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Shionogi Presents Clinical Trial Results of the COVID-19 Therapeutic Drug S-217622

OSAKA, Japan, January, 31, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi presented the results up to day 6 of the Phase 2a part of a Phase 2/3 clinical trial of S-217622, an orally administered antiviral drug for COVID-19, in its third quarter financial results[1].

During the presentation, the antiviral and safety results from the Phase 2a part were announced. This study is a randomized, placebo-controlled, double-blind study in Japanese adults, in which the antiviral effects and safety of this drug given orally once daily for 5 days were evaluated. The information presented is outlined below.

・ A rapid virus reduction effect was confirmed in the S-217622 group compared to placebo.

- A rapid decrease in proportion of patients with viral titer positively in the S-217622 group compared to placebo.
- No high-grade or serious adverse events were observed and tolerability was observed in this trial.

As expressed in the related notifications[2, 3], Shionogi has already been submitting these clinical data to the Pharmaceuticals and Medical Devices Agency (PMDA). Shionogi will continue to submit clinical trial data sequentially, as it is obtained. We will continue to consult closely with the Ministry of Health, Labor and Welfare, PMDA and other organizations regarding future aspects of the submission process and timing.

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, epidemiologic 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. 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. The Phase 2b/3 part of a Phase 2/3 clinical trial is currently underway in mild, moderate, or asymptomatic COVID-19 patients[4, 5].

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. Financial Results for the Third Quarter of FY2021
2. Handling of drugs for approval examination for COVID-19
3. Handling of drugs for approval examination for COVID-19 (ver.2)
4. 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
5. Press release on January 5, 2022
Shionogi Announces Commitment to Fight COVID-19

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

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