PRESSRELEASE

SHIONOGI

**Shionogi Announces Supplemental Approval in Japan for Pediatric Dosage and Administration of XOCOVA® to Treat COVID-19**

**OSAKA, Japan, June 19, 2026 -** Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereinafter "Shionogi") announced that it has received supplemental approval in Japan today for the pediatric dosage and administration of XOCOVA® (generic name: ensitrelvir fumaric acid; hereinafter "XOCOVA"), an anti-SARS-CoV-2 drug, for pediatric patients aged 6 to under 12 years who weigh at least 20 kg for the treatment of COVID-19. In addition, new, smaller 25 mg tablets have also been approved.

The approval is based on the results of a Phase 3 clinical trial conducted in pediatric patients aged 6 to under 12 years with SARS-CoV-2 infection weighing at least 20 kg in Japan.[1] The trial evaluated the safety and pharmacokinetics of once-daily oral administration of XOCOVA for 5 days at weight-based doses, in a total of 117 participants. As a result, no new safety concerns were identified. Furthermore, the pediatric plasma concentration profiles of XOCOVA observed in the trial were confirmed to be comparable to those predicted for adults receiving therapeutic doses, based on a population pharmacokinetic (PPK) analysis. These findings support the appropriateness of the dosing regimen for children aged 6 to under 12 years.

COVID-19 remains a public health threat.[2] With this approval, and in addition to its indication for adults and pediatric patients aged 12 years and older, XOCOVA becomes a new treatment option for pediatric patients aged 6 years and older weighing at least 20 kg, and is expected to contribute to the treatment of a broader pediatric population as an oral anti-SARS-CoV-2 drug that can be used regardless of risk factors for progression to severe disease.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as one of its key focuses, and is working toward the realization of total care for infectious diseases. Shionogi will continue to advance research and development in infectious diseases so that we can rapidly deliver the necessary therapeutics, prophylactics, and vaccines in response to the emergence of new variants and future epidemiological trends.

The impact of this matter on the consolidated financial results for the fiscal year ending March 2027 is expected to be minimal.

**Product Information**

<table>
<tr><td>Product name</td><td colspan="4">XOCOVA® Tablets 125 mg / XOCOVA® Tablets 25 mg</td></tr>
<tr><td>Generic name</td><td colspan="4">ensitrelvir fumaric acid</td></tr>
<tr><td>Indication</td><td colspan="4">For the treatment and post-exposure prophylaxis of SARS-CoV-2 infection</td></tr>
<tr><td rowspan="6">Dosage and Administration</td><td colspan="4">〈Treatment〉<br>The usual dosage is the following amount of ensitrelvir, administered orally once daily.</td></tr>
<tr><td rowspan="2">Age group</td><td rowspan="2">Body weight</td><td colspan="2">Dose</td></tr>
<tr><td>Day 1 dose</td><td>Days 2–5 dose</td></tr>
<tr><td>Adults and pediatric patients aged ≥12 years</td><td>—</td><td>375 mg</td><td>125 mg</td></tr>
<tr><td rowspan="3">Pediatric patients aged 6 to <12 years</td><td>≥40 kg</td><td>375 mg</td><td>125 mg</td></tr>
<tr><td>≥30 kg to <40 kg</td><td>250 mg</td><td>125 mg</td></tr>
<tr><td>≥20 kg to <30 kg*<br>* The 25 mg tablets have not yet been listed in the drug price.</td><td>150 mg</td><td>75 mg</td></tr>
<tr><td colspan="4">〈post-exposure prophylaxis〉<br>For adults and pediatric patients aged 12 years and older, the usual dosage is 375 mg of ensitrelvir on Day 1, followed by 125 mg once daily on Days 2 to 5, administered orally.</td></tr>
<tr><td>Marketing Authorization Holder</td><td colspan="4">Shionogi & Co., Ltd.</td></tr>
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**About ensitrelvir**

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. Ensitrelvir suppresses the replication of SARS-CoV-2 by selectively inhibiting the main protease.

