June 1, 2026

(Corrections) Shionogi Announces FDA Approval of XOCOVA® (ensitrelvir), the First and Only Oral Option to Help Prevent COVID-19 Following Exposure

Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.) hereby announces that there have been corrections made to the above-mentioned disclosure material released on June 1, 2026, at 9:20 a.m. (JST). Note that no corrections have been made to numerical data.

1. Details of corrections

   From page 4 onward, duplicated content in the main text and the References section were identified and has been removed.

2. Reason for corrections

   This was due to the discovery that certain portions of the disclosed English-language material, including the main text and the References section, contained duplicated content.

   <Before Correction>
   - The content, including the main text and the References section, was duplicated throughout the section beginning "OSAKA, Japan, June 1, 2026 – …" on page 4 through to "*Literature search conducted in May 2026" on page 7.
   - Reference numbers 19 through 34 were erroneously included.

   <After Correction>
   - The duplicated content from the section beginning "OSAKA, Japan, June 1, 2026 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, PhD; hereinafter "Shionogi") announced that the U.S. Food and Drug Administration (FDA) has approved XOCOVA® (ensitrelvir)" on page 4 through to "*Literature search conducted in May 2026" on page 7 has been removed.
   - Reference numbers 19 through 34 have been removed.

Please refer to the attached corrected version for the full text

Press Release (Corrected Version)

Shionogi Announces FDA Approval of XOCOVA® (ensitrelvir), the First and Only Oral Option to Help Prevent COVID-19 Following Exposure

*Approval is based on SCORPIO-PEP, the only Phase 3 study of an oral antiviral to meet the primary endpoint of preventing symptomatic COVID-19 following exposure to an infected individual**

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[1,2]

OSAKA, Japan, June 1, 2026 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, PhD; hereinafter "Shionogi") announced that the U.S. Food and Drug Administration (FDA) has approved XOCOVA® (ensitrelvir), an oral antiviral, 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.[3] This approval introduces the first and only oral option to help prevent COVID-19 after exposure in the current therapeutic landscape, addressing a critical gap in prevention. XOCOVA is a five-day oral regimen with three tablets taken on day one and one tablet taken on days two through five.[3] The approval occurred ahead of the Prescription Drug User Fee Act (PDUFA) action date of June 16, 2026.

"The FDA approval of XOCOVA provides an important new approach to preventing COVID-19, which continues to impact lives. COVID-19 can become severe and even when mild or moderate, it can worsen or exacerbate chronic conditions or trigger new ones, including long COVID," said Frederick Hayden, MD, Richardson Professor Emeritus of Clinical Virology and Professor Emeritus of Medicine, University of Virginia School of Medicine. "Ensitrelvir inhibits viral replication, helping protect people who have been exposed to COVID-19 from developing illness. The PEP strategy has the potential to benefit anyone who does not want to get COVID-19. It could be useful not only in household settings but also in other exposure circumstances, such as outbreaks in nursing homes, chronic or acute care facilities and following travel-related exposures."

The approval is based on positive results from SCORPIO-PEP, the only Phase 3 study of an oral antiviral to meet the primary endpoint of preventing symptomatic COVID-19 following exposure to an infected individual.* XOCOVA significantly reduced the risk of symptomatic COVID-19 by 67% in uninfected individuals following exposure to an infected individual through Day 10 compared with placebo (ensitrelvir n=1,030; placebo n=1,011).[3,4] Overall, XOCOVA was generally well tolerated, with similar rates of adverse events across groups (15.1% in the XOCOVA group (n=1,190) and 15.5% in the placebo group (n=1,187)).[4] 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.[3] There were no reports of altered taste (dysgeusia) attributed to XOCOVA in the trial.[4,5] Results from the SCORPIO-PEP trial were published in the *New England Journal of Medicine* on May 14, 2026.

"The FDA approval of XOCOVA is an exciting new chapter in the Shionogi antiviral story, which includes innovative medicines that have changed the way we manage other viruses including HIV and influenza," said Nathan McCutcheon, President and CEO, Shionogi Inc. "XOCOVA is the first and only oral option clinically proven to help prevent symptomatic COVID-19 after exposure among study participants regardless of vaccination status or baseline immunity from prior infection. With XOCOVA, people who are exposed to COVID-19 can act early to help protect themselves."

The impact of this matter on the consolidated financial results for the fiscal year ending March 2027 has already been reflected in the earnings forecast announced on May 12, 2026.

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.[6] The U.S. Centers for Disease and Control estimates that between October 1, 2025 and May 23, 2026 there were 3.8-12.4 million new cases in the U.S., resulting in 800,000 – 2.3 million outpatient visits, 120,000 – 240,000 hospitalizations and 13,000 - 42,000 deaths.[7]

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 renal conditions during the year following infection.[8-17] 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.[18]

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 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.

The trial was conducted from June 2023–September 2024. More than 99% 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.

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

About Shionogi Inc.

Shionogi Inc. is a U.S. subsidiary of Shionogi & Co., Ltd., a global research-driven pharmaceutical company committed to bringing to market the best possible medicines to aid the health and well-being of the patients we serve. Our global expertise in infectious disease began in the 1950s and in addition to discovering and developing multiple innovative antibiotics, today our global portfolio includes an antibiotic for the treatment of serious Gram-negative bacterial infections, antivirals for COVID-19, HIV and influenza and a therapeutic for rare fungal infections. Our U.S. infectious disease franchise includes both approved and investigational novel anti-infectives, and investigational antivirals for COVID-19 and RSV. In parallel, we are advancing a U.S. rare disease franchise that includes an approved therapy for amyotrophic lateral sclerosis (ALS), along with clinical programs in Fragile X syndrome, Jordan's syndrome, and Pompe disease. We are also pursuing research in additional high-unmet need therapeutic areas, including oncology, acute ischemic stroke, sleep apnea, and other quality of life areas. Learn more at shionogi.com.

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 and cardiovascular diseases. 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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