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Execution of Sub-license Agreement from Ping An-Shionogi Hong Kong to Juniper Therapeutics and SAR approval in Singapore regarding ensitrelvir fumaric acid, a treatment drug for the novel coronavirus infection (COVID-19)

OSAKA, Japan, December 19, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced Ping An-Shionogi (Hong Kong) Limited (Head Office: Hong Kong, China; Chairman and Chief Executive Officer: Tatsumori Yoshida; hereafter "Ping An-Shionogi Hong Kong") and Juniper Therapeutics Pte. Ltd. (Headquarters: Singapore; CEO: Raman Singh; hereinafter referred to as "Juniper") signed a sub-license agreement regarding the manufacturing and marketing approval application as well as the post-approval sales of ensitrelvir fumarate (hereinafter referred to as "ensitrelvir") for the treatment of COVID-19 in Singapore.

Juniper is a healthcare company based in Singapore, focusing on the development and sales of pharmaceuticals in the areas of cancer, rare diseases, and infectious diseases. Through this sub-licensing agreement, Shionogi Hong Kong will grant Juniper the rights for the manufacturing and marketing approval application and sales of ensitrelvir in Singapore. After obtaining approval, Shionogi Hong Kong will supply the product to Juniper, and Juniper will be responsible for its sales. Juniper plans to proceed with discussions with the Singaporean authorities and aim for manufacturing and marketing approval application in Singapore based on the Phase 2/3 trial data conducted in Asia.

Ensitrelvir has been approved in Singapore on November 15, 2023, based on the Special Access Route (SAR) application. SAR is a Singapore-specific system for importing and supplying unapproved drugs, focusing on treatments for diseases with particularly high medical needs where there are no other treatment options available.

Shionogi is committed to “Protect people worldwide from the threat of infectious diseases” with research and development of therapeutics, while 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 are accelerating our efforts towards the practical use of ensitrelvir overseas. Through the collaboration between Shionogi Hong Kong and Juniper, we aim to obtain manufacturing and marketing approval for ensitrelvir while also contributing to the treatment of COVID-19 in Singapore, leveraging the SAR approval as an opportunity.

About Juniper Therapeutics
Juniper Therapeutics is a wholly owned company of Juniper Biologics. Juniper Biologics is a science-led healthcare company focused on delivering novel therapies to improve the health and quality of life of patients, by building a growing presence in Oncology and Oncology Supportive Care, Rare/Orphan Diseases, and Gene Therapy. It was founded on a vision to provide treatments for unmet medical needs focused on specialist therapy areas in which it can make the most difference. Through bold and transformative science, Juniper Biologics is committed to creating possibilities that have the potential to become the next generation of life-changing medicines for patient communities in China, Japan, Asia, Australia, New Zealand, the Middle East, and Africa.

About Ping An-Shionogi Hong Kong
Ping An-Shionogi Hong Kong was established in 2020 as a joint venture between Shionogi Hong Kong and Tutum Japan Healthcare Limited, a subsidiary of China Ping An Insurance Overseas (Holdings) Limited and an indirect subsidiary of Ping An Insurance (Group) Company of China Ltd. Its main businesses are capital investment, intellectual property license management, and product supply operations to Asian countries including China.

About ensitrelvir
Ensitrelvir (known in Japan as Xocova®), an oral antiviral drug for COVID-19 currently approved under the emergency regulatory approval system in Japan, is a 3CL protease inhibitor created through joint research between Hokkaido University and Shionogi. SARS-CoV-2 has an enzyme called 3CL protease, which is essential for the replication of the virus. Ensitrelvir suppresses the replication of SARS-CoV-2 by selectively inhibiting the 3CL protease. Ensitrelvir is the first antiviral agent to show both clinical symptomatic efficacy for five typical Omicron-related symptoms (primary endpoint) and antiviral efficacy (key secondary endpoint) in a predominantly vaccinated population of patients with mild to moderate SARS-CoV-2 infection, regardless of risk factors, in the results of the Phase 3 part of the Phase 2/3 study conducted during the Omicron-dominant phase of the epidemic. With regard to safety, most adverse events were mild in severity and no deaths were seen in the study. Among the most common treatment-related adverse events were temporary decreases in high-density lipoprotein and increased blood triglycerides, as observed in previous studies. Initial exploratory analyses from the Phase 2/3 study also indicated a reduced risk of development of long COVID and further evaluations in this regard are still ongoing.

Recently, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to ensitrelvir for COVID-19. FDA Fast Track designation is designed to facilitate the development and expedite the review of potential new therapies that treat serious conditions and fulfill an unmet medical need. Ensitrelvir remains an investigational drug outside of Japan. In addition, the brand name Xocova® has not been approved for use outside of Japan and pertains only to the approved drug in Japan.

About the ensitrelvir Clinical Development Program
As SARS-CoV-2 continuously evolves, Shionogi is studying its investigational oral antiviral, ensitrelvir, across a range of patient populations and disease severity to evaluate how ensitrelvir may address the current needs. Shionogi has a comprehensive, global clinical development program underway for ensitrelvir that includes four Phase 3 trials, including SCORPIO-HR, a trial for non-hospitalized, symptomatic COVID-19 patients who have tested positive for COVID-19. SCORPIO-HR is also evaluating the potential effect of ensitrelvir on the symptoms of long COVID. An investigator-initiated research study is also ongoing in hospitalized patients for the management of COVID-19 as part of the new Strategies and Treatments for Respiratory Infections & Viral Emergencies (STRIVE) platform protocol. Additionally, Shionogi conducted SCORPIO-SR in patients with mild-to-moderate COVID-19 irrespective of risk factors for COVID-19 progression. Furthermore, Shionogi's study, SCORPIO-PEP, is evaluating the safety and efficacy of ensitrelvir for the prevention of symptomatic SARS-CoV-

2 infection in study participants exposed to household contacts who are symptomatic and tested positive for SARS-CoV-2.

About Shionogi in Infectious Disease
Since 1953 Shionogi has been a leader in infectious disease discovery and commercialization. Our R&D story extends beyond antibiotics to include novel medications for HIV and influenza. Today, our global pipeline includes investigational agents developed to address global health challenges including antimicrobial resistance, COVID-19, influenza, rare fungal diseases and respiratory syncytial virus.

As part of our commitment to addressing unmet medical needs, Shionogi is partnering with several non-governmental organizations to increase equitable access to our medications worldwide. Shionogi has a landmark license and technology transfer agreement with Global Antibiotic Research and Development Partnership (GARDP) and a collaboration agreement with the Clinton Health Access Initiative (CHAI) to transform the landscape of access to antibiotics in many low-income countries, most lower middle- and upper middle-income countries, and select high-income countries. We also have a voluntary license agreement with the Medicines Patent Pool (MPP) to facilitate additional production and distribution of ensitrelvir, pending regulatory authorization or approval, by granting sublicences to qualified generic manufacturers, with the goal of expanding access to people living in low- and middle-income countries (LMICs).

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

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