PRESSRELEASE

SHIONOGI

**Acceptance of a New Drug Application for the COVID-19 Treatment, Ensitrelvir Fumaric Acid, in Taiwan and Conclusion of Government Stockpiling Contract**

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**OSAKA, Japan, January 22, 2025 -** Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that the Taiwan Food and Drug Administration has accepted our new drug application (NDA) for ensitrelvir fumaric acid (hereafter "ensitrelvir") for the treatment of COVID-19. This NDA was submitted by Taiwan Shionogi & Co., Ltd., (hereafter "Taiwan Shionogi"), the Taiwan subsidiary of Shionogi. Additionally, Taiwan Shionogi and Taiwan Centers for Disease Control have concluded a contract for the purchase of ensitrelvir for stockpiling by the Taiwanese government.

Ensitrelvir is an investigational oral antiviral that suppresses the replication of SARS-CoV-2 by selectively inhibiting the viral 3CL protease. In Japan, ensitrelvir, known as Xocova®, received emergency regulatory approval in 2022 and full approval in March 2024 for the treatment of COVID-19. Ensitrelvir was also made available in Singapore based on the Special Access Route application in 2023. It remains an investigational drug outside of Japan and Singapore.

COVID-19 continues to mutate and impact the health and lives of many people worldwide, necessitating the ongoing development of effective and safe treatments. It is estimated that there are approximately 1.7 million COVID-19 patients in Taiwan annually*, and ensitrelvir is expected to contribute as a new treatment option for COVID-19.

* Cumulative number of patients visiting outpatient and emergency departments in 2024 (Source: Taiwan Centers for Disease Control website)

**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. Ensitrelvir suppresses the replication of SARS-CoV-2 by selectively inhibiting the 3CL protease.

The U.S. Food and Drug Administration (FDA) granted Fast Track designation to ensitrelvir for COVID-19. FDA Fast Track designation is designed to facilitate the development and expedite the review of potential new therapies that treat serious conditions and fulfill an unmet medical need. Known as Xocova® in Japan, ensitrelvir received emergency regulatory approval in 2022 and full approval in March 2024. Ensitrelvir was made available in Singapore in November 2023 based on the Special Access Route application. Ensitrelvir remains an investigational drug outside of Japan and Singapore. In addition, the brand name Xocova® has not been approved for use outside of Japan and Singapore and pertains only to the approved drug in Japan and Singapore.

**About Shionogi in Infectious Disease**

Since 1953, Shionogi has been a leader in infectious disease discovery and commercialization. Our R&D story extends beyond antibiotics to include novel medications for HIV and influenza. Today, our global pipeline includes investigational agents developed to address global health challenges including antimicrobial resistance, COVID-19, influenza, rare fungal diseases and respiratory syncytial virus.

As part of our commitment to addressing unmet medical needs, Shionogi is partnering with several non-governmental organizations to increase equitable access to our medications worldwide. Shionogi has a landmark license and technology transfer agreement for cefiderocol with Global Antibiotic Research and Development Partnership (GARDP) and a collaboration agreement with the Clinton Health Access Initiative (CHAI) to transform the landscape of access to antibiotics in many low-income countries, most lower middle- and upper middle-income countries, and select high-income countries.

**About the ensitrelvir Clinical Development Program**

Shionogi has a robust clinical development program for ensitrelvir and is committed to making it available to populations worldwide. In addition to SCORPIO-HR and SCORPIO-PEP, Shionogi evaluated the safety and efficacy of ensitrelvir through SCORPIO-SR, a Phase 2/3 study conducted in Asia, during the Omicron-dominant phase of the epidemic. The data from this study were published in JAMA Network Open.

Additionally, an investigator-initiated research study is ongoing in hospitalized patients for the management of COVID-19 as part of the new Strategies and Treatments for Respiratory Infections & Viral Emergencies (STRIVE) platform protocol. STRIVE was developed under the auspices of NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership. Shionogi is also studying the safety and efficacy of ensitrelvir in Japan for children between the ages of 6 to 11 years old.

**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