FDA issues emergency use authorization for second at-home COVID-19 treatment

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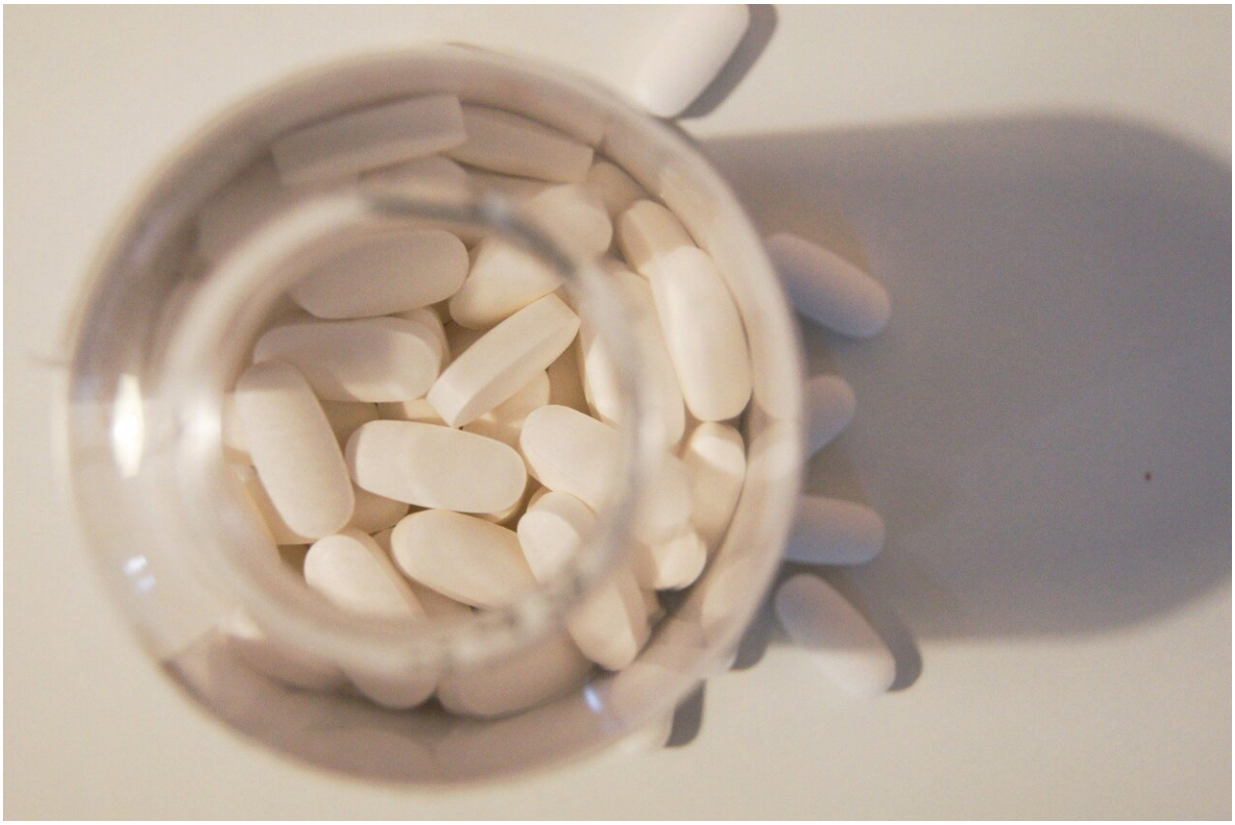

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For the second time in as many days, the Food and Drug Administration (FDA) has granted emergency use authorization for an investigational antiviral pill to treat COVID-19. This time it is Merck's molnupiravir.

According to the company, under the emergency use authorization, the treatment is cleared to treat mild to moderate COVID-19 in adults who have tested positive for the disease, are at high risk for progression to severe COIVD-19 and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate.

"In studies, it reduced the risk of hospitalization in high-risk patients by 30 percent when given within five days of onset of symptoms," says Dr. Priya Sampathkumar, a Mayo Clinic infectious diseases expert and head of Mayo's Infection Prevention and Control Program.

According to Dr. Sampathkumar, the drug has fewer interactions with commonly used medications, and more doses have been prepurchased by the U.S. government, so it will be more available in the near-term.

"While a 30 percent reduction in hospitalizations seems disappointing, this may be counterbalanced by the increased availability and lesser drug-drug interactions." Sampathkumar adds that a major limitation to the use of this and the other recently authorized drug, paxlovid, is identification of patients most likely to benefit, in the early stage of the illness.

While he welcomes the additional option for treatment, Dr. Gregory Poland, an infectious diseases expert and head of Mayo Clinic's Vaccine Research Group notes there are limitations with molnupiravir.

"In particular, some subgroups treated with molnupiravir did not demonstrate efficacy compared to placebo but these groups are too small enough for valid statistical interpretation. In addition there are limitations in its use in patients with renal or hepatic impairment and women of childbearing age, women who are pregnant, women who are breastfeeding, and men who are having sex with women of childbearing age."

The pill is not authorized for use in patients under 18.

On Wednesday, Dec. 22nd, the FDA issued an emergency use authorization was issued for Pfizer's paxlovid, making it the first oral antiviral medication authorized to help people who are infected with COVID-19 before they are hospitalized.

The FDA emphasizes that neither pill is authorized to prevent COVID-19 infection and is not a substitute for COVID-19 vaccinations and boosters.

Provided by Mayo Clinic