PRESSRELEASE

SHIONOGI

Notice Regarding a License Agreement for the Promotion of Ensitrelvir Fumaric Acid, a Therapeutic Drug for COVID-19, in China

OSAKA, Japan, December, 29, 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 Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (Head Office: Lianyungang, Jiangsu Province, China, President; Eric Tse, hereafter "CTTQ"), subsidiaries of Sino Biopharmaceutical Limited (Head Office: Hong Kong; President: Theresa Tse; hereafter "Sino Bio"), a group company of CP Group, for the promotion of Ensitrelvir Fumaric Acid (development number: S-217622, hereafter "ensitrelvir"), a therapeutic drug for COVID-19, in mainland China.

CTTQ is the core pharmaceutical company of the CP Group, which conducts integrated pharmaceutical research, development, manufacturing, and marketing, which has more than 7,000 academic and sales staff, and conducts pharmaceutical promotion activities throughout China. Under this agreement, Ping An-Shionogi will promote elsitrelvir to certain medical institutions, while CTTQ will exclusively promote ensitrelvir at other institutions, utilizing its extensive sales network in China.

Ping An-Shionogi has already begun 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[1]. Ping An-Shionogi is continuing itsclose communication with the CDE following the approval of ensitrelvir in Japan on November 22, 2022[2]. Regarding the import and distribution of ensitrelvir in China, an agreement was already signed on December 23, 2022 with Shanghai Pharmaceutical Co., Ltd[3]. Ping An-Shionogi is engaging in collaborations with partner companies, including CTTQ, to contribute to COVID-19 treatment in China by providing 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[4]. 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 [5]) in non-hospitalized SARS-CoV-2 infected patients is ongoing. In addition, a global Phase 3 trial (STRIVE study[6]) 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 CP group

Founded in Thailand in 1921 by Tse Yee Chu, it has become a diversified corporate group with three core businesses: agriculture and food, wholesale and retail, and telecommunications and television, as well as finance, real estate, pharmaceuticals, and machinery processing, and others, with a presence in over 100 countries and regions. It s known in Thailand as the Charoen Pokphand (CP) Group. It is one of the largest foreign-owned companies in China, with more than 600 companies in the country, employing approximately 100,000 people.

About Sino Bio

The pharmaceutical business company of the CP group, listed on the Hong Kong Stock Exchange from 2000. It is one of China's leading pharmaceutical companies, addressing a range of disease in various therapeutic areas, including liver disease, oncology, orthopedics, infectious diseases, respiratory and cardiovascular diseases.

About CTTQ

As the core pharmaceutical company of the CP Group, it conducts integrated pharmaceutical research, development, manufacturing, and marketing, with more than 14,000 employees. The company has product lines in respiratory and infectious diseases as well as oncology, liver, endocrine, and cardiovascular diseases, and more than 7,000 academic and sales staff to provide information on pharmaceutical products.

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 December 23,2022
   Notice Regarding a License Agreement for Import and Distribution of Ensitrelvir Fumaric Acid,
   a Therapeutic Drug for COVID-19, in China
4. 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
5. ClinicalTrials.gov：NCT05305547
6. ClinicalTrials.gov：NCT05605093

For Further Information, Contact:

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