Shionogi evaluated the safety and efficacy of ensitrelvir through SCORPIO-SR, a Phase 3 trial conducted in Asia, during the Omicron-dominant phase of the epidemic.[3,4,5] In this trial, ensitrelvir showed both clinical symptomatic efficacy (symptom resolution sustained for at least 24 hours) for five typical Omicron-related symptoms (the primary endpoint) and antiviral efficacy (a key secondary endpoint) in patients with mild-to-moderate SARS-CoV-2 infection. Ensitrelvir received emergency regulatory approval in Japan in November 2022[6] and full approval in March 2024 for the treatment of COVID-19.[7] In March 2026, based on the positive results from the global Phase 3 post-exposure prophylaxis trial (SCORPIO-PEP), Shionogi obtained approval in Japan for the indication of COVID-19 post-exposure prophylaxis.[8]

In the U.S., Shionogi Inc., our U.S. subsidiary, received approval from the U.S. Food and Drug Administration (FDA) on May 29, 2026 for the indication of post-exposure prophylaxis of COVID-19.[9] In Europe, ensitrelvir has been under review by the European Medicines Agency for the indication of post-exposure prophylaxis and treatment of COVID-19. It became available in Singapore via a Special Access Route application in November 2023,[10] and is currently under regulatory review for the indication of postexposure prophylaxis of COVID-19 in Taiwan.

In addition, we have entered into a licensing agreement with the Medicines Patent Pool to enable broad access to the drug in low- and middle-income countries (LMICs), and we continue to advance efforts to expand global access.[11,12]

**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.*

**For Further Information, Contact:**

SHIONOGI Website Inquiry Form : https://www.shionogi.com/global/en/contact.html

**Reference List:**


1. Japan Registry of Clinical Trials（jRCT 2031230140）
2. Six years after COVID-19's global alarm: Is the world better prepared for the next pandemic?. World Health Organization. Available at: https://www.who.int/news/item/02-02-2026-six-years-after-covid-19-s-global-alarm-is-the-world-better-prepared-for-the-next-pandemic
3. Yotsuyanagi H., et al. Efficacy and Safety of 5-Day Oral Ensitrelvir for Patients with Mild to Moderate COVID-19. *JAMA Network Open.* 2024
4. Press Release: September 28, 2022
   Shionogi Announces Achievement of the Primary Endpoint for Ensitrelvir Fumaric Acid (S-217622) in the Phase 3 part of the Phase 2/3 Clinical Trial in Asia
5. Press Release: February 22, 2023
   Shionogi Presents Pivotal Ensitrelvir Fumaric Acid Phase 3 Data and Exploratory Long COVID Data at CROI
6. Press Release: November 22, 2022
   Xocova® (Ensitrelvir Fumaric Acid) Tablets 125mg Approved in Japan for the Treatment of SARS-CoV-2 Infection, under the Emergency Regulatory Approval System
7. Press Release: March 5, 2024
   Shionogi Announces Xocova® (Ensitrelvir Fumaric Acid) Obtained Standard Approval in Japan for the Treatment of SARS-CoV-2 Infection
8. Press Release: March 23, 2026
   Shionogi Announces Approval in Japan of a Supplemental Indication for XOCOVA® (Ensitrelvir Fumaric Acid) for the Post-Exposure Prophylaxis of COVID-19.
9. Press Release: June 1, 2026
   Shionogi Announces FDA Approval of XOCOVA® (ensitrelvir), the First and Only Oral Option to Help Prevent COVID-19 Following Exposure
10. Press Release: December 19, 2023
    Execution of Sub-license Agreement from Ping An-Shionogi Hong Kong to Juniper Therapeutics and SAR approval in Singapore regarding ensitrelvir fumaric acid, a treatment drug for the novel coronavirus infection (COVID-19)
11. Press Release: October 4, 2022
    Shionogi and the Medicines Patent Pool (MPP) sign licence agreement for COVID-19 oral antiviral treatment candidate to increase access in low- and middle-income countries

12. Press Release: June 26, 2023
    Seven manufacturers sign sublicence agreements with the Medicines Patent Pool to produce generic versions of Shionogi's COVID-19 oral antiviral ensitrelvir to increase access in low- and middle-income countries.