PRESSRELEASE

SHIONOGI

Initiation of a Phase1/2/3 Clinical Trial (Part 2) and Phase 3 Additional Dose Clinical Trial in Japanese Pediatric Subjects of the COVID-19 Recombinant Protein-based Vaccine, S-268019

OSAKA, Japan, January 17, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it has initiated a Phase 1/2/3 clinical trial (part2) and Phase 3 additional dose clinical trial in Japanese pediatric subjects of its vaccine (code No. S-268019), against COVID-19, caused by the novel coronavirus (SARS-CoV-2) infection.

The Japanese Phase 1/2/3 clinical trial[1] is a clinical trial in the 5 to 11 year old pediatric population and consists of Part 1 and Part 2. Part 1 was conducted to evaluate the safety and tolerability of a primary series of S-268019. Based on the favorable results in Part 1, Part 2 has just been initiated. Part 2 of Phase 1/2/3 trial consists of the primary vaccination part and the booster vaccination part. In the primary vaccination part, immunogenicity after receiving a primary series of S-268019 to children will be compared to the immunogenicity after a primary series of S-268019 to subjects aged 20 years or older in the Phase 3 active control neutralizing antibody comparative clinical trial[2]. The trial will be tested in a blinded control group with a primary series of COMIRNATY. In the booster vaccination part, the immunogenicity after receiving third dose of S-268019, will be compared to the immunogenicity after receiving a primary series of S-268019.
In the Japanese phase 3 additional dose trial[3], the immunogenicity of an additional dose of S-268019 in the 5 to 11 year old pediatric population, 5 months or more after receiving a primary series of COMIRNATY, will be compared to the immunogenicity of an additional dose of S-268019 in subjects aged 20 years or older, 6 months or more after receiving a primary series of COMIRNATY in the Japanese Phase 2/3 additional dose clinical trial[4].

Shionogi has filed for manufacturing and sales approval of S-268019 for use in priming and booster (3rd) doses, against COVID-19, caused by the SARS-CoV-2 infection. S-268019 is currently under review by PMDA (Pharmaceuticals and Medical Devices Agency). In Japan, the options for vaccines that can be given to younger age groups are still limited, and, as with adults, there is a need for vaccination options. By also working on the development of vaccines for adolescents and children, Shionogi will focus on the early development and supply of domestic vaccines for people of a wider age range.

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 bringing forward healthcare solutions to, re-establish the safety and security of society, including by developing, delivering, and producing in Japan, for people of all ages, 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 Phase 1/2/3 clinical trial (Part 1, Part 2) in the Japanese pediatric population[1]】

The Japanese Phase 1/2/3 clinical trial is a clinical trial in the 5 to 11 year old pediatric population and consists of Part 1 and Part 2. Part 1 was conducted to evaluate the safety and tolerability of a primary series of S-268019, and favorable results were confirmed. Part 2 of Phase 1/2/3 trial consists of the primary vaccination part and the booster vaccination part. In the primary vaccination part, immunogenicity after a primary series of S-268019 to children will be compared to the immunogenicity after a primary series of S-268019 to subjects aged 20 years or older in the Phase 3 active control neutralizing antibody comparative clinical trial[2]. The trial will be tested in a blinded control group with a primary series of COMIRNATY. In the booster vaccination part, the immunogenicity after receiving third dose of S-268019, will be compared to the immunogenicity after receiving a primary series of S-268019. For more information about this clinical trial, please refer to jRCT No. 2011220011 and jRCT No. 2031220493

【About the Phase 3 active control neutralizing antibody comparative clinical trial[2]】

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 Phase 3 additional dose trial in the Japanese pediatric population[3]】

In the Japanese phase 3 additional dose trial, the immunogenicity of an additional dose of S-268019 or COMIRNATY in the 5 to 11 year old pediatric population, 5 months or more after receiving a primary series of COMIRNATY, will be compared to the immunogenicity of an additional dose of S-268019 in subjects aged 20 years or older, 6 months or more after receiving a primary series of COMIRNATY in the Japanese Phase 2/3 additional dose clinical trial. For more information about this clinical trial, please refer to jRCT No. 2031220530.

【About the Japanese Phase 2/3 additional dose clinical trial[4]】

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.

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

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