FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults

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Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for molnupiravir for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. Molnupiravir is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset.

Molnupiravir is not authorized for use in patients younger than 18 years of age because molnupiravir may affect bone and cartilage growth. It is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to COVID-19 because benefit of treatment has not been observed in people when treatment started after hospitalization due to COVID-19.

"Today's authorization provides an additional treatment option against the COVID-19 virus in the form of a pill that can be taken orally. Molnupiravir is limited to situations where other FDA-authorized treatments for COVID-19 are inaccessible or are not clinically appropriate and will be a useful treatment option for some patients with COVID-19 at high risk of hospitalization or death," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research. "As new variants of the virus continue to emerge, it is crucial to expand the country's arsenal of COVID-19 therapies using emergency use authorization, while continuing to generate additional data on their safety and effectiveness."

Molnupiravir is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. The FDA has approved one vaccine and authorized others to prevent COVID-19 and serious clinical outcomes associated with a COVID-19 infection, including hospitalization and death. The FDA urges the public to get vaccinated and receive a booster if eligible. Learn more about FDA-approved or -authorized COVID-19 vaccines.

Molnupiravir is a medication that works by introducing errors into the SARS-CoV-2 virus' genetic code, which prevents the virus from further replicating. Molnupiravir is administered as four 200 milligram capsules taken orally every 12 hours for five days, for a total of 40 capsules. Molnupiravir is not authorized for use for longer than five consecutive days.

The issuance of an EUA is different than an FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of the scientific evidence available and carefully balances any known or potential risks with any known or potential benefits of the product. Based on the FDA's review of the totality of the scientific evidence available, the agency has determined that it is reasonable to believe that molnupiravir may be effective for use as treatment of mild-to-moderate COVID-19 in certain adults when alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. The agency has also determined that the known and potential benefits of molnupiravir, when used consistent with the terms and conditions of the authorization, outweigh the known and potential risks of the product. There are no adequate, approved and available alternatives to molnupiravir for the treatment of COVID-19.

The primary data supporting this EUA for molnupiravir are from MOVe-OUT, a randomized, double-blind, placebo-controlled clinical trial studying molnupiravir for the treatment of non-hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe COVID-19 and/or hospitalization. Patients were adults 18 years of age and older with a prespecified chronic medical condition or at increased risk of SARS-CoV-2 infection for other reasons who had not received a COVID-19 vaccine. The main outcome measured in the trial was the percentage of people who were hospitalized or died due to any cause during 29 days of follow-up. Of the 709 people who received molnupiravir, 6.8% were hospitalized or died within this time period compared to 9.7% of the 699 people who received a placebo. Of the people who received molnupiravir one died during the follow-up period compared to nine people who received placebo. Side effects observed in the trial included diarrhea, nausea and dizziness. The safety and effectiveness of molnupiravir for the treatment of COVID-19 continue to be evaluated.

Based on findings from animal reproduction studies, molnupiravir may cause fetal harm when administered to pregnant individuals. Therefore, molnupiravir is not recommended for use during pregnancy. Molnupiravir is only authorized to be prescribed to a pregnant individual after the prescribing healthcare provider has determined that the benefits of being treated with molnupiravir would outweigh the risks for that individual patient and after the prescribing health care provider has communicated the known and potential benefits and the potential risks of using molnupiravir during pregnancy to the pregnant individual. Females of childbearing potential are advised to use a reliable method of birth control correctly and consistently during treatment with molnupiravir and for four days after the final dose. Males of reproductive potential who are sexually active with females of childbearing potential are advised to use a reliable method of birth control correctly and consistently during treatment with molnupiravir and for at least three months after the final dose. Questions and concerns about reliable birth control methods that are appropriate for use during treatment with molnupiravir, as well as how molnupiravir may affect sperm cells, should be directed at one's healthcare provider.

Under the EUA, fact sheets that provide important information about using molnupiravir in the treatment of COVID-19 as authorized must be made available to healthcare providers and to patients and caregivers. These fact sheets include dosing instructions, potential side effects and information about who is able to prescribe molnupiravir.

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dietary supplements, products that give off electronic radiation, and for regulating tobacco products.