Release 2021/10/21

Shionogi Presents the Results of COVID-19 Therapeutic Agent at 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") presented results from non-clinical studies and from the Japanese Phase 1 clinical trial of S-217622, an investigational 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)-World Health Organization (WHO) Virtual Conference.

During ISIRV, the results of non-clinical drug efficacy and pharmacokinetic studies, and a summary of the results from 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.
- S-217622 showed a good drug metabolism and pharmacokinetics profile supporting oral dosing.

The Japanese Phase 1 clinical trial (a single ascending dose study)

- Single oral administration of S-217622 to healthy Japanese subjects was safe and well tolerated.
- The once-daily oral dosing of S-217622 was predicted to exceed the target concentration required for the viral reduction effect from the non-clinical studies.

Based on these results, S-217622 has the potential to 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 toward total care for infectious diseases, through awareness building, epidemic monitoring, prevention, diagnosis, and addressing exacerbations, as well as the treating of the infection itself. As SARS-CoV-2 continues to have a major impact on people’s lives and represents 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. For more information on our COVID-19 inititatives, please visit our website.

About S-217622

S-217622, an investigational 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.

About Shionogi

Shionogi & Co., Ltd. is a Japanese major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of“supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” The company currently markets products in several therapeutic areas including anti-infectives, pain, cardiovascular diseases, and gastroenterology. Our pipeline is focused on infectious disease, pain, CNS, and oncology. For more information on Shionogi & Co., Ltd., visit https://www.shionogi.com/global/en/ . Shionogi Inc. is the U.S. subsidiary of Shionogi & Co., Ltd. based in N.J. For more information on Shionogi Inc., please visit www.shionogi.com .

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

For US Media Inquiries, Contact:
Lindsay Bohlander
Lindsay.bohlander@shionogi.com
+1 973-665-4245

References

1. Press elease 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