

## **Notice Regarding an Initiation of a Additional Dose Clinical Trial for COVID-19 Recombinant-based Vaccine**

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Osaka, Japan, December 3, 2021 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Shionogi has initiated a Japanese additional dose clinical trial of a prophylactic vaccine candidate for COVID-19, caused by the novel coronavirus (SARS-CoV-2) infection.

The primary endpoint of this clinical trial is immunogenicity to SARS-CoV-2. In this trial, the efficacy and safety of an additional dose of an mRNA vaccine or S-268019 in adults, 6 months or more after receiving a primary series of mRNA vaccinations, will be compared. In Japan, administration of additional doses of COVID-19 vaccines started on December 1, and the vaccine is being secured so that all applicants over the age of 18 can be vaccinated. The epidemic continues throughout the world, and it is anticipated that continuous vaccination will be required in the future. In order to realize a stable supply of vaccines in Japan, early development and supply of vaccines are required.

In addition to this additional dose clinical trial, Shionogi is advancing preparations for initiation of a global Phase 3 placebo-controlled prevention trial as well as a comparative neutralizing antibody titer trial in Japan and overseas, for the purpose of verifying the safety and efficacy of the primary administration series of S-268019. 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 result of these phase 3 clinical trials, including the additional dose trial, and the phase 2/3 clinical trial.

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*

# Press Release



*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>