PRESSRELEASE

SHIONOGI

Notice Regarding the Initiation of a Fourth Vaccination Trial in subjects aged 60 and over for the COVID-19 Recombinant Protein-based Vaccine, S-268019

OSAKA, Japan, July 26, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it has initiated a fourth vaccination trial, in subjects aged 60 years and over, for its vaccine (S-268019) against COVID-19, caused by the novel coronavirus (SARS-CoV-2) infection.

The primary objective of this clinical trial is to evaluate the non-inferiority of immunogenicity after the fourth vaccination with S-268019 versus COMIRNATY. The subjects are individuals aged 60 years and over who have previously been vaccinated with the SARS-CoV-2 vaccine COMIRNATY three times.
Advanced age is considered the most important risk factor for aggravation in COVID-19. Since it has been suggested that the effect of vaccination gradually declines over time, implementation of a fourth vaccination for people aged 60 and over and other high-risk persons※ was started in June 2022 in Japan. On the other hand, at present, the vaccines that can be used for the fourth vaccination in Japan are limited, and new options are needed.
※Those who have an underlying disease that is considered to be at high risk of exacerbations from COVID-19 infection, or those who are obese with a BMI of 30 or higher

Starting in February 2022, we have been in prior consultation with the Pharmaceuticals and Medical Devices Agency (PMDA), in preparation for the approval application in Japan. We will continue to consult closely with the Ministry of Health, Labor and Welfare, PMDA and other organizations based on the results from multiple pivotal clinical trials.

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 intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

【About the Japanese Phase 1/2 clinical trial】

The Phase 1/2 clinical trial is a double-blind and placebo-controlled study to evaluate safety, tolerability and immunogenicity of two doses of the vaccine. 60 adults are enrolled in the trial. For more information about this clinical trial, please refer to jRCT No.:2031210269. Subject registration for this trial has been completed. In the evaluation up to 28 days after two doses of the vaccine, tolerability and safety were confirmed, as was a neutralizing antibody titer equal to or higher than that of convalescent serum.

【About the Japanese Phase 2/3 clinical trial】

The Phase 2/3 clinical trial is an open-label study to evaluate safety, tolerability and immunogenicity of S-268019 in 3,100 adults and elderly people. For more information about this clinical trial, please refer to jRCT No.:2031210383. Subject registration for this trial has been completed. In the evaluation up to 28 days after the second inoculation, tolerability and safety, and the increase in neutralizing antibody titer, were all confirmed.

【About the Japanese Phase 2/3 additional dose clinical trial】

This clinical trial is a randomized, active controlled, double-blind trial. In this trial, the efficacy and safety of an additional dose of COMIRNATY or S-268019 in 200 adults, 6 months or more after receiving a primary series of COMIRNATY, will be compared. For more information about this clinical trial, please refer to jRCT No.:2031210470. Subject registration for this trial has been completed and the primary endpoint (neutralizing antibody titer against SARS-CoV-2 28 days after the additional dose) was achieved.

【About the Japanese Phase 3 additional dose clinical trial】

This clinical trial is an open-label trial. This trial is to assess the safety and immunogenicity of an additional dose of S-268019 in 150 adults aged 20 to 64 years who received 2 inoculations of Spikevax intramuscular injection (hereafter "Spikevax"), and elderly people aged 65 years or older who received 2 inoculations of a primary series of COMIRNATY or Spikevax (in each case, between 6 months and 8 months after the second vaccination). For more information about this clinical trial, please refer to jRCT No.:2031210613. Subject registration for this trial has been completed.

【About the Phase 3 active control neutralizing antibody comparative clinical trial】

This clinical trial is a double-blind randomized active controlled trial to evaluate the neutralizing antibody titer after the primary series of Vaxzevria or S-268019 in 1,000 adults and elderly. For more information about this clinical trial, please refer to jRCT No.:2051210151.

【About the Global Phase 3 placebo-controlled onset prevention clinical trial】

This clinical trial is a randomized, placebo-controlled, double-blind trial to evaluate the onset prevention effect for COVID-19 after a primary series of S-268019 compared with placebo. Approximately 50,000 adults and elderly will be enrolled and randomly assigned 2:1 to S-268019 and placebo. This clinical trial includes a crossover assignment, such that all participants have the opportunity to receive active control. Currently, we are proceeding with subject registration in Vietnam, the first country in which this trial has been approved. For more information about this clinical trial, please refer to NCT05212948.

【About the Phase 1/2/3 clinical trial (part1) in the Japanese pediatric population】

The phase 1/2/3 clinical trial in the Japanese pediatric population is a randomized, double-blind, dose-controlled trial. In this trial, the safety and tolerability of a primary series of S-268019 in 48 children who are 5 to 11 years old will be assessed. For more information about this clinical trial, please refer to jRCT No.: 2011220011.

【About the Phase 2/3 clinical trial in Japanese adolescents】

The phase 2/3 clinical trial in Japanese adolescents is a randomized, active-controlled, double-blind trial. In this trial, the efficacy and safety of a primary series and booster doses of S-268019 in 350 adolescents who are 12 to 19 years old (S-268019 group: 300 subjects, COMIRNATY group: 50 subjects) will be assessed. For more information about this clinical trial, please refer to jRCT No.:2031220063.

【About the fourth vaccination trial aged 60 years and over】

The fourth vaccination trial aged 60 years and over is a trial to compare the efficacy of immunogenicity of the fourth vaccination with S-268019 to COMIRNATY. The participants are 60 years and over who received COMIRNATY three times.

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

The phase 1/2 Clinical Trial was supported by the Japan Agency for Medical Research and Development (AMED).

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

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