

Notice Regarding the Initiation of a Global Phase 3 Clinical Trial for COVID-19 Recombinant Protein-based Vaccine, S-268019

Osaka, Japan, December 27, 2021 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Shionogi has initiated a global Phase 3 placebo-controlled onset prevention trial in Vietnam of a prophylactic vaccine candidate (code No. S-268019) for COVID-19, caused by the novel coronavirus (SARS-CoV-2) infection.

The primary endpoint of this clinical trial is the incidence rate of COVID-19 with confirmed infection with SARS-Cov-2. In this trial, the onset prevention effect and safety of two doses of S-268019 will be assessed by comparison with placebo.

A placebo-controlled onset prevention trial is the conventional evaluation method for vaccine development. Even now, there are many countries where the supply of vaccines is inadequate. In order to contribute to effective countermeasures for global health, we are conducting this trial. This time, Shionogi was able to initiate this clinical trial with the support of the Vietnam government, which supported this purpose and the construction of a large-scale clinical trial infrastructure in Asia.¹

As an additional Phase 3 clinical trial, Shionogi is also preparing for a neutralizing antibody trial with an active control which is an approved vaccine, using neutralizing antibody titer as an index. This trial will initiate in January 2022. We will continue to consult closely with the Ministry of Health, Labor and Welfare, Pharmaceuticals and Medical Devices Agency (PMDA) and other organizations regarding applications for approval based on the results of the following three trials: the phase 3 active control trial, a Japanese phase 2/3 clinical trial and an additional dose trial.^{2,3}

* The manufacture of clinical trial materials used in each trial were supported by Japan Agency for Medical Research and Development (AMED)

Shionogi is committed to “Protect people worldwide from the threat of infectious diseases” as our key focus. We are working towards total care for infectious diseases, through building awareness, epidemiological surveillance, prevention, diagnosis, and addressing exacerbations, as well as 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, delivering, and producing, in Japan, a vaccine for COVID-19.

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.

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>

References

1. [Press release on November 25, 2021](#)
Notice Regarding the Signing of a Memorandum of Understanding with Vietnam for Infectious Disease Control, including COVID-19
2. [Press release on October 21, 2021](#)
Notice Regarding the Progress of Phase 2/3 Clinical Trial for New Formulation of COVID-19 Recombinant Protein-based Vaccine
3. [Press release on December 3, 2021](#)
Notice Regarding an Initiation of a Additional Dose Clinical Trial for COVID-19 Recombinant-based Vaccine