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FDA Approves KAPIDEX™ (dexlansoprazole) delayed release capsules for the Treatment of GERD

First proton pump inhibitor (PPI) with a Dual Delayed Release™ (DDR) formulation

Osaka, Japan, January 31,2009 and Deerfield, Ill., January 30, 2009 – – Takeda Pharmaceutical Company Limited and its wholly-owned subsidiary, Takeda Pharmaceuticals North America, Inc., today announced that the U.S. Food and Drug Administration (FDA) approved KAPIDEX™ (dexlansoprazole) delayed release capsules for the once-daily, oral treatment of heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD), the healing of erosive esophagitis (EE) and the maintenance of healed EE. KAPIDEX (30 mg and 60 mg) is the first proton pump inhibitor (PPI) with a Dual Delayed Release™ (DDR) formulation designed to provide two separate releases of medication.

"Through the discovery, development and commercialization of new medicines, Takeda has been a leader in acid-related therapy for more than 15 years and is committed to bringing new therapies to market," said Alan MacKenzie, president and CEO, Takeda Pharmaceuticals North America. "KAPIDEX is a new, innovative treatment option in the well-established PPI market."

PPIs work by reducing acid production by turning off many of the acid pumps in the stomach. KAPIDEX contains two types of enteric-coated granules resulting in a concentration-time profile with two distinct peaks: the first peak occurs one to two hours after administration, followed by a second peak within four to five hours. In addition, KAPIDEX can be taken regardless of when food is consumed.

"People with GERD often suffer with heartburn symptoms during the day and night," said David Peura, MD, professor of medicine, University of Virginia Health System. "In the pivotal Phase 3 clinical studies, KAPIDEX demonstrated the ability to provide up to 24-hour heartburn relief with a side effect profile similar to lansoprazole. KAPIDEX, with its DDR formulation, is a new and exciting treatment option for people with GERD."

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The approval was based on global studies conducted in 20 countries evaluating approximately 6,000 patients with erosive and non-erosive GERD. Two identically designed, double-blind, eight-week, randomized, controlled trials compared treatment with KAPIDEX to treatment with lansoprazole in patients with EE. KAPIDEX (60 mg) produced high overall healing rates at week eight when compared to lansoprazole 30 mg (87%, and 85%, respectively, in the first study; and 85%, and 79%, respectively, in the second study) and was generally well-tolerated.

Data from a six-month maintenance of healed EE study demonstrated that patients treated with KAPIDEX 30 mg experienced consistently high overall maintenance of healed EE and heartburn relief versus patients on placebo.

In a four-week trial in patients who identified heartburn as their primary GERD symptom and did not have esophageal erosions, KAPIDEX demonstrated a statistically significant greater percent of days (median rates) with heartburn-free 24-hour periods over placebo.

About GERD and EE

GERD affects nearly 19 million Americans and is often characterized by frequent and persistent heartburn that occurs two or more days a week despite treatment and diet changes. GERD can affect both men and women, and symptoms are often triggered by certain foods, stress or pressure on the stomach.

GERD is a chronic condition commonly known as acid reflux disease. GERD can occur when the valve at the lower end of the esophagus, called the lower esophageal sphincter (LES), does not work properly. This valve opens to allow food and liquids to enter the stomach and closes to keep acid and food in the stomach.

When the LES does not close as tightly as it should, or relaxes too often, it can cause stomach contents to get into the esophagus repeatedly. The stomach is better equipped to handle acid than the esophagus. If the esophagus is continually exposed to stomach contents, damage to the lining of the esophagus such as breaks or lesions can occur, a condition known as erosive esophagitis (EE).

About KAPIDEX (dexlansoprazole) delayed release capsules

KAPIDEX (dexlansoprazole) delayed release capsules, previously known by the development code TAK-390MR, is a proton pump inhibitor (PPI), which decreases acid production by turning off many of the acid pumps in the stomach, thus helping to protect the esophagus from acidic reflux so that esophageal inflammation can heal. KAPIDEX combines an enantiomer of lansoprazole with a Dual Delayed Release™ (DDR) formulation designed to provide two separate releases of medication. KAPIDEX, taken once-daily, is approved for the healing of all grades of erosive esophagitis (EE) for up to eight weeks, maintaining healing of EE for up to six months, and treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for four weeks.

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Important Safety Information

KAPIDEX is contraindicated in patients with known hypersensitivity to any component of the formulation. Symptomatic response with KAPIDEX does not preclude the presence of gastric malignancy. The most commonly reported treatment-emergent adverse reactions (≥2%): diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting, and flatulence. KAPIDEX should not be co-administered with atazanavir. KAPIDEX may interfere with the absorption of drugs for which gastric pH is important for bioavailability (e.g., ampicillin esters, digoxin, iron salts, ketoconazole). Patients taking concomitant warfarin may require monitoring for increases in international normalized ratio (INR) and prothrombin time.

Please see the complete prescribing information and visit the KAPIDEX Web site at www.kapidex.com.

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, Takeda (TSE:4502) 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.

Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals North America, 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 and gastroenterology treatments and seek to bring innovative products to patients through a pipeline that includes compounds in development for diabetes, cardiovascular disease, oncology, gastroenterology, neurology, rheumatology and other conditions. Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. To learn more about these Takeda companies, visit www.tpna.com.

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