

Pfizer begins trial of COVID drug Paxlovid in kids 6 to 17

March 9 2022



Pfizer Inc. announced Tuesday that it has launched a Phase 2/3 clinical



trial of its COVID antiviral pill known as Paxlovid in children ages 6-17.

A <u>news release</u> from the company said the trial will assess the safety and efficacy of the drug in children with COVID symptoms and a confirmed infection who are not hospitalized and are at risk for severe disease.

"Since the beginning of the pandemic, more than 11 million children under the age of 18 in the United States alone have tested positive for COVID-19, representing nearly 18% of reported cases and leading to more than 100,000 hospital admissions. There is a significant unmet need for outpatient treatments that can be taken by children and adolescents to help prevent progression to severe illness, including hospitalization or death," Mikael Dolsten, chief scientific officer and president of Worldwide Research, Development and Medical at Pfizer, said in the release.

"Paxlovid is already authorized or approved in many countries around the world, with more than 1.5 million treatment courses delivered thus far and 30 million expected by July to help combat this devastating disease," Dolsten said.

Pfizer's trial will include about 140 patients and will evaluate them in two groups to determine the effects of different doses based on weight.

Paxlovid combines two <u>antiviral drugs</u>: nirmatrelvir and ritonavir. Participants in the first group who weigh at least 88 pounds would receive 300 milligrams (mg) of nirmatrelvir and 100 mg of ritonavir by mouth twice a day for five days.

This is the dosage currently authorized by the U.S. Food and Drug Administration for high-risk COVID-19 patients 12 and older who weigh at least 88 pounds.



Participants in the second group who weigh between 44 and 88 pounds will be given 150 mg of nirmatrelvir and 100 mg of ritonavir by mouth twice a day for five days.

<u>Clinical trials</u> in patients 18 and older have shown that Paxlovid cuts the risk of hospitalization or death by 89% if given within a few days of the first symptoms, according to Pfizer.

Although Pfizer's COVID vaccine is authorized for those as young as 5, treatments for children are limited.

"We're working with companies to accrue pediatric data," Dr. John Farley, director of the Office of Infectious Diseases in the Center for Drug Evaluation and Research of New Drugs, said during an American Medical Association webinar last month, CNN reported. He added that safety data, as well as data on how the drugs move through the body, would be key.

Children can become seriously ill from COVID, but they are less likely than adults to be hospitalized. Meanwhile, new COVID cases among U.S. children dropped below 100,000 last week for the first time since early August, the American Academy of Pediatrics <u>reported</u> Monday. New cases dropped nearly 46% last week from the week prior; it was the sixth consecutive weekly decrease from the peak of more than 1.15 million new cases during the week of Jan. 20.

More information: Visit the U.S. National Institutes of Health for more on <u>COVID treatments</u>.

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Citation: Pfizer begins trial of COVID drug Paxlovid in kids 6 to 17 (2022, March 9) retrieved 5 May 2024 from <u>https://medicalxpress.com/news/2022-03-pfizer-trial-covid-drug-paxlovid.html</u>

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