Press Release

Notice Regarding the Initiation of a Phase 2/3 clinical trial in Japanese adolescents for the COVID-19 Recombinant Protein-based Vaccine, S-268019

OSAKA, Japan, May 16, 2022 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it has initiated a Phase 2/3 clinical trial in Japanese adolescents for COVID-19 (code No. S-268019), caused by the novel coronavirus (SARS-CoV-2) infection.

The primary objective of this clinical trial is to evaluate the safety and immunogenicity of the primary series and booster doses of S-268019 in 12 to 19 year old adolescents and to assess the clinical benefit of S-268019 in this population. Since the epidemic of the Omicron variant started, the number of infected young people has increased, so it is expected that vaccination will be useful in preventing the onset and aggravation of COVID-19 in this group. In addition, as vaccination in 5 to 11 year old children is also likely to be beneficial, Shionogi will also initiate a clinical trial in this younger population.

Shionogi has been conducting five pivotal clinical trials of S-268019. Starting in February 2022, we have been in prior consultations 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 these pivotal clinical trials. By pursuing studies in children and adolescents, we will seek to provide new options for COVID-19 vaccination for people of all ages.

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 a Phase 2/3 clinical trial in Japanese adolescent】

The phase 2/3 clinical trial in Japanese adolescent is randomized, active-controlled, double-blind, controlled 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 year old (S-268019 group: 300 subjects, COMIRNATY group: 50 subjects) will be assessed.

(Primary serise part)

In the primary series part, the non-inferiority of the neutralizing antibody titer against SARS-CoV-2 28 days after two inoculations of S-268019 will be verified between adolescents in this study and adults who has participated in a Phase 3 active control neutralizing antibody comparative clinical trial.

(Booster doses part)

In Booster doses part, the non-inferiority of the neutralizing antibody titer against SARS-CoV-2 28 days after third inoculations of S-268019 will be verified agaist the neutralizing antibody titer against SARS-CoV-2 28 days after two inoculations of S-268019 in this study.

【About a Japanese Phase 1/2 clinical trial】

The Phase 1/2 clinical trial is 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 of two doses of the vaccine, confirmed tolerability and safety, neutralizing antibody titer equal to or higher than that of convalescent serum.

【About a 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 inoculations, it was confirmed that the tolerability, safety and the neutralizing antibody titer increased.

【About a 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 was achieved for the neutralizing antibody titer against SARS-CoV-2 28 days after additional dose.

【About a Japanese Phase 3 additional dose clinical trial】
This clinical trial is an open-label trial. In this trial, the safety and immunogenicity of an additional dose of S-268019 in 150 adults aged 20 to 64 years who received 2 inoculation of Spikevax intramuscular injection (hereafter "Spikevax") and elderly people aged 65 years or older who received 2 inoculation of a primary series of COMIRNATY or Spikevax (in each case, those who have passed 6 months or more and 8 months or less 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 Phase 3 active control neutralizing antibody comparative clinical trial】
This clinical trial is a double-blind randomized active controlled trial to evaluate a neutralizing antibody titer after the primary series of Vaxzevria or S-268019 in 1,000 adults and the elderly people.For more information about this clinical trial, please refer to jRCT No.: 2051210151.

【About 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 primary series of S-268019 compared with placebo. Approximately 50,000 adults and the elderly people will be enrolled and randomly assigned 2:1 to S-268019 and placebo. This clinical trial adopted crossover assignment, then all participant can get an opportunity to access active control. Currently, we are proceeding with subject registration in Vietnam, the first country in which this trial have been approved. For more information about this clinical trial, please refer to NCT05212948.

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

Phase 1/2 Clinical Trial was supported by 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