PRESSRELEASE

SHIONOGI

COVGOZE® for Intramuscular Injection (LP.8.1-adapted), Recombinant Protein COVID-19 Vaccine, Receives Partial Change Approval in Japan

OSAKA, Japan, November 9, 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, a Recombinant Coronavirus (SARS-CoV-2) Vaccine against COVID-19, changing its antigen strain to Omicron LP.8.1, the recommended strain for the 2026/2027 vaccination season. Shionogi is preparing to supply COVGOZE® in fiscal year 2026.

The vaccine is a recombinant protein vaccine developed and manufactured in Japan. 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.

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.

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®】

COVGOZE® is a recombinant protein vaccine based on BEVS (Baculovirus Expression Vector System), a protein expression technology using insect cells. Antigen proteins are expressed using the genetic information of the virus, and unnecessary substances used during the vaccine manufacturing process are removed to obtain purified antigen proteins, which are then used as the drug substance.

For Further Information, Contact:

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