

## Shionogi Presents Japanese Phase 1/2 Clinical Trial Results of COVID-19 Recombinant Protein-based Vaccine at Conference

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**OSAKA, Japan, December, 7, 2021** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi presented results from the Japanese Phase 1/2 clinical trial of S-268019, a recombinant protein-based vaccine for COVID-19, caused by the novel coronavirus (SARS-CoV-2), at The 25<sup>th</sup> Annual Meeting of The Japanese Society for Vaccinology.

During the meeting, preliminary results of the Japanese Phase 1/2 clinical trial by new formulation of S-268019, which started in August 2021<sup>1</sup>, including the results of humoral immunity induction studies, were presented. In this trial, the safety, tolerability, and immunogenicity of two doses of the vaccine will be assessed, and then the optimal dose will be investigated, including antigen protein. Trial participants will be followed up for a year after vaccination. The information presented is outlined below.

- The side effects after vaccination were the same as that seen in normal vaccination.
- From 2 weeks after the 2<sup>nd</sup> injection of S-268019, it was confirmed that the neutralizing antibody titer increased to the same level as that seen in recovered serum.
- Both Th1 and Th2 reactions were induced, but the Th1 / Th2 balance did not dominate Th2.\*

\*A balance of two helper T cells types that regulate the immune response. For details, refer to “About Th1/Th2 Balance”

※The Japanese Phase 1/2 clinical trial was supported by Japan Agency for Medical Research and Development (AMED)

Based on these results, Shionogi is currently conducting a Japanese Phase 2/3 clinical trial<sup>2</sup>. We will continue to consult closely with the Ministry of Health, Labor and Welfare, Pharmaceuticals and Medical Devices Agency (PMDA) and other organizations for future applications for approval.

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 awareness building, epidemiological surveillance, 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, 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,*

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*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>

## **About Th1/Th2 Balance**

Immune responses are controlled by two types of helper T cells, Th1 and Th2. It is known that Th1 cells mainly activate cell-mediated immunity, whereas Th2 cells mainly activate humoral immunity involved in antibody production. Once the balance of Th1/Th2 immunity is disrupted due to genetic factors, transplant surgery, vaccination, and other external factors, various immune disease can be caused. From previous studies on Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), it has been considered that when the Th1 / Th2 balance becomes dominant in Th2, the risk of immune-related vaccine-related disease exacerbation (VDE) and antibody-dependent enhancement (ADE) increases. Therefore the Th1/ Th2 balance is important to reduce the risk of immune-related vaccine induced disease enhancement (VDE) and antibody-dependent enhancement (ADE).

## **References**

1. [Press release on August 24, 2021](#)  
Notice Regarding the Progress of Phase 1/2 Clinical Trial for New Formulation of COVID-19 Recombinant Protein-based Vaccine
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

Our efforts against COVID-19, in addition to other valuable information regarding to COVID-19 may be found on our global website under Sustainability. We hope you find this information useful and of value: [SHIONOGI website](#)