PRESSRELEASE

SHIONOGI

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

OSAKA, Japan, July, 4, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that, a joint venture between Shionogi and Ping An Life Insurance Company of China, Ltd. ※1 (Headquarters: Guangdong Province, China), Ping An-Shionogi Co., Ltd. (Head Office: Shanghai, China; Chairman and CEO: Tatsumori Yoshida, hereafter" Ping An-Shionogi ") has initiated the submission of preparation materials for an application for new drug approval application for S-217622, an orally administered antiviral drug for COVID-19, to the Center for Drug Evaluation, NMPA (hereafter "CDE").

Prior to the formal submission of the new drug application, Ping An-Shionogi has submitted a communication meeting application to the CDE for this therapeutic drug to facilitate the new drug application process.

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, the good tolerability, and has been suggested to improve a composite score of five “respiratory and fever-related” symptoms. It is expected to contribute to the COVID-19 treatment in China, after approval.

As the COVID-19 pandemic continues to have a significant impact on people’s lives globally, Shionogi will continue the development of COVID-19 therapeutic agents in Japan and other countries to contribute to the restoration of safety and security to society.

※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 S-217622

S-217622, a therapeutic drug for COVID-19, 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. S-217622 suppresses the replication of SARS-CoV-2 by selectively inhibiting 3CL protease. Shionogi has already been submitting the non-clinical, manufacturing/CMC data, and clinical trial data obtained so far to the PMDA. By now, the trials up to Phase 2b have been completed, and currently the Phase 3 part of a Phase 2/3 clinical trial in patients with mild/moderate symptoms and the Phase 2b/3 part in patients with asymptomatic/only mild symptoms are in progress.[1,2,3]

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 realease 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