

## **U.S. Food and Drug Administration Priority Review Designation for HIV Integrase Inhibitor “Dolutegravir”**

**Osaka, Japan, February 18, 2013** - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that ViiV Healthcare (Head Office: London; Chief Executive Officer: Dr. Dominique Limet) distributed a press release on February 15, 2013, UK Time, and announced that the U.S. Food and Drug Administration (FDA) granted a priority review designation to the investigational integrase inhibitor dolutegravir for the treatment of HIV infection, in combination with other anti-HIV agents, in adults and adolescents.

According to the timelines established by the Prescription Drug User Fee Act (PDUFA), the target date for the completion of the review of the new drug application (NDA) for dolutegravir is August 17, 2013.

Dolutegravir is an investigational integrase inhibitor for the treatment of HIV, which had been developed by Shionogi-ViiV Healthcare LLC, and is currently in development by ViiV Healthcare following the new agreement between Shionogi and ViiV Healthcare announced in October 2012. ViiV Healthcare filed the NDA of dolutegravir in the US, EU and Canada on December 17, 2012.

### **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, unavailability 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:**

Corporate Communications

Shionogi & Co., Ltd.

Osaka    Telephone: +81-6-6209-7885    Fax: +81-6-6229-9596

Tokyo    Telephone: +81-3-3406-8164    Fax: +81-3-3406-8099