News Release

FOR IMMEDIATE RELEASE

Takeda Receives FDA Approval for Three New Type 2 Diabetes Therapies, NESINA (alogliptin) and Fixed-Dose Combinations OSENI (alogliptin and pioglitazone) and KAZANO (alogliptin and metformin HCl)

Deerfield, Ill., January 25, 2013, and Osaka, Japan, January 26, 2013 – Takeda Pharmaceutical Company Limited (Takeda) and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc. today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved NESINA (alogliptin) and the fixed-dose combination (FDC) therapies OSENI (alogliptin and pioglitazone) and KAZANO (alogliptin and metformin HCl) for the treatment of type 2 diabetes in adults as adjuncts to diet and exercise.

"Takeda is pleased with the FDA approval of NESINA, OSENI and KAZANO for the treatment of type 2 diabetes, a therapeutic category in which we have more than twenty years of clinical and patient experience," said Douglas Cole, president, Takeda Pharmaceuticals U.S.A., Inc. "Millions of people are affected by diabetes and, as a leader in the diabetes arena, Takeda is dedicated to working to advance patient care and helping to meet the needs of this growing patient population."

NESINA is a dipeptidyl peptidase-4 inhibitor (DPP-4i) that is designed to slow the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic peptide). OSENI, which combines alogliptin with pioglitazone, is the first product in the U.S. to include both a DPP-4i and a thiazolidinedione (TZD) in a single tablet. KAZANO combines alogliptin with metformin HCl, a widely used anti-diabetes medication, in a single tablet.

The most common adverse events (≥4%) reported with NESINA include nasopharyngitis, headache and upper respiratory tract infection. With regard to OSENI, common adverse events (≥4%) reported include nasopharyngitis, back pain and upper respiratory tract infection. Common adverse events (≥4 %) reported with KAZANO include upper respiratory tract infection, nasopharyngitis, diarrhea, hypertension, headache, back pain and urinary tract infection.

Takeda is committed to providing type 2 diabetes patients with treatment options that help address their needs, and is planning to commercially launch NESINA, OSENI and KAZANO in the summer of 2013.

Takeda's consolidated financial statements for the 2012 fiscal year will not be impacted by the FDA approvals.

Clinical Trial Program

U.S.-based Takeda Global Research & Development Center, Inc. conducted worldwide placebo- and active-controlled clinical trials of NESINA involving more than 13,000 patients. The safety and efficacy of NESINA was studied as a once-daily monotherapy and in combination with several other classes of anti-diabetic medications, including biguanides, TZDs, insulin and sulfonylureas. In these studies, NESINA 25 mg, taken once daily, demonstrated clinically meaningful and statistically significant improvements in hemoglobin A1C compared to placebo.

Of the total number of patients included in the NESINA clinical trial program, more than 3,000 were included in the studies used to support the FDA approval of OSENI, and more than 4,000 were included in those to support the FDA approval of KAZANO. Study results indicated that alogliptin co-administered with either pioglitazone or metformin HCl produced significant improvements in glycemic control as compared to the respective monotherapies.

About Type 2 Diabetes

Type 2 diabetes is the most common form of diabetes affecting millions of people globally. In fact, more than 23 million people in the U.S. alone currently live with the disease. Type 2 diabetes is a progressive and chronic condition and patients should work with a health care professional to manage and monitor their disease. In addition to diet and exercise, patients often need to take multiple medications in order to help them manage their blood glucose levels. According to the International Diabetes Federation, the global health care expenditures for diabetes (both type 1 and 2) were estimated at $471.6 billion in 2012. By 2030, this number is projected to exceed $595 billion.

About NESINA, OSENI and KAZANO

NESINA is a DPP-4i for the treatment of type 2 diabetes as an adjunct to diet and exercise. DPP-4is slow the inactivation of incretin hormones GLP-1 and GIP. As a result, an increased amount of active incretins enables the pancreas to secrete insulin in a glucose-dependent manner, thereby assisting in the management of blood glucose levels. A New Drug Application (NDA) for NESINA was approved in April 2010 by the Japanese Ministry of Health, Labour and Welfare for the treatment of type 2 diabetes, and the therapy is available under the same brand name in Japan.

