



Shionogi Receives U.S. FDA Fast Track Designation for Ensitrelvir Fumaric Acid, an Investigational Oral Antiviral for COVID-19

OSAKA, Japan, April 4, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for their investigational COVID-19 oral antiviral ensitrelvir (Generic name: ensitrelvir fumaric acid, Code No.: S-217622, hereafter "ensitrelvir"). 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.

Ensitrelvir, known as Xocova® 125 mg tablet in Japan, recently received emergency regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for the treatment of SARS-CoV-2 infection. It remains an investigational drug outside Japan.

COVID-19 is a serious and potentially life-threatening illness.¹ As of mid-January 2023, over 660 million cases have been reported globally, with more than 101 million cases of COVID-19 in the United States.²

"There is a need for additional COVID-19 treatment options as SARS-CoV-2 continues to affect people in the U.S. Receiving Fast Track designation from the FDA recognizes the potential of ensitrelvir as a once-daily, oral antiviral for SARS-CoV-2," said Nathan McCutcheon, CEO, Shionogi Inc., the U.S. subsidiary of Shionogi. "We look forward to our continued discussions with the FDA to bring ensitrelvir to patients as soon as possible."

Ensitrelvir is an oral antiviral agent administered once daily for five days that suppresses the replication of SARS-CoV-2 by selectively inhibiting the viral 3CL protease. Shionogi [recently](#) presented results from the Phase 3 part of the pivotal SCORPIO-SR trial (Phase 2/3 study) conducted in Japan, South Korea, and Vietnam at the Conference on Retroviruses and Opportunistic Infections (CROI). Several additional [Phase 3 clinical studies](#) evaluating the safety and efficacy of ensitrelvir across a wide range of COVID-19 patient populations are planned and ongoing.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" with research and development of therapeutics, while also working towards total care through awareness building, epidemiologic monitoring, prevention, diagnosis, and addressing exacerbations, as well as treating infections directly. As SARS-CoV-2 continues to have a major impact on people's lives and to represent a global threat, Shionogi will seek to contribute to re-establishing the safety and security of society by developing new products and services to address this pandemic. Shionogi is committed to equitable access worldwide, including working with the [Medicines Patent Pool to provide access to low- and middle-income countries \(LMICs\)](#), and strengthening its manufacturing and global supply chain.

About ensitrelvir

Ensitrelvir (known in Japan as Xocova®), an oral antiviral drug for COVID-19, is currently approved under the emergency regulatory approval system in Japan. Ensitrelvir is an investigational drug outside of Japan, and has

not been approved outside of Japan. In addition, the brand name Xocova[®] has not been approved for use outside of Japan and pertains only to the approved drug in Japan.

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 3CL protease. Ensitrelvir is the first antiviral agent to show both clinical symptomatic efficacy 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 in the Phase 3 part of the Phase 2/3 study conducted during the Omicron-dominant phase of the epidemic. With regard to safety, most adverse events were mild in severity and no deaths were seen in the study. Among the most common treatment-related adverse events were temporary decreases in high-density lipoprotein and increased blood triglycerides, as observed in previous studies. Currently, the Phase 2b/3 part of the Phase 2/3 study targeting SARS-CoV-2 infected persons who were asymptomatic or only had mild symptoms is being conducted in Asia, mainly in Japan.

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:

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References:

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2. COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). Johns Hopkins University Medicine. Accessed April 2023. Available at <https://coronavirus.jhu.edu/map.html>.