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FDA: Merck COVID pill effective, experts will review safety

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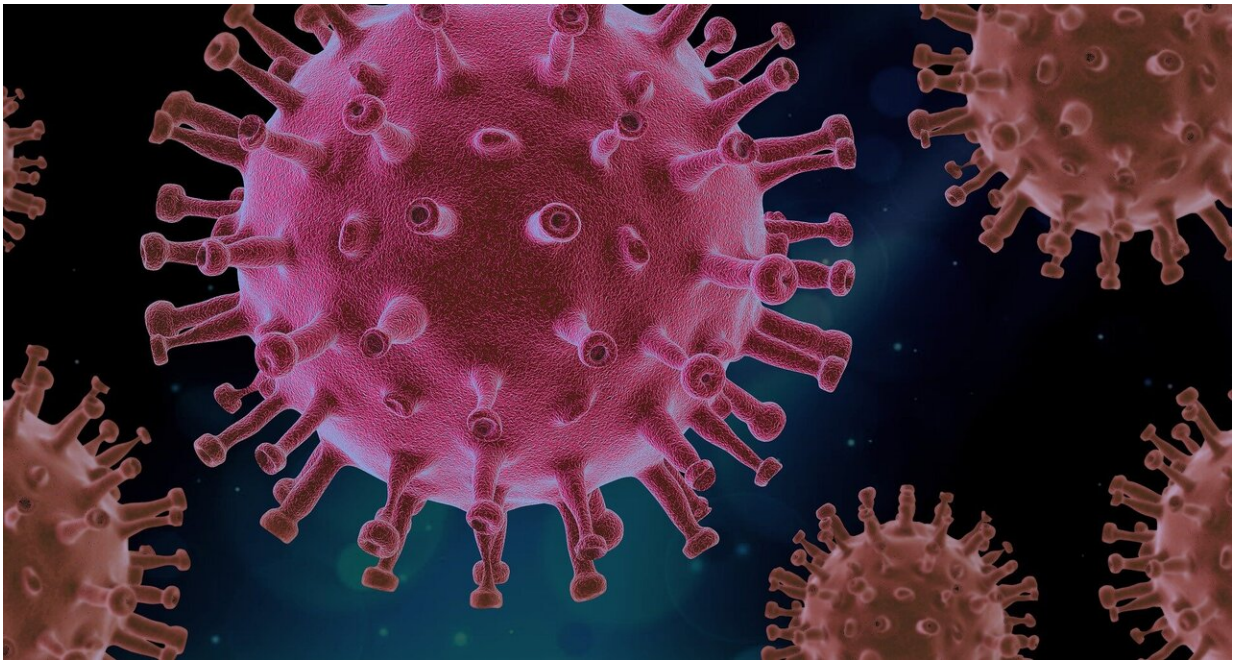

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Federal health regulators say an experimental COVID-19 pill from Merck is effective against the virus, but they will seek input from outside experts on risks of birth defects and other potential problems during pregnancy.

The Food and Drug Administration posted its analysis of the pill ahead

of a public meeting next week where academic and other experts will weigh in on its safety and effectiveness. The agency isn't required to follow the group's advice.

The FDA scientists said their review identified several potential risks, including possible toxicity to developing fetuses and birth defects that were identified in studies of the pill in animals.

Given those risks the FDA will ask its advisers next Tuesday whether the drug should never be given during pregnancy or whether it could be made available in certain cases.

Under that scenario, the FDA said the drug would carry warnings about risks during pregnancy, but doctors would still have the option to prescribe it in certain cases where its benefits could outweigh its risks for patients.

Given the safety concerns, FDA said Merck agreed the drug would not be used in children.

Other side effects were mild and rare, with about 2% of patients experiencing diarrhea.

Regulators also noted that Merck collected far less safety data overall on its drug than was gathered for other COVID-19 therapies.

"While the clinical safety data base was small, there were no major safety concerns identified," FDA reviewers concluded.

Additionally, the FDA flagged a concern that Merck's drug led to small changes in the coronavirus' signature spike protein, which it uses to penetrate human cells. Theoretically, FDA cautioned, those changes could lead to dangerous new variants.

FDA will ask its independent advisers to discuss all those issues and then vote on whether the drug's overall benefits outweigh its risks.

All COVID-19 drugs currently authorized by the FDA require an injection or IV and can only be given by health professionals. If authorized, Merck's drug would be the first that U.S. patients could take at home to ease symptoms and speed recovery. It is already authorized for emergency use in the U.K.

The meeting marks the first time regulators have publicly reviewed a new drug for COVID-19, reflecting the intense interest and scrutiny of a pill that could be soon used by millions of Americans.

The drug, molnupiravir, has been shown to significantly cut the rate of hospitalizations and deaths among people with mild-to-moderate coronavirus infections.

Merck's drug uses a novel approach to fight COVID-19: it inserts tiny mutations into the coronavirus' genetic code to stop the virus from reproducing.

But that genetic effect has raised concerns that in rare cases the drug could cause birth defects or even spur more virulent strains of the virus.

Pregnant women were excluded from Merck's study, and both women and men in the study were instructed to use contraception or abstain from sex.

For its part, Merck says results from two company studies in rodents show the drug does not cause mutations or damage to DNA at the doses studied .

FDA reviewers also confirmed previously reported interim results from

Merck that the pill cut the rate of hospitalization and death by about half among patients with early symptoms of COVID-19 who faced increased risk due to health problems.

However, on Friday morning Merck announced updated results from the same study that showed a smaller benefit from the drug. The FDA said it is still reviewing the updated data and would present a new assessment of the drug's effectiveness next Tuesday.

Among more than 1,400 adults in a company study, molnupiravir reduced the combined risk of hospitalization and death by 30%, less than the 50% initially reported based on incomplete results.

Nearly 7% of patients who received Merck's drug within five days of COVID-19 symptoms ended up in the hospital and one died. That compared to 10% of patients hospitalized who were taking the placebo and nine deaths.

Merck didn't study its drug in people who were vaccinated for COVID-19. But the FDA will ask advisers to recommend which patients may stand to benefit the most from the drug, based on vaccination status and underlying health problems.

While Merck's drug is likely to be the first pill for coronavirus in the U.S., more are expected to follow.

Rival drugmaker Pfizer has submitted its own antiviral for FDA review after initial study results showed it cut the combined rate of hospitalization and death by nearly 90%.

Pfizer's drug is part of a decades-old family of antiviral pills known as protease inhibitors, which revolutionized the treatment of HIV and hepatitis C. They work differently than Merck's pill and haven't been

linked to the kind of mutation concerns that have been raised with Merck's drug.