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News Release

Takeda Submits a New Drug Application in the U.S. for Alogliptin (SYR-322) / ACTOS® (pioglitazone HCl) for the Treatment of Type 2 Diabetes

Osaka, Japan, September 24, 2008 --- Takeda Pharmaceutical Company Limited (Takeda) announced today that its wholly owned subsidiary, Takeda Global Research & Development Center Inc. (U.S.), submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of alogliptin (SYR-322) and ACTOS® (pioglitazone HCl) ("alogliptin/ACTOS") in a single tablet for the treatment of type 2 diabetes.

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 inihibitors 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.

"Alogliptin/ACTOS, if approved, will be the first type 2 diabetes treatment option which includes a DPP-4 inhibitor and a TZD," said Yasuchika Hasegawa, President of Takeda. "Given the increased global incidence of type 2 diabetes and the need for new treatment options, we will strive to provide alogliptin/ACTOS, as a potentially important treatment option, to patients and healthcare providers."

The NDA submission was supported by two phase 3 clinical trials, involving more than 2,000 patients worldwide. The studies assessed the efficacy and safety of this therapy for the treatment of patients with type 2 diabetes not achieving glycemic targets with diet and exercise alone, or for patients uncontrolled on metformin. Study results showed that alogliptin/ACTOS produced significant improvements in glycemic control and measures of insulin resistance and beta cell function. In clinical trials, alogliptin/ACTOS was generally well-tolerated. Side effects included headache, cold-like symptoms and back pain.

Important Safety Information About ACTOS® (pioglitazone HCl)

ACTOS works by directly targeting insulin resistance, a condition in which the body does not efficiently use the insulin it produces to control blood glucose levels. ACTOS, a prescription medication, is taken once daily as an adjunct to diet and exercise, and is approved for use for type 2 diabetes as monotherapy to lower blood glucose and in combination therapy with insulin, sulfonylureas or metformin.

ACTOS is not for everyone. Certain patients with heart failure should not start taking ACTOS. ACTOS can cause or worsen congestive heart failure. Talk to your doctor immediately if you experience rapid weight gain, fluid retention, or shortness of breath.

Do not take ACTOS if you have active liver disease. Your doctor should perform a blood test to check for liver problems before you start ACTOS and periodically thereafter. Talk to your doctor immediately if you experience nausea, vomiting, stomach pain, tiredness, loss of appetite, dark urine, or yellowing of the skin. If you are of childbearing age, talk to your doctor before taking ACTOS, as it could increase your chance of becoming pregnant. Some people taking ACTOS may experience flulike symptoms, mild-to-moderate swelling of legs and ankles, and anemia. Some people, particularly women, are at higher risk of having bone fractures while taking ACTOS. When taking ACTOS with insulin or sulfonylureas, you may be at risk for low blood sugar. Patients with diabetes should have regular eye exams. If you experience vision problems, consult your doctor immediately. Very rarely, some patients have experienced visual changes while taking ACTOS.

Please visit the ACTOS Web site at www.actos.com for Complete Prescribing Information.

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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