

Notice Regarding the Progress of Phase 2/3 Clinical Trial for New Formulation of COVID-19 Recombinant Protein-based Vaccine

OSAKA, Japan, October 21, 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 Phase 2/3 clinical trial of a prophylactic vaccine candidate for COVID-19 (code No. S-268019), caused by the novel coronavirus (SARS-CoV-2) infection on October 20.

This vaccine candidate is a new formulation with a modified adjuvant¹, and a Japanese Phase 1/2 clinical trial started in August 2021². In this trial, tolerability, safety and immunogenicity were evaluated in 60 Japanese adults, and the tolerability of this vaccine has been confirmed so far, and no major safety issues have been identified. Furthermore, we confirmed a highly increased neutralizing antibody titer in subjects receiving this vaccine candidate. We then initiated the Japanese Phase 2/3 clinical trial.

1 Substance that strengthens vaccine efficacy by immune activation

2 This research was supported by Japan Agency for Medical Research and Development (AMED)

The Phase 2/3 clinical trial that began in October (jRCT No.: [2031210383](#)) is an open-label study. The safety and immunogenicity of two doses of the vaccine will be assessed and then we will confirm clinical benefit. In parallel with this clinical trial, we will prepare for the implementation of multiple clinical trials globally. We will continue to consult closely with the Ministry of Health, Labor and Welfare, Pharmaceuticals and Medical Devices Agency (PMDA) and other organizations regarding the design and implementation of these large-scale trials and regarding application for approval.

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, 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. Furthermore, we continue to be committed to bring forward new oral therapeutics, which are being progressed with the highest priority along with vaccines, to support early containment of the pandemic.

Press Release



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>

References

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](#)