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Shionogi Receives US FDA Approval for Oral COVID-19 Post-Exposure Prophylaxis

June 9, 2026 | News

XOCOVA becomes the first oral option approved in the US to help prevent COVID-19 after exposure, supported by Phase III SCORPIO-PEP data.

Shionogi has received US FDA approval for XOCOVA, or ensitrelvir, as an oral post-exposure prophylaxis option for COVID-19 in adults and adolescents aged 12 years and older following contact with an individual who has COVID-19.

The approval addresses a remaining gap in COVID-19 prevention by offering an oral antiviral option that can be used after exposure, during the window before symptom onset. This may be relevant for household contacts, long-term care settings, healthcare facilities and other exposure scenarios where preventing symptomatic infection remains clinically and operationally important.

XOCOVA is a five-day oral regimen consisting of three tablets on the first day and one tablet daily on days two through five. The medicine selectively inhibits the SARS-CoV-2 main protease, an enzyme essential for viral replication.

The approval was supported by SCORPIO-PEP, a global, double-blind, randomised, placebo-controlled Phase III study. The trial enrolled 2,387 participants aged 12 years and older who were exposed to a household member with symptomatic COVID-19 and had no symptoms at enrolment.

In the primary analysis, XOCOVA reduced the risk of symptomatic COVID-19 by 67 percent through Day 10 compared with placebo among uninfected individuals following exposure. Overall adverse event rates were similar between XOCOVA and placebo, at 15.1 percent and 15.5 percent, respectively.

The approval was granted ahead of the June 16, 2026 Prescription Drug User Fee Act action date. XOCOVA is approved in both the United States and Japan for post-exposure prophylaxis of COVID-19, although it is not approved for COVID-19

treatment in the United States.

Commercial adoption will depend on prescriber awareness, testing and exposure-identification workflows, drug interaction management, access pathways and how healthcare systems prioritise COVID-19 prevention in the current endemic phase. The product also carries important safety considerations, including contraindicated medicines and pregnancy-related precautions.

As COVID-19 management moves beyond vaccination and treatment of established infection, post-exposure antiviral prophylaxis could become a more targeted prevention tool. XOCOVA's approval highlights how antiviral strategies may continue evolving to protect exposed individuals and reduce downstream healthcare burden.