PRESSRELEASE

SHIONOGI

Shionogi Announces Approval in Japan of a Supplemental Indication for XOCOVA® (Ensitrelvir Fumaric Acid) for the Post-Exposure Prophylaxis of COVID-19.

- *This approval is based on the positive results from the global Phase 3 post-exposure prophylaxis study, SCORPIO-PEP, which 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*[*,1]*
- *XOCOVA® is the first and only oral antiviral available for the post-exposure prophylaxis of COVID-19.*

OSAKA, Japan, March 23, 2026 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that it has received approval in Japan for an expanded indication of XOCOVA® (generic name: ensitrelvir fumaric acid; hereafter 'XOCOVA'), an anti SARS-CoV-2 drug, for post-exposure prophylaxis of COVID-19. The approval is based on the positive results from the Global Phase 3 Study, SCORPIO-PEP.[1]

COVID-19 remains a public health threat.[2,3] While vaccination is considered the foundation of COVID-19 prevention, declining vaccination rates, waning immunity following vaccination, and the potential emergence of new variants make it difficult to fully prevent SARS-CoV-2 infection, symptom onset, or disease severity through vaccination alone.[4,5,6,7] Under these circumstances, post-exposure prophylaxis with an antiviral agent represents an important option for the prevention of COVID-19, particularly for individuals with risk factors for severe disease who have been exposed to a person with COVID-19.[8]

Ensitrelvir, known as XOCOVA in countries where it is approved, received emergency regulatory approval in Japan in November 2022 and full approval in March 2024 for the treatment of COVID-19. Furthermore, in 2025, based on the positive results from the global Phase 3 post-exposure prophylaxis study (SCORPIO-PEP), Shionogi submitted a supplemental New Drug Application in Japan for an expanded indication of ensitrelvir for the post-exposure prophylaxis of COVID-19. In addition, a Phase 3 study in Japan in pediatric patients demonstrated favorable safety and tolerability, and showed that the pharmacokinetics of ensitrelvir in pediatric patients were similar to those observed in adults.[9] Based on these results, Shionogi also submitted an application to expand the approved dosage and administration from the current treatment indication for patients aged 12 years and older to include pediatric patients aged 6 years and older weighing 20 kg or more.
It became available in Singapore via a Special Access Route application in 2023, and it is currently under regulatory review for the treatment of COVID-19 in Taiwan.
Ensitrelvir is currently under review by the U.S. Food and Drug Administration (FDA) for the prevention of COVID-19 following exposure, with a Prescription Drug User Fee Act (PDUFA) target action date of June 16, 2026. Ensitrelvir is also under regulatory review with the European Medicines Agency for COVID-19 post-exposure prophylaxis and treatment.[10]

Product Information	
Product name	XOCOVA® Tablets 125mg
Generic Name	ensitrelvir fumaric acid

Indication	Treatment and post-exposure prophylaxis of SARS-CoV-2 infection
Dosage Regimen※	The usual dosage for children aged 12 years or older and adults is 375 mg of ensitrelvir orally on Day 1 and 125 mg once daily from Days 2 to 5.
Drug price	JPY7,090 per 125mg tablet
Marketing Authorization Holder	Shionogi & Co., Ltd.

※The dosage and administration of this product are the same for both treatment and post-exposure prophylaxis.

About ensitrelvir

Ensitrelvir is a 3CL protease inhibitor created through joint research between Hokkaido University and Shionogi. SARS-CoV-2 has an enzyme called 3CL protease, which is essential for the replication of the virus.[11] Ensitrelvir suppresses the replication of SARS-CoV-2 by selectively inhibiting the 3CL protease.[11]

Shionogi evaluated the safety and efficacy of ensitrelvir through SCORPIO-SR, a Phase 3 study conducted in Asia, during the Omicron-dominant phase of the epidemic.[12] In this study, ensitrelvir showed both clinical symptomatic efficacy (symptom resolution sustained for at least 24 hours) for five typical Omicron-related symptoms (primary endpoint) and antiviral efficacy (key secondary endpoint) in a predominantly vaccinated population of patients with mild-to-moderate SARS-CoV-2 infection, regardless of risk factors.[12] Regarding safety, most adverse events were mild in severity and no deaths were seen in the study.[12] Among the most common treatment-related adverse events were temporary decreases in high-density lipoprotein and increased blood triglycerides, as observed in previous studies.[12] The data from this study were published in JAMA Network Open.

Additionally, the Phase 3 SCORPIO-HR study assessed ensitrelvir in a broad range of symptomatic, non-hospitalized participants with COVID-19, regardless of past SARS-CoV-2 infection. The study did not meet its primary endpoint of a statistically significant reduction in time to sustained resolution (symptom resolution sustained for at least 48 hours) of 15 common COVID-19 related symptoms for once-daily ensitrelvir compared to placebo.[13] No new safety concerns were identified in the study, and treatment with ensitrelvir was well tolerated, with a similar adverse event profile as placebo.

Shionogi recently announced that its global, double-blind, randomized, placebo-controlled Phase 3 study (SCORPIO-PEP) assessing ensitrelvir as oral post-exposure prophylaxis met the primary endpoint of preventing COVID-19.[1] SCORPIO-PEP is the first and only Phase 3 study of a COVID-19 oral antiviral as a post-exposure prophylaxis to meet the primary endpoint of preventing COVID-19.*

SCORPIO-PEP assessed 2,387 study participants aged 12 years and older with a negative 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. Study participants were randomly assigned in a 1:1 ratio to receive ensitrelvir (125 mg) or placebo, once daily, and began treatment within three days of when the household member with COVID-19 began showing symptoms. Participants then continued ensitrelvir or placebo for five days. Overall, ensitrelvir was generally well tolerated, with similar rates of adverse events in the ensitrelvir group and the placebo group (15.1% and 15.5%, respectively).[1] There were no COVID-19 related hospitalizations or deaths.

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 January 2026.

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