



COVGOZE® for Intramuscular Injection (Monovalent: Original Strain), Recombinant Protein COVID-19 Vaccine, Approved for Manufacturing and Marketing as Initial Immunization in Japan

OSAKA, Japan, June 24, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter, "Shionogi") announced that it has obtained domestic manufacturing and sales approval for COVGOZE®, a single-strain preventive vaccine against COVID-19, listing "prevention of infection caused by SARS-CoV-2" as its efficacy and effects for initial immunization.

The vaccine developed by Shionogi is a recombinant protein vaccine containing the spike protein of SARS-CoV-2 as its active ingredient. Recombinant protein vaccines, widely used internationally, are based on a technology with proven long-term efficacy and safety. This vaccine adds to the existing options for COVID-19 prevention in Japan, different from the mRNA vaccines that have been primarily used for COVID-19 prevention in the country.

For the 2024/2025 season, Japan's domestic vaccination program recommended the JN.1 lineage monovalent vaccine for COVID-19 prevention. However, the vaccine approved in this instance, a recombinant protein vaccine targeting the original strain, is not scheduled for distribution. Shionogi is advancing development with consideration for future recommended strains and is committed to promptly supplying a COVID-19 vaccine that addresses healthcare needs.

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 COVGOZE® : A Recombinant Protein Vaccine】

COVGOZE® is produced using the unique and reliable Baculovirus Expression Vector System (BEVS) technology, owned by UMN Pharma Inc., a group company of Shionogi. The recombinant protein vaccine is formulated with a purified antigen protein, which is expressed and refined using the genetic information of the virus. The vaccine is then administered with an adjuvant. COVGOZE® is designed for adult immunization, including the first and second doses, to prevent COVID-19 and has obtained manufacturing and marketing approval in Japan.

The research and development of COVGOZE® intramuscular injection are being carried out with the support of the National Research and Development Corporation Japan Agency for Medical Research and Development (AMED) and the Ministry of Health, Labour and Welfare.

For Further Information, Contact:

SHIONOGI Website Inquiry Form: <https://www.shionogi.com/global/en/contact.html>