OSENI is an FDC therapy which combines alogliptin and pioglitazone in a single tablet, for the treatment of type 2 diabetes in adults as an adjunct to diet and exercise. Pioglitazone is a TZD that decreases insulin resistance, a condition in which the body does not efficiently use the insulin it produces to control blood glucose levels, and is approved in adults for the treatment of type 2 diabetes as an adjunct to diet and exercise. An NDA for alogliptin and pioglitazone was approved in July 2011 by the Japanese Ministry of

Health, Labour and Welfare for the treatment of type 2 diabetes, and the therapy is currently available under the brand name LIOVEL in Japan.

KAZANO is an FDC therapy for the treatment of type 2 diabetes, which combines alogliptin and metformin HCl in a single tablet. Metformin HCl is a biguanide, a widely used anti-diabetes medication that acts primarily by reducing the amount of glucose produced by the liver.

Indications

Indications for NESINA (alogliptin) 6.25 mg, 12.5 mg, and 25 mg Tablets; KAZANO (alogliptin and metformin HCl) 12.5 mg/500 mg and 12.5 mg/1000 mg Tablets; and OSENI (alogliptin and pioglitazone) 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg, 12.5 mg/15 mg, 12.5 mg/30 mg, and 12.5 mg/45 mg Tablets

NESINA, KAZANO, and OSENI are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Use OSENI with caution in patients with liver disease.

NESINA, KAZANO, and OSENI are not for treatment of type 1 diabetes or diabetic ketoacidosis.

Important Safety Information

WARNING: CONGESTIVE HEART FAILURE—for OSENI
Thiazolidinediones, including pioglitazone, which is a component of OSENI, cause or exacerbate congestive heart failure in some patients. After initiation of OSENI, and after dose increases, monitor patients carefully for signs and symptoms of heart failure (e.g., excessive, rapid weight gain, dyspnea, and/or edema). If heart failure develops, it should be managed according to current standards of care and discontinuation or dose reduction of pioglitazone in OSENI must be considered. OSENI is not recommended in patients with symptomatic heart failure. Initiation of OSENI in patients with established New York Heart Association (NYHA) Class III or IV heart failure is contraindicated.

WARNING: LACTIC ACIDOSIS—for KAZANO
Lactic acidosis is a rare, but serious complication that can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure. The onset is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate. If acidosis is suspected, KAZANO should be discontinued and the patient hospitalized immediately.

NESINA, KAZANO, and OSENI are contraindicated in patients with a history of serious hypersensitivity reaction to any of the components of these products, such as anaphylaxis, angioedema, or severe cutaneous adverse reactions. KAZANO is contraindicated in patients with renal impairment (e.g., serum creatinine levels ≥1.5 mg/dL for men, ≥1.4 mg/dL for women or abnormal creatinine clearance), which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarctions, and septicemia. KAZANO is contraindicated in patients with acute or chronic metabolic acidosis, including diabetic ketoacidosis. Do not initiate OSENI in patients with established NYHA Class III or IV heart failure.

Warnings and Precautions—for KAZANO

Lactic acidosis: Warn against excessive alcohol intake. KAZANO is not recommended in hepatic impairment and is contraindicated in renal impairment. Ensure normal renal function before initiating and at least annually thereafter. Temporarily discontinue in patients undergoing radiologic studies with intravascular iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids. Lactic acidosis due to metformin accumulation during therapy is fatal in approximately 50% of cases. The risk increases in patients with renal impairment, congestive heart failure requiring drug treatment, and with increasing age.

Vitamin B12 deficiency: Metformin may lower Vitamin B12 levels. Monitor hematologic parameters annually.

Warnings and Precautions—for OSENI

Congestive heart failure: Fluid retention may occur and can exacerbate or lead to congestive heart failure. Combination use with insulin and use in congestive heart failure NYHA Class I and II may increase risk. Monitor patients for signs and symptoms.

