PRESSRELEASE

SHIONOGI

Notice Regarding the Signing of an Additional Purchasing Contract with the Ministry of Health, Labor and Welfare for Domestic Supply of Xocova® (Ensitrelvir Fumaric Acid) Tablets 125mg, a Novel Anti-SARS-CoV-2 Drug for COVID-19

OSAKA, Japan, December 13, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi has entered into an additional purchasing contract of Xocova® (Generic name: ensitrelvir fumaric acid), recently obtained emergency regulatory approval in Japan for the indication of SARS-CoV-2 infection [1], with the Ministry of Health, Labour and Welfare (MHLW) on December 12, 2022.

This contract is for the Japanese government to purchase additional Xocova® tablets for 1 million courses. Shionogi and the MHLW have been discussing to secure a certain number of courses of Xocova® beside the first contract for the Japanese government to purchase 1 million courses of Xocova® immediately after approval, so that Xocova® can be widely provided to COVID-19 patients, primarily in Japan, in accordance with the basic agreement for domestic supply of Xocova® signed by Shionogi and the MHLW in March 2022 [2]. As stated in the administrative notice of the MHLW, which was revised yesterday, from December 15, 2022, medical institutions and pharmacies selected by each prefecture will be able to prescribe and prepare Xocova®, in addition to existing facilities that can be registered. Both parties have reached the conclusion of this contract since the supply of Xocova® is expected to increase.

Xocova® 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 plan to deliver this additional quantity by the end of the year so that we can contribute a steady supply of this new option for the treatment of SARS-CoV-2 infected patients. To achieve a more stable supply of this drug, Shionogi will continue to work closely with the MHLW and cooperating institutions regarding management of the distribution of Xocova®, and will discuss with the MHLW the transition to general distribution in Japan. Since Xocova® has received emergency approval, Shionogi will continue to diligently collect clinical safety information and to provide that information to medical institutions in a timely manner.

Shionogi is committed to “Protect people worldwide from the threat of infectious diseases” as our key focus. We are not only pursuing the research and development of therapeutics, but are also working towards total care for infectious diseases, through awareness building, 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, and will keep all stakeholders informed regarding the progress of our efforts.

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About Xocova®

Xocova® (ensitrelvir fumaric acid, 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. Xocova® suppresses the replication of SARS-CoV-2 by selectively inhibiting 3CL protease. Xocova® 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 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.

To that end, we note that 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.

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

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 March 25,2022
   Notice Regarding the Signing of a Basic Agreement with the Ministry of Health, Labor and Welfare for Domestic Supply of S-217622, a Therapeutic Drug for COVID-19
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