# Shionogi-ViiV Healthcare Starts Phase III Trial for "572-Trii" Fixed-Dose Combination HIV Therapy

**London, UK, 3 February 2011** – Shionogi-ViiV Healthcare, LLC announced today that the first patient has entered the clinical study, SINGLE (ING114467), designed to support a new fixed-dose combination (FDC) therapy for the treatment of HIV. The new investigational regimen, known as 572-Trii, will combine the investigational integrase inhibitor S/GSK1349572 ('572) and ViiV Healthcare's combination nucleoside reverse transcriptase inhibitor (NRTI) Kivexa®/Epzicom® (ABC/3TC).

"ViiV Healthcare's goal is to understand and be responsive to the needs of people living with HIV," stated Dominique Limet, Chief Executive Officer, ViiV Healthcare. "With this programme, we are seeking to create an integrase-based, once-daily fixed dose combination that helps meet patient needs. We know that even with the successes of current therapies, patients still need additional treatment options and we will continue to evaluate existing and pipeline compounds for new combination therapies."

"The study of a fixed-dose combination therapy that includes '572 is a signal of ShionogiViiV Healthcare's confidence in the compound's potential," said Dr. Sapan Shah, President & CEO, Shionogi Inc. "We're optimistic that '572 will continue to show promise through this research and in the other ongoing Phase III studies that are evaluating it in other HIV treatment regimens."

# **About the Study: SINGLE (ING114467)**

The SINGLE study (ING114467) is a multi-centre, multinational, double-blind, two arm study designed to compare the efficacy and safety of 572-Trii ('572 plus ABC/3TC) with that of efavirenz/tenofovir/emtricitabine (EFV/TDF/FTC). This study will include approximately 800 HIV-1 infected treatment-naïve patients.

The primary objective for the SINGLE study will be to demonstrate the antiviral activity of 572-Trii once-daily therapy compared to EFV/TDF/FTC over 48 weeks. Secondary objectives include the assessment of the tolerability, long-term safety, and antiviral and immunologic activity of 572-Trii once-daily compared to EFV/TDF/FTC over 96 weeks. Investigators will also evaluate viral resistance in patients experiencing virologic failure.

Together with the planned FDC bioequivalence study (ING114580) comparing the 572-Trii FDC tablet with '572 plus KIVEXA/EPZICOM, the SINGLE study is designed to support a regulatory filing for 572-Trii as a new fixed dose combination of '572/ABC/3TC.

### About KIVEXA/EPZICOM

KIVEXA/EPZICOM (abacavir/lamivudine) is a once-a-day HIV medication that combines abacavir sulfate and lamivudine in a single tablet and is indicated for the treatment of HIV-1 infection in adults. Important Information about EPZICOM

EPZICOM, in combination with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in adults.

EPZICOM is one of 3 medicines containing abacavir. Before starting EPZICOM, your healthcare professional will review your medical history in order to avoid the use of abacavir if you have experienced an allergic reaction to abacavir in the past.

In one study, more patients had a severe hypersensitivity reaction in the abacavir once-daily group than in the abacavir twice-daily group.

**EPZICOM** should not be used as part of a triple-nucleoside regimen.

EPZICOM does not cure HIV infection/AIDS or prevent passing HIV to others. Important Safety Information

EPZICOM contains abacavir, which is also contained in ZIAGEN® (abacavir sulfate) and TRIZIVIR® (abacavir sulfate, lamivudine, and zidovudine). Patients taking EPZICOM may have a serious allergic reaction (hypersensitivity reaction) that can cause death. The risk of this allergic reaction is much higher if one has a gene variation called HLA-B\*5701 than if one does not. Your doctor can determine with a blood test if you have this gene variation. If you get a symptom from 2 or more of the following groups while taking EPZICOM, call your doctor right away to determine if you should stop taking this medicine:

- 1. Fever
- 2. Rash
- 3. Nausea, vomiting, diarrhea, or abdominal (stomach area) pain
- 4. Generally ill feeling, extreme tiredness, or achiness
- 5. Shortness of breath, cough, or sore throat

Carefully read the Warning Card that your pharmacist gives you and carry it with you at all times.

If you stop EPZICOM because of an allergic reaction, NEVER take EPZICOM or any other abacavir-containing medicine (ZIAGEN, TRIZIVIR) again. If you take EPZICOM or any other abacavir-containing medicine again after you have had an allergic reaction, WITHIN HOURS you may get life-threatening symptoms that may include very low blood pressure or death.

If you stop EPZICOM for any other reason, even for a few days, and you are not allergic to EPZICOM, talk with your healthcare professional before taking it again. Taking EPZICOM again can cause a serious or life-threatening reaction, even if you never had an allergic reaction before. If your healthcare professional tells you that you can take EPZICOM again, start taking it when you are around medical help or people who can call a doctor if you need one.

A build-up of lactic acid in the blood and an enlarged liver, including fatal cases, has been reported.

Do not take EPZICOM if your liver does not function normally.

Some patients infected with both hepatitis B virus (HBV) and HIV have worsening of hepatitis after stopping lamivudine (a component of EPZICOM). Discuss any change in treatment with your doctor. If you have both HBV and HIV and stop treatment with EPZICOM, you should be closely monitored by your doctor for at least several months.

Worsening of liver disease (sometimes resulting in death) has occurred in patients infected with both HIV and hepatitis C virus who are taking anti-HIV medicines and are also being treated for hepatitis C with interferon with or without ribavirin. If you are taking EPZICOM as well as interferon with or without ribavirin and you experience side effects, be sure to tell your doctor.

When you start taking HIV medicines, your immune system may get stronger and could begin to fight infections that have been hidden in your body, such as pneumonia, herpes virus, or tuberculosis. If you have new symptoms after starting your HIV medicines, be sure to tell your doctor.

Changes in body fat may occur in some patients taking antiretroviral therapy. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the trunk. Loss of fat from the legs, arms, and face may also occur. The cause and long-term health effects of these conditions are not known at this time.

Some HIV medicines, including those containing abacavir (ZIAGEN, EPZICOM or TRIZIVIR), may increase one's risk of heart attack. If one has heart problems, smoke, or suffers from diseases that increase the risk of heart disease such as high blood pressure, high cholesterol, or diabetes, they should tell their doctor.

The most common side effects seen with the drugs in EPZICOM dosed once-daily were allergic reaction, trouble sleeping, depression, headache, tiredness, dizziness, nausea, diarrhea, rash, fever, stomach pain, abnormal dreams, and anxiety. Most of the side effects do not cause people to stop taking EPZICOM.

For additional important information about EPZICOM please visit www.epzicom.com. For additional important information about ZIAGEN please visit www.treathiv.com.

# 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 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.shionogiinc.com.

## **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.

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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.