PRESSRELEASE

SHIONOGI

Notice Regarding a License Agreement for Import and Distribution of Ensitrelvir Fumaric Acid, a Therapeutic Drug for COVID-19, in China

OSAKA, Japan, December, 23, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Ping An-Shionogi Co., Ltd. (Head Office: Shanghai, China; Chairman and CEO: Tatsumori Yoshida, hereafter "Ping An-Shionogi ") a joint venture between Shionogi and Ping An Life Insurance Company of China, Ltd. ※1 (Headquarters: Guangdong Province, China), has signed a license agreement with Shanghai Pharmaceutical Co., Ltd (Head Office: Shanghai, China; Chairman: Yongzhong Li; hereafter "SHAPHAR"), for import and distribution of Ensitrelvir Fumaric Acid (development number: S-217622, hereafter "ensitrelvir"), a therapeutic drug for COVID-19, in mainland China.

SHAPHAR, a subsidiary of Shanghai Pharmaceuticals Holding Co., Ltd. (Head Office: Shanghai, China; Executive Director and President: Man Cho; hereafter "SPH"), is a modern provider of pharmaceutical supply chain services that focuses on pharmaceutical distribution. According to this license agreement for the import and distribution of ensitrelvir, SHAPHAR will exclusively import ensitrelvir into China and deliver it after the approval. And with the conclusion of this agreement, Ping An-Shionogi and SPH also started to explore various collaboration opportunities in the future, including the import, distribution, and manufacture of new drugs, and expansion of the sales network of generic drugs. Both companies will continue to discuss how to provide the better healthcare products synergistically to the people living in China.

Ping An-Shionogi has already started to submit materials to the Center for Drug Evaluation ("CDE") of the National Medical Products Administration of China ("NMPA") in preparation for the new drug application for ensitrelvir. Ping An-Shionogi is continuing close communication with the CDE, following the approval of ensitrelvir in Japan on November 22, 2022. Both companies will cooperate to contribute to COVID-19 treatment in China by providing a stable supply of ensitrelvir as soon as possible.

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 we 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.

※1 Ping An Life Insurance Company of China, Ltd.; A subsidiary of Ping An Insurance (Group) Company of China Ltd. (Headquarters: Guangdong Province, China)

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.

About Shanghai Pharmaceuticals Holding Co., Ltd.

SPH is a large pharmaceutical group with dual listings on the Shanghai and Hong Kong's stock exchanges (SSE Stock Code 601607 and HK Ex Stock Code 02607). The company's core business is in pharmaceuticals and covers four major activities: Research & Development, Manufacturing, Distribution and Retailing.

About Shanghai Pharmaceutical Co., Ltd

SHAPHAR, a subsidiary of SPH, is a modern provider of pharmaceutical supply chain services that focuses on pharmaceutical distribution. Relying on a distribution network covers more than 30,000 medical institution terminals nationwide and strong service innovation，SHAPHAR has taken a leading position in the industry.

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 July 4,2022
   Notice Regarding the Initiation of the Submission of Preparation Materials
   for a New Drug Application for S-217622, a Therapeutic Drug for COVID-19, in China
2. 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
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