PRESSRELEASE

SHIONOGI

New Drug Application of Ensitrelvir Fumaric Acid, a Therapeutic Drug for COVID-19 Accepted for Review in South Korea

OSAKA, Japan, January, 4, 2023 - OSAKA, Japan, January, 4, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D., hereafter "Shionogi") announced that its partner Ildong Pharmaceutical Co., Ltd. (Head Office: Seoul, South Korea; Vice Chairman and Chief Executive Officer: Yun Paul Woongsup, hereafter "Ildong") who has been sub-Licensed South Korean rights to Ensitrelvir Fumaric Acid (development number: S-217622, hereafter "ensitrelvir"), has filed a New Drug Application (NDA) with the MFDS (Ministry of Food and Drug Safety) for the indication of SARS-CoV-2 infection, and this application has been accepted for review by MFDS.

Following the approval of ensitrelvir in Japan on November 22, 2022[1], which was based on the data from the Asian Phase 2/3 clinical trials that SHIONOGI have been conducting, mainly in Japan, Ildong has been in discussions with the MFDS and the Korean Disease Control and Prevention Agency (KDCA) in order to obtain approval in South Korea[2]. Accordingly, Ildong has now submitted a conditional approval application to MFDS on January 3, 2023, which was accepted for review. Shionogi group will continue to work closely with Ildong to provide the necessary support for approval and commercial launch in South Korea.

Shionogi is committed to “Protect people worldwide from the threat of infectious diseases” as our key focus. We are not only conducting research and development of novel therapeutics, but we are also working towards total care for infectious diseases, through building awareness, epidemiologic monitoring, prevention, diagnosis, and addressing exacerbations, as well as treating the infection itself. As SARS-CoV-2 continues to have a major impact on people’s lives and to represent a global threat, we will seek to contribute to re-establishing the safety and security of society by developing new products and services to address this pandemic. We will continue to pursue global registration, including working with the Medicines Patent Pool to provide access to low- and middle-income countries (LMICs), and to expand and strengthen our manufacturing and global supply chain, in parallel with accumulating additional evidence on efficacy and safety.

About Ensitrelvir Fumaric Acid

Ensitrelvir (Code No.: S-217622), an antiviral drug for COVID-19 currently approved under the emergency regulatory approval system in Japan, 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 patients with mild to moderate SARS-CoV-2 infection, regardless of risk factors or vaccination status, in the Phase 3 part of the Phase 2/3 study conducted during the Omicron-dominant phase of the epidemic [3]. Currently, the Phase 2b/3 part of the Phase 2/3 study targeting SARS-CoV-2 infected persons with asymptomatic/mild symptoms only is being conducted in Asia, mainly in Japan. With regard to safety, ensitrelvir was well tolerated, and there were no treatment-related serious adverse events or deaths in the study. The most common treatment-related adverse

events were transient decreases in high-density lipoprotein and increases in blood triglycerides, as observed in previous studies. A global Phase 3 trial (SCORPIO-HR study[4]) in non-hospitalized SARS-CoV-2 infected patients is ongoing. In addition, a global Phase 3 trial (STRIVE study[5]) for hospitalized SARS-CoV-2 infected patients is scheduled to initiate soon. An onset prevention study for household members living with SARS-CoV-2 infected individuals and a pediatric study for children under the age of 12 are also in preparation.

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.

Reference

1. Press release on 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
2. Press release on September 16,2022
   Execution of Sub-license Agreement from Ping An-Shionogi Hong Kong to Ildong for Ensitrelvir Fumaric Acid (S-217622), a Therapeutic Drug for COVID-19, for South Korea
3. Press release on 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
4. ClinicalTrials.gov：NCT05305547
5. ClinicalTrials.gov：NCT05605093

For Further Information, Contact:

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