PRESSRELEASE

SHIONOGI

Initiation of a Phase 3 Additional Dose Clinical Trial in Japanese Subjects of the Monovalent Vaccine for the XBB1.5 Strain, S-268023

OSAKA, Japan, December 18, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that it has initiated a Phase 3 additional dose clinical trial in Japanese subjects of the monovalent vaccine for the XBB1.5 strain (code No. S-268023), against COVID-19, caused by the novel coronavirus (SARS-CoV-2) infection.

This clinical trial (jRCT2031230503) is a randomized, active controlled, double-blind trial. In this trial, the efficacy and safety of an additional dose of S-268023 or COMINATY RTU (Monovalent: XBB.1.5) in 600 adults who have received the approved COVID-19 vaccine two or more times, will be compared.

Shionogi is committed to “Protect people worldwide from the threat of infectious diseases” as our key focus. We are not only conducting research and development of novel therapeutics, but we are also working towards total care, through building awareness, epidemiologic monitoring, prevention, diagnosis, and addressing exacerbations, as well as treating the infection itself. By obtaining manufacturing and sales approval for S-268023, along with S-268019, which is currently undergoing manufacturing and sales approval application in Japan, we will establish a platform as the first domestically produced recombinant protein vaccine. This achievement will contribute to the provision of domestically produced vaccines in the future.

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.

【About S-268019 and S-268023】

S-268019 is produced using a unique and reliable recombinant protein vaccine technology, "BEVS", established by UMN Pharma Inc., a subsidiary of Shionogi. The recombinant protein vaccine contains the purified target antigen protein, produced using genetic information from the virus, and produced by the BEVS technology, which is used in already approved and marketed vaccines, such as an influenza prophylactic vaccine. S-268019 is a recombinant protein vaccine that contains components derived from the original strain (conventional strain), while S-268023 is a recombinant protein vaccine that contains components derived from the Omicron variant strain XBB.1.5 lineage. Shionogi has filed for manufacturing and sales approval of S-268019 for use in priming and booster (3rd) doses, against COVID-19 on November 24, 2022. S-268019 is currently under review.

【About the Omicron variant XBB.1.5 strain vaccine】

The Omicron variant XBB.1.5 strain vaccine is designed to prevent COVID-19 infection caused by the currently circulating SARS-CoV-2 variant. The Vaccination and Vaccine Subcommittee of the Ministry of Health, Labour and Welfare has approved the use of a new monovalent vaccine specifically targeting the XBB lineage of the Omicron variant for COVID-19 vaccination in the autumn and winter of 2023.

In the clinical trial, subjects can decline to participate in the trial at any time during the trial period if they so elect.

For Further Information, Contact:
SHIONOGI Website Inquiry Form : https://www.shionogi.com/global/en/contact.html