Pharmaceutical giant Merck & Co. said Friday that it will

seek federal approval for emergency use of its new antiviral pill molnupiravir, after a clinical trial showed the drug halved the risk of hospitalization or death when given to high-risk people shortly after infection with COVID-19.

The new medication is just one of several antiviral pills now being tested in studies, and experts say these medications could give doctors a powerful new weapon to battle the virus.

"More tools and treatments are urgently needed to fight the COVID-19 pandemic, which has become a leading cause of death and continues to profoundly affect patients, families and societies, and strain health care systems all around the world," Merck CEO and President Robert Davis said in a company statement. "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, he added, "We will continue to work with regulatory agencies on our applications and do everything we can to bring molnupiravir to patients as quickly as possible."

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

Infectious disease experts embraced the news.

"I think it will translate into many thousands of lives being saved worldwide, where there's less access to monoclonal antibodies, and in this country, too," Dr. Robert Shafer, an infectious disease specialist and

expert on antiviral therapy at Stanford University, told *The New York Times*.

Angela Rasmussen, a virologist and research scientist at the Vaccine and Infectious Disease Organization at the University of Saskatchewan in Canada, agreed that antiviral pills can reach more people than cumbersome antibody treatments.

"If that holds up at the population scale, that is going to translate to an objectively larger number of lives saved potentially with this drug," she told the *Times*. "Maybe it isn't doing the same [efficacy] numbers as the monoclonal antibodies, but it's still going to be huge."

Other antiviral pills in the works

Late-stage study results of two other antiviral pills, one developed by Pfizer and the other by Atea Pharmaceuticals and Roche, are expected within the next few months, the *Times* reported.

In the Merck trial, which has not been peer-reviewed or published, molnupiravir was taken twice a day for five days.

Merck said that an independent board of experts monitoring its study data recommended that the trial be halted early because the drug's benefits to patients were so convincing. The company added that the U.S. Food and Drug Administration had agreed with that decision.

By early August, the study had enrolled 775 volunteers in the United States and overseas. They had to take the pills within five days of infection. For volunteers who were given the drug, their risk of being hospitalized or dying fell by 50%, without any concerning side effects, compared with those who received placebo pills, Merck said.

Just 7% of volunteers in the group that received the antiviral pills were hospitalized and none of those patients died, compared with a 14% rate of hospitalization and eight deaths in the placebo group.

Lab and animal experiments suggest the pill may also work against the Delta variant, the *Post* reported. Unlike vaccines or antibodies that target specific proteins on the surface of the virus, molnupiravir introduces nonsense mutations that scramble the coronavirus's genetic code so it can't replicate. That means it might even work on other coronaviruses or RNA viruses.

Merck's pill may fight other coronaviruses

"As a virologist, that's one of the things I find particularly exciting," Hazuda told the *Post*. "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."

The Merck pill's efficacy was lower than that of monoclonal antibody treatments, which mimic antibodies that the immune system generates naturally when needed, the *Times* reported.

Those drugs have been in high demand recently, but they are expensive and are time-consuming to administer because they are delivered intravenously. But studies have shown that they reduce hospitalizations and deaths by 70% to 85% in high-risk patients, the *Times* reported.

The federal government has already placed advance orders for 1.7 million courses of Merck's antiviral pill, at a price of about $700 per patient, which is one-third of the current cost of a monoclonal antibody treatment, the *Times* reported.

Merck—which is developing the pill with Ridgeback Biotherapeutics of Miami—did not say which patients it would ask the FDA to approve for the treatment.

Initially, that group may be limited to patients who are eligible to receive monoclonal antibody treatments, possibly older people and those with medical conditions that put them at high risk for bad outcomes from COVID-19 infection. But experts noted that they expected that the drug might eventually be used in many people who test positive for the virus, the *Times* reported.

If authorized, Merck's drug would be the second COVID-19 antiviral treatment. The first, remdesivir, must be infused and has lost favor among doctors as studies have suggested it only offers a modest benefit, the *Times* reported.

More information: Visit the U.S. Centers for Disease Control and Prevention for more on COVID antivirals.

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