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News Release

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Takeda Submitted an Application for an Additional Indication of Alogliptin for Combination Therapy with Thiazolidinediones, and a New Drug Application of Fixed-Dose Combination of Alogliptin and Pioglitazone HCl in Japan

OSAKA, Japan, June 29, 2009 – Takeda Pharmaceutical Company Limited (Takeda) today announced that it submitted an application for an additional indication of alogliptin (generic name, development code: SYR-322) for combination therapy with thiazolidinediones, and a new drug application (NDA) of fixed-dose combination (FDC) of alogliptin and pioglitazone HCl (generic name, tradename in Japan: Actos®) to the Ministry of Health, Labour and Welfare in Japan. An NDA for alogliptin monotherapy was submitted on September 29, 2008 and is now under evaluation by regulatory authorities. [*]

The applications submitted were based on the clinical data of concomitant therapy of alogliptin and ACTOS conducted both in Japan and abroad.

Alogliptin was discovered by Takeda's wholly-owned subsidiary, Takeda San Diego, Inc. and is a member of the DPP-4 inhibitors class, which are newer oral agents for the treatment of type 2 diabetes. DPP-4 inhibitors slow the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic peptide). The incretins play a major role in regulating blood glucose levels and have the potential to improve pancreatic beta-cell function. GLP-1 and GIP are produced by the digestive tract in response to food and regulate glucose balance, primarily by stimulating glucose-dependent insulin secretion. In addition, GLP-1 suppresses pancreatic glucagon secretion and subsequent liver glucose production, enhances glucose disposal, slows gastric emptying, and elicits satiety, a feeling of fullness. Takeda is the originator of the thiazolidinedione (TZD) class of oral anti-diabetes medications. ACTOS is a TZD that directly targets insulin resistance, a condition in which the body does not efficiently use the insulin it produces to control blood glucose levels.

It is expected that alogliptin in concomitant therapy with a thiazolidinedione or a fixed-dose combination tablet with ACTOS will contribute to improving decreased insulin secretion and insulin resistance, which are primary pathologies of type II diabetes. Moreover, it is anticipated that the fixed-dose combination tablet of alogliptin with ACTOS will provide an improved compliance profile for patients. Takeda will continue with its efforts to provide new treatment options for type II diabetes to both patients and healthcare professionals.

[*] As announced on June 27, 2009 Japan time, in the U.S., the Food and Drug Administration (FDA) notified Takeda of a need to conduct an additional cardiovascular safety study for alogliptin.

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. Additional information about Takeda is available through its corporate Web site, www.takeda.com.

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