Press Release

Notice Regarding the Initiation of a Phase 2/3 Clinical Trial for a COVID-19 Therapeutic Agent in Japan

OSAKA, Japan, September, 28, 2021 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi has initiated a Japanese Phase 2/3 clinical trial of S-217622, an orally administered antiviral drug for COVID-19, caused by the novel coronavirus (SARS-CoV-2) on September 27. Prior to this, a Japanese Phase 1 clinical trial was initiated in July 2021, and, in this clinical trial, the safety results support progression and pharmacokinetic analyses confirm that blood drug concentrations meeting or exceeding the target concentration are achieved.

The Phase 2/3 clinical trial will evaluate the efficacy and safety of oral administration of this drug once daily for 5 days in patients with mild COVID-19 or asymptomatic SARS-CoV-2 infection, in comparison with placebo. Currently, in Japan, mild COVID-19 patients or asymptomatic infected people are mainly recovering at home or in accommodation facilities. Therefore, this study will recruit not only at medical facilities but also at accommodation facilities, in collaboration with medical instituitions, as COVID-19 can rapidly become severe even if it is initially mild or asymptomatic. In addition, although there is a placebo arm to the study, sufficient medical support from doctors and nurses will be provided for subjects throughout the trial period.

Currently, antibody therapy is approved treatment for mild COVID-19 patients in Japan. Antibody therapy has not been widely used because it is intended for patients at increased risk of exacerbation, and requires certain medical resources for infusion and patient monitaring. With the medical system currently under intense pressure, with limited treatment options, oral antiviral drugs that can reduce viral burden from the initial stages of infection and are easy to use are required. This therapeutic agent is expected to contribute to the early treatment of patients and to help to relieve the pressure on the medical system.

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 are also working towards total care for infectious diseases, through awareness building, epidemic monitoring, prevention, diagnosis, and addressing exacerbations, as well as the 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, and will keep all stakeholders informed regarding the progress of our efforts.

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. The new coronavirus (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. In non-clinical trials using SARS-CoV-2 infected animals, it has been confirmed that the viral load is rapidly and significantly reduced. Japanese Phase 1 clinical trials began in July 2021[1], and a Phase 2/3 clinical trial is currently underway in mild or asymptomatic COVID-19 patients.

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 July 26, 2021
   Notice Regarding the Initiation of a Phase 1 Clinical Trial for a COVID-19 Therapeutic Agent 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