PRESSRELEASE

SHIONOGI

Shionogi Receives Award Through BARDA's Rapid Response Partnership Vehicle to Advance Long-Acting Formulation of S-892216, an Antiviral for COVID-19 Pre-Exposure Prophylaxis in At-Risk Populations

OSAKA, Japan, January 17, 2025 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced Shionogi Inc., a New Jersey-based subsidiary of Shionogi, has been awarded a $375 million project agreement through the Rapid Response Partnership Vehicle (RRPV), to advance the development of S-892216, a 3CL protease inhibitor, as a long-acting injectable for COVID-19 pre-exposure prophylaxis.

RRPV is a consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS).

This project award will address a gap for pre-exposure prophylaxis therapeutics that have the potential to provide protection against severe outcomes of COVID-19. Shionogi plans to file an investigational new drug application in the U.S. and begin phase 1 studies this year.

"COVID-19 continues to be a serious global health risk even with available vaccines and treatments. We share BARDA's recognition of this unmet need and appreciate its selection of S-892216 for this important program," said John Keller, Ph.D., Senior Executive Officer, Senior Vice President, R&D Supervisory Unit at Shionogi. "With our deep expertise in antiviral drug development, continually expanding knowledge of COVID-19 and support from BARDA, we will advance the pre-exposure prophylaxis program for S-892216 at pace with public health needs."

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50123D00005.

About S-892216

S-892216, an investigational second generation 3CL protease inhibitor, is being developed both as a long-acting injectable and as an oral drug, intended for prophylaxis and treatment of SARS-CoV-2 infection respectively.

In pre-clinical trials, S-892216 demonstrated a strong antiviral effect. S-892216 was discovered by Shionogi and its research and development is supported by the Japan Agency for Medical Research and Development (AMED) under Grant Numbers 21fk0108584 and 22fk0108522h0001.

The S-892216 oral formulation is being studied in a Phase 1 clinical trial in Japan to evaluate the pharmacokinetics, safety, and tolerability in healthy adults. A Phase 1 clinical trial with the long-acting injectable formulation is expected to begin in 2025.

In addition to S-892216, Shionogi continues its extensive global development program for the novel COVID-19 oral antiviral ensitrelvir (generic name: ensitrelvir fumaric acid, Code No.: S-217622), known as Xocova® 125 mg tablet in Japan. Ensitrelvir was granted Fast Track designation by the U.S. Food and Drug Administration in 2023 and it was approved in Singapore based on the Special Access Route application in 2023. It remains an investigational drug outside of Japan and Singapore.

About Shionogi in Infectious Disease

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" with research and development of therapeutics, whilst also working towards total care through awareness building, epidemiologic monitoring, prevention, diagnosis, and addressing exacerbations, as well as treating infections directly. As SARS-CoV-2 continues to have a major impact on people's lives and to represent a global threat, Shionogi will seek to contribute to re-establishing the safety and security of society by developing new products and services to address this pandemic. Shionogi is committed to equitable access worldwide, including by working with the Medicines Patent Pool to provide access to low- and middle-income countries (LMICs), and by strengthening its manufacturing and global supply chain.

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.

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