PRESSRELEASE

SHIONOGI

**Shionogi Announces U.S. Availability of XOCOVA® (ensitrelvir), the First and Only Oral Option to Help Prevent COVID-19 Following Exposure***

Once-daily oral XOCOVA is now available by prescription for adults and adolescents 12 years of age and older[1]

In a global clinical trial, XOCOVA significantly reduced the risk of symptomatic COVID-19 by 67% following exposure to an infected individual, compared to placebo[2]

XOCOVA availability comes ahead of anticipated summer surge in COVID-19 cases[3]

**OSAKA, Japan, July 29, 2026** – Shionogi & Co., Ltd., (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, PhD; hereinafter "Shionogi") announced the U.S. availability of XOCOVA® (ensitrelvir), an oral antiviral approved for post-exposure prophylaxis (PEP) of COVID-19 in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19[2]. XOCOVA is now available in the United States through Shionogi Inc., Shionogi's U.S. subsidiary.

XOCOVA offers a new approach to help prevent COVID-19 by blocking viral replication during the critical window between exposure and COVID-19 symptom onset.[4,5] XOCOVA is taken once daily, with three 125 mg tablets (375 mg) taken at the same time on the first day, followed by one 125 mg tablet on days two to five. XOCOVA should be taken as soon as possible and within 72 hours following contact with an individual who has COVID-19.[1]

"With XOCOVA, we have a novel oral option to help prevent COVID-19 after exposure and it is available just in time for the annual late summer spike," said Charles Vega, MD, FAAFP, Health Sciences Clinical Professor, University of California, Irvine, School of Medicine. "Taking XOCOVA to help prevent COVID-19 in the critical window between exposure and symptom onset makes sense for anyone who wants to avoid illness, and it could be especially beneficial for older adults and individuals with health conditions that may put them at higher risk for severe illness. Now, in addition to recommending my patients stay updated with vaccinations, I'll be talking to them about XOCOVA, so they are ready to act quickly in the event of an exposure."

The U.S. has experienced a COVID-19 summer spike every year since 2020.[3] Biobot Analytics, a wastewater intelligence company with continuous and longitudinal data on pathogens from wastewater, reports that SARS-CoV-2 levels are beginning to rise, providing an early, population-level signal that another COVID-19 summer wave may be taking shape.[6] Scenario modeling from The Centers for Disease Control and Prevention indicates there may be increased COVID-19 activity in regions (South and West) which did not experience a substantial level of COVID-19 activity during the most recent winter months.[3]

"Post-exposure prophylaxis, or PEP for short, has been used successfully with influenza as well as HIV and other sexually transmitted infections, and it has the potential to help reduce the burden of COVID-19," said David Wohl, MD, Professor of Medicine, The University of North Carolina at Chapel Hill, School of Medicine. "The availability of XOCOVA means that now, for the first time, there's an oral option that can help prevent COVID-19 after exposure. Since XOCOVA must be taken within 72 hours of exposure, having it on hand can help ensure it is taken within the critical window between exposure and COVID-19 symptom onset."

Having XOCOVA on hand can help appropriate patients be prepared in the event of a COVID-19 exposure. Before taking XOCOVA, individuals should review the dosing and administration instructions and check the expiration date on the blister pack. They should also speak with a healthcare professional if there are any changes to their medications (including prescription and over-the-counter medicines), vitamins or supplements and verify they are not pregnant or are not breastfeeding.

In the United States, Shionogi Inc. is supporting the availability of XOCOVA through professional and consumer education initiatives and partnerships with national and regional pharmacies to help ensure product availability.

In the United States, Shionogi Inc. offers a commercial co-pay program for XOCOVA that helps eligible, commercially insured patients with out-of-pocket costs.

For the U.S. market, all components of XOCOVA are produced in the U.S., including active pharmaceutical ingredient production, drug product formulation, packaging, quality control, release testing, supply chain management and distribution.

