# Shionogi-ViiV Healthcare LLC Initiates Phase III Clinical Programme for Investigational Once-Daily HIV Integrase Inhibitor

***Phase III Treatment-naïve and Treatment-experienced Trials Underway for S/GSK1349572 ('572)***

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**London, UK, 21 October 2010** – Shionogi-ViiV Healthcare LLC today announced the start of the Phase III clinical programme evaluating its once-daily, unboosted investigational integrase inhibitor, S/GSK1349572 ('572). The Phase III clinical programme, which began this month, includes two studies (SPRING-2 and SAILING) that will evaluate '572 in both treatment-naïve patients and treatment-experienced, but integrase-naïve patients.

"Progression of one of our lead pipeline compounds into late stage development for use in treatment-naïve and treatment-experienced patients is an important milestone for ViiV Healthcare in its first year and ultimately we hope for those living with HIV. We believe that this clearly demonstrates the benefit of our 100% focus on HIV and commitment to delivering new or improved treatment options," stated Dr. John Pottage, Chief Scientific and Medical Officer, ViiV Healthcare.

"We are pleased to see '572 progressing into Phase III clinical trials and are optimistic about its potential for HIV-infected patients," said Dr. Sapan Shah, President & CEO, Shionogi Inc. "As the only once-daily, unboosted integrase inhibitor in Phase III clinical development, '572 may help address certain treatment challenges that continue to face people living with HIV."

**About the Phase III Trials**

**SPRING-2 Study Design (ING113086)**

SPRING-2 is a Phase III, randomized, blinded, active-controlled, multicenter, parallel group, non-inferiority study. The study will include approximately 788 HIV-1 infected treatment-naïve patients. The non-inferiority study will compare efficacy and safety outcomes of '572 and raltegravir (RAL);

both treatment arms will be administered with investigator-selected dual nucleoside reverse transcriptase inhibitor therapy (either ABC/3TC or TDF/FTC).

The primary objective for SPRING-2 will be to demonstrate the antiviral activity of ‘572 50mg administered once-daily compared to RAL 400mg administered twice daily over 48-weeks. Secondary objectives include the assessment of antiviral activity of ’572 compared to RAL at 96-weeks, to compare the tolerability, long-term safety and antiviral and immunologic activity of ’572 to RAL, and to evaluate viral resistance in subjects experiencing virological failure.

**SAILING Study Design (ING111762)**

SAILING is a Phase III, randomized, double-blind, active-controlled, multicenter, parallel group, non-inferiority study. The study will include approximately 688 HIV-1 infected treatment-experienced, integrase-naïve subjects. The non-inferiority study will assess the antiviral efficacy of ’572 compared to RAL.

The primary objective for SAILING will be to demonstrate the antiviral efficacy of ‘572 50mg once-daily compared to RAL 400mg twice-daily both in combination with a background regimen consisting of one to two fully active agents at 48-weeks. Secondary objectives will evaluate the long-term antiviral activity, pharmacokinetics (PK), the relationship between PK and antiviral activity, tolerability and safety of ’572 versus RAL.

**About Shionogi-ViiV Healthcare LLC**

‘572 is the lead compound in Shionogi-ViiV Healthcare LLC. It is currently the only once-daily, unboosted integrase inhibitor in Phase III clinical development. Shionogi-ViiV Healthcare LLC is also developing other second-generation integrase inhibitors, including S/GSK1265744, currently in Phase II development.

**About ViiV Healthcare**

ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (NYSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV. Our 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 new HIV medicines 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 Shionogi & Co., Ltd**

Headquartered in Osaka, Japan, Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on patients. Shionogi's Research and Development currently targets three therapeutic areas: Infectious Diseases, Pain, and Metabolic Syndrome. The Company is the originator of innovative medicines which have been successfully delivered to millions of patients worldwide. In addition, Shionogi is engaged in new research areas such as allergy and cancer. Contributing to the health of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit www.shionogi.co.jp. For more information on Shionogi Inc. headquartered in Florham Park, NJ, please visit www.shionogi-inc.com.

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**Cautionary statement regarding forward-looking statements**

***GlaxoSmithKline disclosure notice***: Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK' s operations are described under 'Risk Factors' in the 'Business Review' in the company' s Annual Report on Form 20-F for 2009.

***Pfizer disclosure notice***: Pfizer assumes no obligation to update any forward-looking statements contained in this release as a result of new information or future events or developments.

This release contains forward-looking information about Pfizer, GlaxoSmithKline and ViiV Healthcare and about the prospects of the companies, including revenues from in-line products and the potential benefits of product candidates that

will be contributed to that company, as well as the potential financial impact of the transaction. Such information involves substantial risks and uncertainties including, among other things, decisions by regulatory authorities regarding whether and when to approve any drug applications that have been or may be filed for such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates; and competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer's Annual Report of Form 10-K for the fiscal year ended December 31, 2009 and in its reports on Form 10-Q and Form 8-K.

***Shionogi forward-looking statement***: 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. 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. This announcement contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kind.