

Shionogi Announces Commitment to Fight COVID-19

Osaka, Japan, January 5, 2022 - Shionogi & Co., Ltd. (President & CEO: Isao Teshirogi, Ph.D., hereafter: “Shionogi”) has been continuing efforts on an oral antiviral drug and a preventive vaccine for COVID-19. The progress of each of these efforts can be summarized as follows:

1. Commitment to the discovery of novel therapeutic drugs

Regarding an oral antiviral drug (development number: S-217622) that selectively inhibits 3CL protease, enrolment has been completed in the Phase 2a Part of Phase 2/3 clinical trial[※] and Phase 2b/3 Part is currently underway. Shionogi has completed the procedures for opening clinical trial sites not only in Japan but also in South Korea, Singapore, Vietnam, etc., and is accelerating patient enrollment. Shionogi will continue discussions with regulatory authorities so that Shionogi can provide this therapeutic drug in Japan and overseas as soon as possible. Regarding supply, Shionogi has already started commercial production, and there is no change in the plan to provide S-217622 for 1 million people by the end of FY2021.

[※] Phase 2/3 clinical trials consist of Phase 2a and Phase 2b/3 Parts. For details on Phase 2/3 clinical trials, see jRCT2031210350 (<https://jrct.niph.go.jp/latest-detail/jRCT2031210350>).

2. Commitment to vaccine development

Regarding a preventive vaccine (development number: S-268019), of the four final stage clinical trials, Phase 2/3 clinical trial and an additional dose clinical trial are currently being conducted in Japan, and enrollment of necessary cases and inoculation have already been completed. In addition, of the two remaining clinical trials, a global phase 3 placebo-controlled onset prevention trial was started on December 25, 2021 in Vietnam. Shionogi prepares for another global Phase 3 neutralizing antibody titer comparison trial using an approved vaccine as a control and is scheduled to start in January 2022.

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 oral therapeutics and preventive vaccine to address this pandemic, and will keep all stakeholders informed regarding the progress of our efforts.

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

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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.

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](#)

For Further Information, Contact:

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>