Press Release

SHIONOGI announces out-licensing agreement with ViiV Healthcare to develop third-generation HIV integrase inhibitor, S-365598, with potential for ultra long-acting dosing intervals

S-365598 aims to build on the success of dolutegravir and cabotegravir with potential to anchor the next generation of our future pipeline of innovative long-acting therapies for HIV

OSAKA, Japan, September, 28, 2021 - Shionogi & Co., Ltd. (hereafter "Shionogi") today announced that it has entered into an out-licensing agreement with ViiV Healthcare (hereafter "ViiV"), the global specialist HIV company majority owned by GlaxoSmithKline ("GSK"), with Pfizer and Shionogi as shareholders, to develop third-generation HIV integrase inhibitor with potential for use in ultra long-acting HIV regimens (regimens with dosing intervals of three months or longer).

Under the terms of the agreement, Shionogi will receive an upfront payment of £20 million from ViiV , a £15 million payment for the achievement of a clinical development milestone and royalties on net sales. The royalty levels are aligned with those in Shionogi's existing integrase inhibitor agreements with ViiV healthcare. Shionogi will contribute to development costs up to an annual maximum.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare said: "Our 20-year relationship with Shionogi has been incredibly successful, producing what are arguably two of the most important HIV medicines of the last decade. Dolutegravir is now taken by 17 million people globally, and cabotegravir has allowed us to develop the first long-acting regimen for treatment. With today's announcement about the in-licensing of a third integrase inhibitor from Shionogi, we will continue this collaboration and explore the potential of S-365598 to anchor ViiV Healthcare's pipeline beyond 2030."

John Keller, Ph.D., Senior Executive Officer, Senior Vice President, Corporate Strategy Division at Shionogi [and member of the Board of Directors of ViiV Healthcare], said "Many people living with HIV and those vulnerable to infection with HIV have concerns about daily oral medication, such as the daily reminder of living with HIV, HIV status disclosure, and consistency of adherence. Long-acting HIV medications have the potential to bring considerable benefit to these individuals. We are looking forward to continuing to work with ViiV to further advance this innovative approach to HIV therapies."

Preliminary data has shown that S-365598 has a high genetic barrier and a resistance profile that is distinct from that of dolutegravir and cabotegravir. Its long half-life may support its development as an ultra-long medicine that could be delivered with infrequent dosing of every three months or longer. Preclinical studies are underway. ViiV Healthcare and Shionogi intend to initiate first time in human studies with S-365598 by 2023.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as our key focus and is promoting efforts for the world's three major infectious diseases" including HIV. We will continue to collaborate with ViiV to contribute to maximizing the value of S-365598 in addition to dolutegravir and cabotegravir in anticipation of the HIV market after 2030. In addition, by continuing to commit to drug discovery for HIV, we will work toward the creation of compounds that can be the partner drugs of cabotegravir or S-365598 and achieve functional cure for HIV.

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

About ViiV Healthcare
ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of becoming infected with HIV. Shionogi joined in October 2012. The company's aim is to take a deeper and broader interest in HIV/AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV. For more information on the company, its management, portfolio, pipeline and commitment, please visit www.viivhealthcare.com.

About GSK
GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

Reference
1. Scarsi KK, Havens JP, Podany AT, Avedissian SN, Fletcher CV. HIV-1 Integrase Inhibitors: A Comparative Review of Efficacy and Safety. Drugs. 2020 Nov;80(16):1649-1676. doi: 10.1007/s40265-020-01379-9.