Press Release

SHIONOGI

Shionogi Presents COVID-19 Therapeutic Agent Results at the ISIRV-WHO Virtual Conference

OSAKA, Japan, October, 21, 2021 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi presented results from non-clinical studies and from the Japanese Phase 1 clinical trial of S-217622, an oral antiviral drug for COVID-19, caused by the novel coronavirus (SARS-CoV-2), at the International Society for Influenza and Other Respiratory Virus Diseases (ISIRV)-WHO Virtual Conference.

During ISIRV, the results of non-clinical drug efficacy and pharmacokinetic studies, and a summary of the results of the Japanese Phase 1 clinical trial[1] which started in July 2021, were presented. The information presented is outlined below: .

- Non-clinical studies
  - S-217622 showed *in vitro* antiviral activity against a broad range of strains, including the δ strain.
  - A dose-dependent viral reduction effect of S-217622 was observed in multiple animal studies.
  - In addition to high metabolic stability, S-217622 showed a long plasma half life and excellent oral absorption in multiple animals.
- The Japanese Phase 1 clinical trial (a single ascending dose study)
  - Single oral administration of S-217622 to Japanese healthy subjects was safe and well tolerated.
  - Once-daily oral dosing of S-217622 resulted in plasma concentrations in excess of the target concentration required for viral reduction as predicted from non-clinical studies.

Based on these results, we expect that S-217622 will effectively reduce SARS-CoV-2 viral load with once-daily oral administration.

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 antiviral drug for COVID-19, is a 3CL protease inhibitor created through joint research between Hokkaido University and Shionogi. The novel 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 studies using SARS-CoV-2 infected animals, it has been confirmed that the viral load is rapidly and significantly reduced. The Japanese Phase 1 clinical trials began in July 2021[1], and a Japanese Phase 2/3 clinical trial[2] 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
2. Press release on September 28, 2021
   Notice Regarding the Initiation of a Phase 2/3 Clinical Trial for a COVID-19 Therapeutic Agent in Japan

Our efforts against COVID-19, in addition to other valuable information regarding to COVID-19 may be found on our global website under Sustainability. We hope you find this information useful and of value: SHIONOGI website