

PRESS RELEASE**Antiviral Activity of S/GSK1265744, a Once-Daily, Unboosted Integrase Inhibitor in Clinical Development, Evaluated in Phase 1-2a Study in Healthy and HIV-Infected Subjects**

San Francisco, CA – September 14, 2009 – Shionogi-GlaxoSmithKline Pharmaceuticals, LLC announced today results from a Phase 1-2a study evaluating the pharmacokinetics (PK), safety and antiviral activity of its investigational integrase inhibitor (INI) S/GSK1265744 in healthy subjects and HIV-infected patients. The data showed a significant decline in viral load in HIV-infected patients, as well as favorable pharmacokinetic and short-term safety profiles in healthy subjects and HIV-infected patients. The results of this study were presented at the 49th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) held this week in San Francisco, California.

“Shionogi-GlaxoSmithKline Pharmaceuticals is committed to the integrase inhibitor class of antiretrovirals because new treatments are urgently needed to address issues of viral resistance and dosing complexity faced by many HIV patients,” said Garrett Nichols, MD, Project Leader, GlaxoSmithKline (GSK). “We have created a series of compounds that includes our lead candidate S/GSK1349572 and our backup S/GSK1265744 to help address these needs. In this study, S/GSK1265744 had similar attributes to S/GSK1349572 including once-daily, unboosted dosing, potent antiretroviral activity and low PK variability - which, if confirmed in further studies, would be important in the long-term management of HIV disease.”

“The joint venture between Shionogi and GSK was formed for the purpose of driving the successful research and development of new treatments for HIV,” said Tamio Fujiwara, PhD, HIV Integrase Inhibitor Project Leader, Pharmaceutical Development Division, Shionogi & Co., Ltd. “While the data presented today on S/GSK1265744 are encouraging and demonstrate our commitment to HIV integrase as a target, we will continue advancing S/GSK1349572 as our lead candidate.”

Results

This Phase 1-2a, double-blind, randomized, placebo-controlled study of S/GSK1265744 was composed of three parts: single (Part A) and multiple (Part B) oral dose escalation conducted in 48 healthy subjects and a multiple oral dose study (Part C) in 11 HIV-infected patients.

During Part A, two cohorts of nine subjects received alternating doses of 5, 10, 25 and 50mg of S/GSK1265744 suspension or placebo. During Part B, three cohorts of 10 subjects received doses of 5, 10 or 25mg of S/GSK1265744 suspension or placebo once-daily for 14 days. During Part C, subjects received 30mg (six 5mg tablets) of S/GSK1265744 or placebo once-daily for 10 days. Lab tests, vital signs, ECG and PK sampling were performed at regular intervals.

In Part C of this study in INI-naïve, HIV-1 infected adults, a 2.6 log₁₀ median reduction in viral load occurred from baseline to Day 11 with S/GSK1265744 monotherapy. At the 30mg dose, 88 percent of subjects receiving S/GSK1265744 achieved undetectable levels of HIV in their blood (below 50 copies/mL) by Day 14, despite receiving no other antiretroviral medications.

S/GSK1265744 was generally well tolerated in healthy and HIV-infected subjects. In subjects who received repeat doses of S/GSK1265744 in the study, the most common drug-related adverse events were mild with headache being the most common (occurring in 7 percent of S/GSK1265744 recipients vs. 15 percent of placebo recipients). Pharmacokinetic data from healthy subjects and INI-naïve HIV patients showed that S/GSK1265744 has a long plasma half-life (approximately 30 hours) and low inter-patient pharmacokinetic variability and achieved

therapeutic concentrations with once-daily dosing without the need for pharmacokinetic boosting agents. Further studies are necessary to conclusively determine the safety and efficacy profile of this investigational compound in HIV-infected patients.

- ends -

About Integrase Inhibitors

Integrase inhibitors are a new class of anti-HIV drugs that blocks HIV replication by preventing viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV-1 replication cycle. Integrase inhibitors are of great interest because they have a different mechanism of action from other anti-HIV drugs, and there is a need for new medications that help address resistance issues and provide additional treatment options. Patients need multiple, active antiretroviral drugs that can be administered in combination to attain viral suppression, as well as new drugs that offer different resistance profiles and simplified dosing.

About Shionogi-GlaxoSmithKline Pharmaceuticals, LLC

Shionogi-GlaxoSmithKline Pharmaceuticals, LLC is a long-standing joint venture between Shionogi & Co., Ltd. and GlaxoSmithKline (GSK) which has made considerable progress in developing next-generation integrase inhibitors for the treatment of HIV. Launched in 2001, the joint venture was originally established for the development and commercialization of new agents to fight HIV and neurological disorders, including Alzheimer's, stroke, and head injury. More recently, the company has focused exclusively on several new integrase inhibitor candidates jointly discovered by Shionogi & Co., Ltd. and GSK.

GlaxoSmithKline Enquiries

Robin Fastenau
Director, Global Pipeline Communications
Email: robin.e.fastenau@gsk.com

Tel: +1 919 483 7966

Shionogi & Co., Ltd. Enquiries

Corporate Communications Department
Osaka

Tel: +81 6 6209 7885

Fax: +81 6 6229 9596