PRESSRELEASE

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Shionogi Announces European Commission Approval of Zokovea® (ensitrelvir) for Post-Exposure Prophylaxis of COVID-19

- **Zokovea becomes the first oral antiviral medicine authorized in the European Union for the post-exposure prophylaxis of COVID-19***
- **Approval is based on the Phase 3 SCORPIO-PEP study evaluating Zokovea following household exposure to COVID-19[1]**

OSAKA, Japan, September 28, 2026 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that the European Commission (EC) has granted marketing authorization for Zokovea® (ensitrelvir) for post-exposure prophylaxis (PEP) of COVID-19 in adults and adolescents aged 12 years and older.[2]

The approval of Zokovea as the first oral antiviral medicine authorized in the EU for post-exposure prophylaxis of COVID-19* adds a new option to the range of measures available to support COVID-19 preparedness. Together with vaccines, diagnostics and surveillance, antiviral medicines can form part of a broader range of complementary measures that support public health preparedness.[3]

* Based on a search of the European Commission Union Register of medicinal products and European Medicines Agency records for antiviral medicines authorized for post-exposure prophylaxis of COVID-19, conducted August 2026

Matteo Bassetti, Head of the Infectious Diseases Clinic of the Policlinico San Martino University Hospital in Genoa and Full Professor of Infectious Diseases of the University of Genoa, said: "This approval marks a significant shift in the role of oral antivirals for COVID-19: moving from treating patients with confirmed infection to the possibility of early intervention following known exposure to an infected contact, with the aim of preventing symptomatic disease. Alongside vaccination, this introduces an additional prevention strategy, expanding the range of tools available to help protect at-risk individuals."

The EC's decision is supported by results from the global Phase 3 SCORPIO-PEP, a multicenter, randomized, double-blind, placebo-controlled trial evaluating Zokovea in household contacts of individuals with COVID-19.[1] In the primary analysis population, treatment with Zokovea was initiated within 72 hours of when the household member with COVID-19 began showing symptoms.[1] Zokovea significantly reduced the risk of developing symptomatic COVID-19 through Day 10 by 67% compared with placebo (Zokovea n=1,030; placebo n=1,011).[1] The study enrolled more than 2,300 adults and adolescents aged 12 years and older and

represents the first Phase 3 study of an oral antiviral to demonstrate efficacy for the post-exposure prophylaxis of COVID-19.[1]

Huw Tippett, CEO, Shionogi Europe, said: "The European Commission approval of Zokovea represents an important regulatory milestone for Shionogi and reflects the strength of the clinical evidence supporting Zokovea for post-exposure prophylaxis of COVID-19. Shionogi remains committed to advancing innovative medicines for infectious diseases and supporting public health preparedness through scientific innovation."

Outside the EU, ensitrelvir, marketed as Xocova® in Japan and the United States, is also approved in Japan for the treatment of COVID-19 and, in Japan and the United States, for post-exposure prophylaxis in adults and adolescents aged 12 years and older.[4,5,6]

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About SCORPIO-PEP

The global, double-blind, randomized, placebo-controlled Phase 3 study, SCORPIO-PEP, assessed the safety and efficacy of Zokovea as post-exposure prophylaxis for COVID-19.[1] 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 enrolment, who were exposed to a person living in their household with symptomatic COVID-19.[1] The primary analysis included 2,041 household contact participants with a central laboratory-confirmed negative SARS-CoV-2 test at baseline.[1]

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.[1]

Study participants were randomly assigned at a 1:1 ratio to receive Zokovea (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.[1]

In the primary analysis population, Zokovea significantly reduced the risk of symptomatic COVID-19 by 67% in individuals following exposure to an infected individual through Day 10 compared with placebo (Zokovea n=1,030; placebo n=1,011).[1] Overall, Zokovea was generally well tolerated, with similar rates of adverse events across groups (15.1% in the Zokovea group and 15.5% in the placebo group).[1] The most common adverse events (regardless of causality) occurring in greater than or equal to 1% of the Zokovea group and at a greater frequency compared to placebo were headache, diarrhea, and cough.[1]

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 symptomatic COVID-19 following exposure to an infected individual.[1]

About Zokovea

Zokovea (ensitrelvir) is a SARS-CoV-2 main protease inhibitor created through joint research between Hokkaido University and Shionogi.[4] SARS-CoV-2 has an enzyme called the main protease, which is essential for the replication of the virus.[4] Zokovea suppresses the replication of SARS-CoV-2 by selectively inhibiting the main protease.[4]

Ensitrelvir is approved as Zokovea® in the EU and as Xocova® 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.[2,5,6]

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.[4,7] Results from this study were published in JAMA Network Open. Xocova received supplemental approval in June 2026 in Japan for pediatric patients aged 6 to under 12 years who weigh at least 20 kg for the treatment of COVID-19.[8]

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 target 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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