Press Release

SHIONOGI

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

OSAKA, Japan, March, 25, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Shionogi has entered into a basic agreement with the Ministry of Health, Labor and Welfare (MHLW) for the supply of S-217622, an orally administered antiviral drug for COVID-19, in Japan.

The basic agreement was concluded on the condition that Shionogi initiates manufacturing and marketing of S-217622 after receiving regulatory approval in Japan. This is the first such contract for a domestically-produced oral therapeutic drug for COVID-19. The main provision is that the Company and the MHLW will advance negotiations toward the conclusion of a purchasing contract and a distribution consignment contract until regulatory approval is obtained. The expectation is that the Japanese government will purchase 1 million courses of S-217622 immediately after approval, so that S-217622 can be widely provided to COVID-19 patients, primarily in Japan, and will continue to purchase a certain number of courses of S-217622 after that.

Shionogi is seeking to contribute to re-establishing the safety and security of society by focusing on the research and development of S-217622 to address this pandemic. Based on the results of clinical trials obtained thus far[1, 2], on February 25, 2022, Shionogi has filed for manufacturing and sales approval to the Pharmaceuticals and Medical Devices Agency (PMDA), requesting review under the conditional approval system[2]. Shionogi will engage in consultations related to this basic agreement, in parallel with providing information for the PMDA review, while also progressing manufacturing and supply preparations as well as accelerating the progress of the ongoing clinical trials, all to achieve rapid availability of S-217622 to patients.

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. 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, mainly in Japan. Shionogi is also working with The AIDS Clinical Trials Group (ACTG, Headquarters: Los Angeles, Calif.) to initiate global Phase 3 clinical trials.

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

References

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
   Shionogi Files for Approval of S-217622, a Therapeutic Drug for COVID-19, in Japan

Our efforts against COVID-19 are updated on our website as needed. A considerable amount of valuable information on COVID-19 from other websites is also summarized on this page, so please use it for reference: SHIONOGI website