Press Release

Shionogi Presents Phase 2/3 Clinical Trial Results (Phase 2a Part) for the COVID-19 Therapeutic Drug S-217622

OSAKA, Japan, February, 7, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announces that Shionogi has completed its analysis of the Phase 2a part of a Phase 2/3 clinical trial of S-217622, an orally administered antiviral drug for COVID-19, and presented the results today.

During the presentation, in addition to results from secondary analyses of the antiviral effect, which is the primary endpoint of the Phase 2a part of the Phase 2/3 clinical trial, symptom improvement, exacerbation prevention, and safety results were newly disclosed.

This study is a randomized, placebo-controlled, double-blind study in Japanese adults, in which the efficacy and safety of this drug given orally once daily for 5 days was evaluated. The information presented is outlined below.

- Antiviral effect
  - The S-217622 arms showed a significant difference in comparison to placebo with respect to each of the following:
    - Rapid reductions in viral titer and viral RNA
    - On day 4 (after the 3rd dose), the proportion of subjects with positive viral titer decreased by approximately 60-80%, compared to the placebo group
    - Median time to the negative SARS-CoV-2 viral titer shortened by 2 days compared to the placebo group
- Clinical symptom improvement
  - S-217622 showed a tendency toward improvement in total score of 12 COVID-19 symptoms
    - No cases of exacerbation required hospitalization or similar therapy as hospitalization were found in the S-217622 group
- Safety
  - No high-grade or serious adverse events have been observed
  - No adverse events resulting in discontinuation have been observed
  - Almost all TEAE were mild and all treatment-related TEAE were mild

As expressed in the related notifications[1, 2], Shionogi plans to submit these clinical data to the Pharmaceuticals and Medical Devices Agency (PMDA) in the near future. Furthermore, for subjects with mild/moderate SARS-CoV-2 infection, we plan to complete enrollment of the Phase 2b part on February 8 2022 and initiate the Phase 3 part in the near future. We will continue to consult closely with the Ministry of Health, Labor and Welfare, PMDA and other organizations regarding future steps in the submission process.

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 building awareness, 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[3, 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. Handling of drugs for approval examination for COVID-19
2. Handling of drugs for approval examination for COVID-19 (ver.2)
3. 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
4. Press release on January 5, 2022
   Shionogi Announces Commitment to Fight COVID-19
5. Press release on January 31, 2022
   Shionogi Presents Clinical Trial Results of the COVID-19 Therapeutic Drug S-217622

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