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Pfizer seeks EUA for novel oral COVID-19 pill

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Pfizer Inc. has announced that it is seeking Emergency Use Authorization (EUA) of its investigational oral antiviral candidate, PAXLOVID™ (PF-07321332; ritonavir), for the treatment of mild to moderate COVID-19 in patients at increased risk of hospitalizations or death.

This submission to the U.S. Food and Drug Administration (FDA) includes clinical data from the Phase 2/3 EPIC-HR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **H**igh-**R**isk Patients) interim analysis. Rolling submission of non-clinical data for PAXLOVID was initiated with the U.S. FDA in October 2021.

If authorized or approved, PAXLOVID would be the first oral antiviral of its kind, a 3CL protease inhibitor specifically designed to combat SARS-CoV-2 that could be prescribed as an at-home treatment to high-risk patients at the first sign of infection, potentially helping patients avoid severe illness which can lead to hospitalization and death.

Pfizer has begun and will continue to invest up to approximately $1 billion of its own funds to support the manufacturing and distribution of this investigational treatment candidate. Additionally, Pfizer has signed a voluntary licensing agreement with the Medicines Patent Pool (MPP) to help expand access, pending regulatory authorization or approval, in 95 low- and middle-income countries that account for approximately 53% of the world's population.