**The Ongoing Impact of COVID-19**

COVID-19 remains highly transmissible, driven by Omicron and its subvariants, and up to 47% of people living with an infected individual may develop COVID-19.[7] The U.S. Centers for Disease and Control and Prevention estimates that between October 1, 2025, and July 4, 2026, there were 4.2-12.7 million new cases in the U.S., resulting in 860,000 – 2.3 million outpatient visits, 130,000 – 250,000 hospitalizations and 14,000 - 42,000 deaths.[8]

Beyond acute infection, COVID-19 can have lasting impacts. People diagnosed with COVID-19 had increased rates of both new and worsening neurologic, cardiovascular, respiratory, and chronic kidney conditions during the year following infection.[9-18] COVID-19 also disproportionately affects older adults with greater risk for severe illness and death in close-community settings, such as long-term care facilities.[19]

**About SCORPIO-PEP**

The global, double-blind, randomized, placebo-controlled Phase 3 study, SCORPIO-PEP, assessed the safety and efficacy of XOCOVA as post-exposure prophylaxis for COVID-19. The study was conducted

from June 2023–September 2024. It included 2,387 study participants aged 12 years and older with a negative local screening test for SARS-CoV-2 infection and no symptoms at the time of enrollment, who were exposed to a person living in their household with symptomatic COVID-19. The primary analysis included 2,041 household contact participants with a central laboratory-confirmed negative SARS-CoV-2 test at baseline.

More than 98% of household contacts tested positive for antibodies against SARS-CoV-2 N (nucleocapsid) or S (spike) proteins, indicating that nearly all had evidence of previous SARS-CoV-2 infection or vaccination, or both.[2]

Study participants were randomly assigned at a 1:1 ratio to receive XOCOVA (375 mg on Day 1 and 125 mg on Days 2-5) or placebo, once daily, and began treatment within 72 hours of when the household member with COVID-19 began showing symptoms. Participants then continued XOCOVA (125 mg) or placebo for five days.

In the primary analysis population, XOCOVA significantly reduced the risk of symptomatic COVID-19 by 67% in individuals following exposure to an infected individual through Day 10 compared with placebo (ensitrelvir n=1,030; placebo n=1,011).2 The most common adverse events (regardless of causality) occurring in greater than or equal to 1% of the XOCOVA group and at a greater frequency compared to placebo were headache, diarrhea, and cough.[1] There were no reports of altered taste (dysgeusia) attributed to XOCOVA in the trial.[2,20]

Results from the SCORPIO-PEP trial were published in the New England Journal of Medicine on May 14, 2026. SCORPIO-PEP is the first and only Phase 3 study of an oral antiviral to meet the primary endpoint of preventing COVID-19 following exposure to an infected individual.

**About XOCOVA**

XOCOVA® (ensitrelvir) is a SARS-CoV-2 main protease inhibitor created through joint research between Hokkaido University and Shionogi. SARS-CoV-2 has an enzyme called the main protease, which is essential for the replication of the virus. XOCOVA suppresses the replication of SARS-CoV-2 by selectively inhibiting the main protease.

XOCOVA is approved in the U.S. and Japan for post-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19.

XOCOVA received emergency regulatory approval in Japan in November 2022 and full approval in March 2024 for the treatment of COVID-19 in adults and adolescents 12 years of age and older based on results from SCORPIO-SR, a Phase 3 study conducted in Asia during the Omicron-dominant phase of the pandemic. Results from this study were published in *JAMA Network Open*. XOCOVA received supplemental approval in June 2026 for pediatric patients aged 6 to under 12 years who weigh at least 20 kg for the treatment of COVID-19.

XOCOVA is not approved for the treatment of COVID-19 in the U.S.

**About Shionogi & Co., Ltd.**

Shionogi & Co., Ltd. is a 148-year-old global, research-driven pharmaceutical company headquartered in Osaka, Japan, that is dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." The company currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders. Shionogi's research and development currently targets two therapeutic areas: infectious diseases and diseases with unmet medical needs in pain/CNS, including Alzheimer's disease, oncology, rare diseases, and sleep apnea. For more information on Shionogi & Co., Ltd., please visit https://www.shionogi.com/global/en.

**Forward-Looking Statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

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*Literature search conducted in May 2026

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