

August 15, 2006
Shionogi & Co., Ltd.

GLAXOSMITHKLINE AND SHIONOGI COMPLETE INITIAL CLINICAL STUDY FOR HIV INTEGRASE INHIBITOR

GlaxoSmithKline (GSK) and Shionogi & Co., Ltd. (Shionogi) announced today that they have completed an initial clinical study in humans with an investigational integrase inhibitor, 364735, which is being developed for the treatment of HIV/AIDS. Integrase inhibitors are a new class of anti-HIV drugs that block viral replication by preventing the virus from integrating into the genetic material of human immune cells. 364735 is being developed by a joint venture between GSK and Shionogi.

"Development of new antiretroviral drugs with different viral targets, resistance profiles and improved safety and tolerability is urgently needed for both treatment-naïve and treatment-experienced patients, especially those with multi-drug resistant HIV," commented Dr. Lynn Marks, Senior Vice President, Medicines Development Centre for Infectious Diseases at GSK. "Recent findings suggest integrase inhibitors may help meet many of these continuing medical needs. GSK is committed to discovering new solutions to address the challenges of treating HIV/AIDS."

"Integrase continues to be an important target in the search for new treatments to address HIV/AIDS. Shionogi remains committed to discovering and advancing new drug candidates in this area, and we look forward to further progress with 364735," remarked Dr. Isao Teshirogi, Director of the Board and Senior Executive Officer responsible for Research & Development at Shionogi.

A Phase I study of 364735 was recently conducted in the United States to assess safety and pharmacokinetics in healthy volunteers. Results from this clinical trial will be submitted for presentation at an upcoming medical conference in 2007. Data from this study of 364735 have enabled selection of doses for a Phase II study, the next step in its clinical development, which is planned to start in late 2006 in HIV-infected adults.

The integrase enzyme is unique to the virus and is not found in humans, which makes it an attractive drug target. New treatments are critical for HIV treatment-experienced patients who have exhausted other available options. These patients need multiple, active antiretroviral drugs that can be administered in combination to attain a high degree of viral suppression against drug-resistant virus, new drugs with improved safety profiles that can fit into patients' daily lives, and drugs that act by novel mechanisms of action that are additive or synergistic with drugs in existing pharmacologic classes.

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