Edema: Dose-related edema may occur. Use with caution in patients with edema.

Fractures: Increased incidence in female patients. Apply current standards of care for assessing and maintaining bone health.

Bladder cancer: Data suggest an increased risk of bladder cancer in pioglitazone users. Data also suggest that the risk increases with duration of use. Do not use OSENI in patients with active bladder cancer. Use caution when using in patients with a prior history of bladder cancer. Tell patients to promptly report any sign of hematuria or other symptoms such as dysuria or urinary urgency as these may be due to bladder cancer.

Macular edema: Macular edema has been reported in some patients taking pioglitazone. Recommend

regular eye exams. Instruct patients to report any visual changes promptly.

Ovulation: Therapy with pioglitazone may result in ovulation in some premenopausal anovulatory women.

Warnings and Precautions—for NESINA, KAZANO, and OSENI

Acute pancreatitis: There have been postmarketing reports of acute pancreatitis. If pancreatitis is suspected, promptly discontinue NESINA, KAZANO, or OSENI.

Hypersensitivity: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with alogliptin such as anaphylaxis, angioedema or severe cutaneous adverse reactions. In such cases, promptly discontinue NESINA, KAZANO, or OSENI, assess for other potential causes, institute appropriate monitoring and treatment, and initiate alternative treatment for diabetes. Use caution in a patient with a history of angioedema with another DPP-4i because it is unknown whether such patients will be predisposed to angioedema.

Hepatic effects: Postmarketing reports of hepatic failure, sometimes fatal. Causality cannot be excluded. Baseline liver test panel is recommended. If liver injury is detected, promptly interrupt NESINA, KAZANO, or OSENI and assess patient for probable cause, then treat cause if possible, to resolution or stabilization. Do not restart NESINA, KAZANO, or OSENI if liver injury is confirmed and no alternate etiology can be found. Use with caution in patients with liver disease.

Hypoglycemia: Insulin and insulin secretagogues are known to cause hypoglycemia. A lower dose of the insulin or insulin secretagogue may be required to minimize the risk when used in combination with NESINA, KAZANO, or OSENI.

Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with NESINA, KAZANO, OSENI, or any other anti-diabetic drug.

Adverse Reactions

Most common adverse reactions (≥4% of patients treated with NESINA 25 mg and more frequently than in patients who received placebo) were nasopharyngitis (4.4%), headache (4.2%), and upper respiratory tract infection (4.2%).

Most common adverse reactions (≥4% of patients treated with co-administration of alogliptin and metformin) were upper respiratory tract infection (8%), nasopharyngitis (6.8%), diarrhea (5.5%), hypertension (5.5%), headache (5.3%), back pain (4.3%), and urinary tract infection (4.2%).

Most common adverse reactions (≥4% of patients treated with co-administration of alogliptin and pioglitazone) were nasopharyngitis (4.9%), back pain (4.2%), and upper respiratory tract infection (4.1%).

Drug Interactions

Use of OSENI with CYP2C8 strong inhibitors (e.g., gemfibrozil) will, or inducers (e.g., rifampin) may, require dose adjustment.

Cationic drugs eliminated by renal tubular secretion should be used with caution if taken with KAZANO.

Please see accompanying Full Prescribing Information, including Medication Guide, for NESINA.

Please see accompanying Full Prescribing Information, including Medication Guide, for KAZANO.

Please see accompanying Full Prescribing Information, including Medication Guide, for OSENI.

Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc.
Based in Deerfield, Ill., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. are subsidiaries of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. The respective companies currently market oral diabetes, insomnia, rheumatology, gastroenterology, and cardiovascular treatments and seek to bring innovative products to patients through a pipeline that includes compounds in development for metabolic and cardiovascular disease, gastroenterology, neurology and other conditions. To learn more about these Takeda companies, visit www.takeda.us.

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 strive towards better health for patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they

are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the United States and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.

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