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Pfizer Receives U.S. FDA Emergency Use Authorization for Novel COVID-19 Oral Antiviral Treatment

- *PAXLOVID™ (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) is authorized for emergency use in both high-risk adults and high-risk pediatric patients 12 years of age and older weighing at least 40 kg*
- *EUA based on clinical data from EPIC-HR study, showing PAXLOVID reduced risk of hospitalization or death by 89% (within three days of symptom onset) and 88% (within five days of symptom onset) compared to placebo*
- *Pfizer is ready to start immediate delivery in the U.S., in accordance with its agreement with the U.S. government to supply 10 million treatment courses between 2021 and 2022*
- *Pfizer raises production projections from 80 million to 120 million courses of treatment in 2022, as a result of continued investments to support the manufacturing and distribution of PAXLOVID*
- *The company plans to file a New Drug Application (NDA) with the FDA for full regulatory approval in 2022*

Pfizer Inc. (NYSE: PFE) has announced that the U.S. Food and Drug Administration (FDA) has authorized the emergency use of PAXLOVID™ (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg [88 lbs]) 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. The treatment includes nirmatrelvir, a novel main protease (Mpro) inhibitor originating in Pfizer's laboratories, which was specifically designed to block the activity of the SARS-CoV-2 Mpro, an enzyme that the coronavirus needs to replicate.

"Today's authorization of PAXLOVID represents another tremendous example of how science will help us ultimately defeat this pandemic, which, even two years in, continues to disrupt and devastate lives across the world. This breakthrough therapy, which has been shown to significantly reduce hospitalizations and deaths and can be taken at home, will change the way we treat COVID-19, and hopefully help reduce some of the significant pressures facing our healthcare and hospital systems," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "Pfizer stands ready to begin delivery in the U.S. immediately to help get PAXLOVID into the hands of appropriate patients as quickly as possible."

The FDA based its decision on clinical data from the Phase 2/3 EPIC-HR (Evaluation of Protease Inhibition for COVID-19 in High-Risk Patients) trial, which enrolled non-hospitalized adults aged 18 and older with confirmed COVID-19 who are at increased risk of progressing to severe illness. The data demonstrated an 89% reduction in the risk of COVID-19-related hospitalization or death from any cause in adults treated with PAXLOVID, compared to placebo, within three days of symptom onset (primary endpoint). No deaths occurred in the treatment group compared to nine deaths in the placebo group by Day 28. Similar results were seen in those treated within five days of symptom onset (secondary endpoint), with an 88% reduction in risk and no deaths observed in the treatment group. Treatment-emergent adverse events were comparable between PAXLOVID (23%) and placebo (24%), most of which were mild in intensity. While PAXLOVID clinical trials did not include patients under the age of 18, the authorized adult dosing regimen is expected to result in comparable blood concentration levels of PAXLOVID in pediatric patients 12 years of age and older weighing at least 40 kg. Additional Phase 2/3 clinical trials are ongoing in adults at standard risk (i.e., low risk of hospitalization or death) of progressing to severe illness, and in those who have been exposed to the virus through household contacts.

With PAXLOVID now authorized for emergency use, Pfizer stands ready to start delivery in the U.S. immediately. In November 2021, Pfizer announced an agreement with the U.S. government to supply 10 million treatment courses of PAXLOVID, with delivery fulfillment expected to be completed in 2022.

Source: Pfizer

Published on : Wed, 22 Dec 2021