

# Pfizer asks US officials to OK promising COVID-19 pill

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Pfizer asked U.S. regulators Tuesday to authorize its experimental pill for COVID-19, setting the stage for a likely launch this winter of a promising treatment that can be taken at home.

The company's filing comes as new infections are rising once again in the United States, driven mainly by hot spots in states where colder weather is driving more Americans indoors.

Pfizer's pill has been shown to significantly cut the rate of hospitalizations and deaths among people with coronavirus infections. The Food and Drug Administration is already reviewing a competing pill from Merck and several smaller drugmakers are also expected to seek authorization for their own antiviral pills in the coming months.

"We are moving as quickly as possible in our effort to get this potential treatment into the hands of patients, and we look forward to working with the U.S. FDA on its review of our application," said Pfizer CEO Albert Bourla, in a statement.

Specifically, Pfizer wants the drug available for adults who have mild-to-moderate COVID-19 infections and are at risk of becoming seriously ill. That's similar to how other drugs are currently used to treat the disease. But all FDA-authorized COVID-19 treatments require an IV or injection given by a health professional at a hospital or clinic.

The FDA is holding a public meeting on the Merck pill later this month to get the opinion of outside experts before making its decision. The agency isn't required to convene such meetings and it's not yet known whether Pfizer's drug will undergo a similar public review.

Some experts predict COVID-19 treatments eventually will be combined to better protect against the worst effects of the virus.

[Pfizer reported earlier this month](#) that its pill cut hospitalizations and deaths by 89% among high-risk adults who had early symptoms of COVID-19. The company studied its pill in people who were unvaccinated and faced the worst risks from the virus due to age or

health problems, such as obesity. If authorized, the FDA will have to weigh making the pill available for vaccinated people dealing with breakthrough infections, since they weren't part of the initial tests.

For best results, patients need to start taking the pills within three days of symptoms, underscoring the need for speedy testing and diagnosis. That could be a challenge if another COVID-19 surge leads to testing delays and shortages seen last winter.

Pfizer's drug is part of a decades-old family of antiviral drugs known as protease inhibitors, which revolutionized the treatment of HIV and hepatitis C. The drugs block a key enzyme which viruses need to multiply in the human body. That's different than the Merck pill, which causes tiny mutations in the coronavirus until the point that it can't reproduce itself.

On Tuesday, [Pfizer signed a deal a with U.N.-backed group](#) to allow generic drugmakers to produce low-cost versions of the pill for certain countries. Merck has a similar deal for its pill, which was authorized in Britain earlier this month.

The U.S. has approved one other antiviral drug for COVID-19, remdesivir, and authorized three antibody therapies that help the immune system fight the virus. But they usually have to be given via time-consuming infusions by health professionals, and limited supplies were strained by the last surge of the delta variant.

The U.S. government has already committed to purchasing Merck's pill. Federal authorities were in negotiations with Pfizer to buy millions of doses of its pill, according to an official familiar with the matter.

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