



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

OSAKA, Japan, September 16, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Ping An-Shionogi (Hong Kong) Limited (Head Office: Hong Kong, China; Chairman and Chief Executive Officer: Tatsumori Yoshida; hereafter "Ping An-Shionogi Hong Kong") and Ildong Pharmaceutical Co., Ltd. (Head Office: Seoul, South Korea; Vice Chairman and Chief Executive Officer: Yun Paul Woongsup hereafter "Ildong") signed a sub-license agreement regarding the pursuit of Emergency Use Authorization (hereafter "EUA") application and government procurement of S-217622, an orally administered antiviral drug for COVID-19, in South Korea.

Ping An-Shionogi Hong Kong has exclusive development and commercialization rights for S-217622 in Asian territories, excluding Japan, under license agreement with Shionogi. Under this sub-license agreement, Ping An-Shionogi Hong Kong will license S-217622 to Ildong for South Korea, and, based on the data from the Asian Phase 2/3 clinical trials conducted mainly in Japan, Ildong will begin consultation with government authorities to prepare for an EUA in South Korea and subsequent government purchase after obtaining approval. In addition, if certain conditions are met, Ildong will be granted manufacturing rights in South Korea and will manufacture products for the South Korean market, with technical assistance from Shionogi and Ping An-Shionogi Hong Kong. Until the transfer of technology to Ildong is completed, our group will supply S-217622. Ping An-Shionogi Hong Kong will receive an upfront payment in connection with this agreement as well as a certain amount of revenue when there are government purchases.

S-217622 is an oral antiviral agent, administered once daily for 5 days, that is capable of suppressing the growth of SARS-CoV-2 by selectively inhibiting the 3CL protease. So far, S-217622 has shown the ability to rapidly reduce viral load, as well as good tolerability. Regarding the improvement of symptoms, as a secondary endpoint in the Phase 2b part of the Phase 2/3 clinical trial, a significant improvement in the total score of respiratory symptoms (stuffy or runny nose, sore throat, cough, shortness of breath) was observed. Furthermore, a post-hoc analysis of the same clinical trial also suggested a similar effect on 5 highly characteristic symptoms of Omicron variant infection, including fever in addition to the 4 respiratory symptoms. This drug is expected to contribute to South Korean society's ability to address the ongoing COVID-19 pandemic.

Shionogi will continue the development of COVID-19 therapeutic agents and vaccines in Japan and other countries to help to restore safety and security to society.

About S-217622

S-217622, a therapeutic drug for COVID-19, is a 3CL protease inhibitor created through joint research between Hokkaido University and Shionogi. Clinical trials through Phase 2b part of a Phase 2/3 clinical trial in patients with mild/moderate symptoms have been completed, and the Phase 3 part of a Phase 2/3 clinical trial in patients with mild/moderate symptoms and the Phase 2b/3 part of a trial in patients with asymptomatic/only mild symptoms are in progress, in Asia, mainly in Japan.^{1,2,3} Globally, the global Phase 3 trial (SCORPIO-HR) for SARS-CoV-2 infected patients without hospitalization is in progress.

About Ping An-Shionogi Hong Kong

Ping An-Shionogi Hong Kong was established in 2020 as a joint venture between Shionogi Hong Kong and Tutum Japan Healthcare Limited, a subsidiary of China Ping An Insurance Overseas (Holdings) Limited and an indirect subsidiary of Ping An Insurance (Group) Company of China Ltd. Its main businesses are capital investment, intellectual property license management, and product supply operations to Asian countries including China.

About Ildong Pharmaceutical Co., Ltd.

As a leading pharmaceutical company in South Korea, Ildong Pharmaceutical Co., Ltd. has been dedicated and committed to the development and supply of superior pharmaceutical products that contribute to the health and well-being of people. Ildong is steadfast in its vision of continuously growing with customers as a leading global company, providing solutions for disease prevention and developing new solutions to support healthier and happier lives. For more information, please visit <https://mobile.ildong.com/eng/main/main.id>

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 February 7,2022
Shionogi Presents Phase 2/3 Clinical Trial Results (Phase 2a Part) for the COVID-19 Therapeutic Drug S-217622
2. Press release on February 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 April 24,2022
New Data for Shionogi's COVID-19 Once-Daily Oral Antiviral S-217622 Show Rapid Virus Clearance

For Further Information, Contact:

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