PRESSRELEASE

SHIONOGI

Regarding Filing for Ensitrelvir Fumaric Acid, a Therapeutic Drug for COVID-19 in South Korea

OSAKA, Japan, Dec 19, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that its partner Ildong Pharmaceutical Co., Ltd. (Head Office: Seoul, South Korea; Vice Chairman and Chief Executive Officer: Yun Paul Woongsup, hereafter "Ildong") who has been sub-licensed South Korean rights to Ensitrelvir Fumaric Acid (hereafter "ensitrelvir"), have announced their new plan to resubmit a New Drug Application (NDA) for ensitrelvir in South Korea with additional data.

The Ministry of Food and Drug Safety (MFDS) in South Korea has been reviewing the NDA submitted by Ildong[1]. As the review progressed, Ensitrelvir demonstrated a favorable effect in preventing symptomatic COVID-19 in the SCORPIO-PEP trial (post-exposure prophylaxis trial)[2]. Based on this result, Shionogi and Ildong have agreed that to revise and augment the NDA for Ensitrelvir, including all currently available data in the application package, similar to the approach taken for applications in the United States and Europe, is the best way to deliver ensitrelvir to patients in South Korea. Consequently, the current application has been withdrawn voluntarily by Ildong, and a new application with additional data will be submitted.

Shionogi is committed to the principle “Protecting people worldwide from the threat of infectious diseases” as our key focus, and is working on the realization of total care for infectious diseases. Shionogi is continuing to progress its extensive global development program for ensitrelvir, and will continue research and development for COVID-19 so as to be prepared for the swift provision of therapeutic drugs and vaccines as necessary depending on the situation, such as the emergence of new variants or increases in the future prevalence of, or threat from, the disease.

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.

For Further Information, Contact:

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

References

1. Press release on Dec 27, 2023
   Filing for a Manufacturing License for Ensitrelvir Fumaric Acid, a Therapeutic Drug for COVID-19 to Build a Domestic Drug Product Production and Supply System in South Korea
2. Press release on Oct 31, 2024
   Shionogi Announces Global Phase 3 Trial Demonstrates Post-Exposure Prophylactic Use of Ensitrelvir Prevents Symptomatic COVID-19