Press Release

Notice Regarding the Media Coverage about S-217622, a Therapeutic Drug for COVID-19

OSAKA, Japan, April 13, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Shionogi has summarized its views regarding recent media coverage relating to S-217622, an orally administered antiviral drug for COVID-19.

[Background]
On April 4, 2022, Shionogi received a request from a Japanese wire service agency to confirm information they obtained from their own interviews regarding certain non-clinical data of S-217622 and to present our own views in response. The information was that fetal skeletal morphological abnormalities were observed in the non-clinical safety study of S-217622. On April 6, we responded that such observations occurred and shared our assessment of the meaning of these non-clinical results from a clinical perspective. The results of the non-clinical study had been reported to the Ministry of Health, Labor and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) in December 2021, were included in the NDA documents submitted on February 25, 2022, and do not constitute new information arising at the time of this media coverage.

[Supplemental information and perspective]
The below provides supplemental information and our perspective on the media coverage.

- ✧ This non-clinical study was conducted as one of the regulatory safety studies required in drug development. These observations were made at doses higher than the clinical dose, exceeding the expected human blood concentration and administration period.
- ✧ Pregnant, lactating, and potentially pregnant women are typically excluded from clinical trials and this has been the case for S-217622.
- ✧ The results from this non-clinical study were promptly reported to the medical institutions conducting the clinical trial, and clinical subjects were informed of risk-related information, including this result, and then participated in the clinical trial after their informed consent.
- ✧ The clinical implications of this non-clinical finding will be comprehensively judged in the ongoing approval review by the PMDA, and the contents of the package insert will be decided through that process.

Based on the above, Shionogi believes that this matter would not affect the decision for approval of S-217622. We will continue to cooperate with the PMDA review, in parallel with progressing the clinical trials currently underway to collect further information on safety and efficacy.

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. Shionogi has already been submitting the non-clinical, manufacturing/CMC data, and clinical trial data obtained so far to the PMDA. Currently the Phase 3 part of a Phase 2/3 clinical trial in patients with mild/moderate symptoms and the Phase 2b/3 part in patients with asymptomatic/only mild symptoms are in progress.

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

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