Press Release

Notice Regarding an Initiation of Phase 1/2 Clinical Trial for COVID-19 Recombinant Protein-based Vaccine

Osaka, Japan, December 16, 2020 – 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 1/2 clinical trial of a prophylactic vaccine candidate for COVID-19, caused by the novel coronavirus (SARS-CoV-2) infection, and the first dose has been administered successfully.

Since April 2020, Shionogi has been pursuing the discovery and development of a recombinant protein vaccine for COVID-19 (code No. S-268019), using a unique technology, "BEVS*", established by UMN Pharma Inc., a subsidiary of Shionogi. The recombinant protein vaccine contains a purified target antigen protein, produced using genetic information from the virus. Compared to other technologies, such as mRNA vaccines, which rely on the subject's body to produce the target antigen protein, the recombinant protein vaccine needs a certain development period for antigen expression and purification before initiating dosing trials. However, recombinant protein vaccine technology is well established and reliable, and already approved and marketed vaccines, such as an influenza prophylactic vaccine, utilize BEVS. So far, Shionogi has obtained positive efficacy and safety results in nonclinical studies with the antigen protein and adjuvant selected**. The stability of our vaccine formulation under refrigerated conditions has also been confirmed over a certain period of time.

* Baculovirus Expression Vector System

** Substance that strengthens vaccine efficacy by immune activation

This phase 1/2 clinical trial is a randomized, double-blind and placebo-controlled study testing multiple doses of antigen protein and adjuvant in combination. More than 200 Japanese adults are enrolled in the trial. The safety, tolerability, and immunogenicity of two doses of the vaccine, administered 3 weeks apart, will be assessed in the Phase 1 part and Phase 2 part of the study, and then the optimal dose will be determined. The trial will be followed up for a year after vaccination. Flash reports from the trial are expected to be obtained sequentially from the end of February 2021. Based on these results, and on the status of the pandemic worldwide, including in Japan, we will consult with the Ministry of Health, Labor and Welfare, Pharmaceuticals and Medical Devices Agency (PMDA) and other organizations regarding the design and implementation of additional clinical studies needed for registration, including Phase 3 trials.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as our key focus. We are not limiting ourselves to the research and development of therapeutics, but are also pursuing total care for infectious diseases, through awareness building, 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. Shionogi will work closely with

the National Institute of Infectious Diseases and other collaborators, including manufacturing sites (Api Co., Ltd. and its group company, UNIGEN Inc.), clinical trial sites, and related ministries and agencies, as well as the PMDA, to accelerate our efforts. Furthermore, we continue to be committed to bring forward new tools and technologies for the diagnosis and treatment of COVID-19 to support early containment of the 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 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 outcomes 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, unavailability 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.

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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