THE CORONAVIRUS CRISIS

FDA authorizes 1st antiviral pill for COVID

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Pfizer's antiviral pill Paxlovid was authorized to treat COVID-19, by the Food and Drug Administration on Wednesday.

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In a highly anticipated decision, the Food and Drug Administration authorized the first antiviral pill to treat COVID-19 at home.

The pill, called Paxlovid, is made by Pfizer. It's taken twice a day for five days in combination with a second medicine called ritonavir, a generic antiviral.

"Today's authorization introduces the first treatment for COVID-19 that is in the form of a pill that is taken orally — a major step forward in the fight against this global pandemic," said Dr. Patrizia Cavazzoni, director of the FDA's Center for Drug Evaluation and Research. "This authorization provides a new tool to combat COVID-19 at a crucial time in the pandemic as new variants emerge and promises to make antiviral treatment more accessible to patients who are at high risk for progression to severe COVID-19."

The Pfizer treatment could help keep people infected with the coronavirus from getting so sick that they need to be hospitalized.

The results from a Pfizer study involving more than 2,200 people at high risk for developing serious COVID-19 found Paxlovid reduced the risk of hospitalization or death by 89%, compared with a placebo, when taken within three days of first symptoms of illness. When taken within five days, the drug reduced the risk of hospitalization and death by 88%.

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Early results from another Paxlovid study showed a 70% reduction in hospitalization risk among several hundred people at lower risk for severe disease.

Although it's not certain, Paxlovid's efficacy is unlikely to be reduced in treating people infected with the omicron variant of the coronavirus virus. The drug, which belongs to a family called protease inhibitors, doesn't target the virus's spike protein, as the vaccines do.

The federal government has a contract with Pfizer to buy 10 million courses of the treatment for $5.3 billion. But initial supplies of Paxlovid will be limited. The company says it will have 180,000 course of treatment ready by the end of the year.

The FDA is also weighing a COVID-19 pill from Merck and Ridgeback Biotherapeutics that is also taken twice a day for five days.

There's more of the Merck drug to go around. Merck says it will have 10 million packs available by the end of the month.

But the effectiveness of the Merck COVID-19 pill may make it less attractive. An interim analysis of a clinical study of the drug found that molnupiravir cut the risk of hospitalization or death in half. However, the final study analysis released a couple of days before a public meeting of advisers to the FDA, found only a 30% reduction in the risk of hospitalization or death. And FDA advisers raise concern about the possibility the drug could cause birth defects.

paxlovid covid treatments pfizer fda