



COVGOZE® for Intramuscular Injection (JN.1-adapted), Recombinant Protein COVID-19 Vaccine, Receives Partial Change Approval in Japan

OSAKA, Japan, September 16, 2026 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that it has obtained approval for a partial change to the manufacturing and marketing authorization of COVGOZE® for Intramuscular Injection (JN.1-Adapted), a recombinant protein vaccine against COVID-19, to add a booster dose indication.

The vaccine has been developed to address the continuously evolving SARS-CoV-2 virus. Building on the approvals of its original-strain vaccine¹ and JN.1-adapted vaccine, Shionogi has been advancing the establishment of a platform* that enables the rapid development and manufacturing of vaccines tailored to the recommended strains designated for each vaccination season. With this latest approval, the foundation for the platform has now been established. Shionogi will continue its efforts to fully establish the platform by fiscal year 2026 and advance development toward obtaining approval for a vaccine adapted to the recommended strain.

* Once established as a vaccine platform, vaccines adapted to the latest recommended strains can be supplied rapidly through a review process based primarily on quality evaluations and non-clinical study data, subject to the collection of post-marketing data.

The approved vaccine is different from the strain-adapted vaccine designated for use in Japan during the 2026/2027 vaccination season. Therefore, Shionogi does not plan to supply this vaccine.

Shionogi has identified "Protect People from the Threat of Infectious Diseases" as one of its material issues and is advancing initiatives toward realizing total care for infectious diseases. By providing a wide range of solutions covering the prevention, diagnosis, and treatment of infectious diseases, Shionogi will continue to contribute to a safer and more secure society.

The impact of this matter on the consolidated financial results for the fiscal year ending March 2027 has already been reflected in the earnings forecast announced on May 12, 2026.

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® for Intramuscular Injection is a recombinant protein vaccine developed using the BEVS technology**. 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. Recombinant protein technology has been used for many years in vaccine development, including influenza vaccines, both in Japan and internationally, and a substantial body of knowledge regarding its efficacy and safety has been accumulated.

** BEVS (Baculovirus Expression Vector System): a protein expression technology utilizing insect cells and other host cells.

Reference:

1. [Press release on June 24,2024](#)
COVGOZE® for Intramuscular Injection (Monovalent: Original Strain), Recombinant Protein COVID-19 Vaccine, Approved for Manufacturing and Marketing as Initial Immunization in Japan

For Further Information, Contact:

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