News Release

Takeda Receives Marketing Authorization from China's CFDA for New Type 2 Diabetes Therapy NESINA (alogliptin)

Osaka, Japan, and Shanghai, China, July 31, 2013– Takeda Pharmaceutical Company Limited (TSE: 4502, "Takeda") and its wholly-owned subsidiary, Takeda (China) Holdings Co., Ltd. today announced that the China Food and Drug Administration (CFDA) has issued an Import Drug License (IDL) for NESINA (alogliptin) for the treatment of type 2 diabetes.

NESINA is an orally-administered dipeptidyl peptidase-4 inhibitor (DPP-4i) designed to slow the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic peptide). 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[1]. NESINA was originally created by Takeda California, Inc., Takeda's wholly-owned subsidiary located in San Diego, California.

"We are pleased with the CFDA approval of NESINA for the treatment of type 2 diabetes. It is an important milestone for the company and very good news for diabetes patients in China, and also for doctors who now have a new treatment that helps address the needs of their patients," said Haruhiko Hirate, Corporate Officer and Head of North Asia at Takeda. "Diabetes has become a rapidly growing public health problem in China. Takeda has built a strong foundation in and maintained a robust focus on diabetes over the past 20 years, and remains committed to developing a diverse range of innovative products for the growing type 2 diabetes population."

Takeda has conducted extensive clinical research around NESINA, including placebo- and active-controlled clinical trials worldwide involving more than 13,000 patients[2].

On June 23, Takeda presented new data from ENDURE (Durability of the Efficacy and Safety of Alogliptin Compared to Glipizide Over 2 Years When Used in Combination with Metformin) study at the American Diabetes Association (ADA) Scientific Sessions. The data from ENDURE showed that the efficacy of alogliptin was sustained for two years in patients with type 2 diabetes, with notably less hypoglycemic episodes and no negative impact on weight compared with glipizide[3].

In a multicenter, randomized, double-blind, placebo-controlled, phase 3 study conducted in mainland China, Taiwan and Hong Kong evaluating the safety and efficacy of alogliptin in patients with type 2 diabetes, alogliptin 25mg tablet, taken once daily, significantly reduced HbA1c and FPG compared to placebo when used as monotherapy, add-on to ongoing metformin or add-on to pioglitazone therapy (with or without metformin). Alogliptin also showed a safety profile comparable to placebo[4].

Professor Changyu Pan, Chief Physician in the Department of Endocrinology, Chinese PLA General Hospital, and lead investigator in the study, commented, "China is seeing a rapid increase in the prevalence of diabetes according to several reports. Even though a variety of drugs are available, many patients still fail to achieve treatment goals. Intensive diabetes therapy can improve the success rate, however, the associated increased frequency of hypoglycemic episodes and weight gain still remain the common clinical challenges. The introduction of alogliptin provides physicians with a new treatment option to help patients meet their treatment goals."

NESINA was approved and launched in Japan in 2010, where Takeda has gained a wealth of post-marketing data surrounding this therapy in an Asian population. It is now available in the United States as a monotherapy and also in fixed-dose combinations with metformin (KAZANO) and pioglitazone (OSENI). These medications were approved by the U.S. Food and Drug Administration (FDA) in January 2013 for the treatment of type 2 diabetes in adults, as adjuncts to diet and exercise.

In China, rapid economic development has brought mass urbanization, changing diets and increasingly sedentary lifestyles. These factors greatly increase the risk of developing type 2 diabetes. China has the largest number of people with diabetes compared to any other country, with approximately 92.3 million adults suffering from the disease, 58.5% of which are undiagnosed. By 2030, an additional 37.4 million Chinese adults are expected to develop type 2 diabetes[5].

In April 2013, Takeda entered an agreement with Sanofi to co-promote alogliptin in China to expand its reach to Chinese physicians treating patients with type 2 diabetes. Takeda and Sanofi teams in China are preparing for the launch of NESINA, to ensure that this important medicine reaches to type 2 diabetes patients as soon as possible.

Notes

[1] Nauck MA, Ellis GC, Fleck PR, et al. Efficacy and safety of adding the dipeptidyl peptidase-4 inhibitor alogliptin to metformin therapy in patients with type 2 diabetes and inadequately controlled with metformin monotherapy: a multicentre, randomised, double blind, placebo-controlled study. Int J Clin Pract 2009;63(1):46-55.

[2] NESINA Clinical Trial Program

[3] Del Prato S, Camisasca R et al. Durability of the Efficacy and safety of Alogliptin Compared to Glipizide over 2 Years When Used in Combination with Metformin. Poster #66-LB presented at the 73rd Scientific Sessions of the American Diabetes Association (ADA), Chicago, Illinois, June 21-25, 2013.

[4] Changyu Pan, Efficacy and safety of alogliptin in subjects with type 2 diabetes: A multicenter, randomized, double-blind, placebo-controlled, phase 3 study in mainland China, Taiwan and Hong Kong (Poster# - 1150-P) presented at the 73rd Scientific Sessions of the American Diabetes Association (ADA), Chicago, Illinois, June 21-25, 2013.

[5] International Diabetes Federation: IDF DIABETES ATLAS 5th edition 2012 update

About NESINA

NESINA (alogliptin) is a DPP-4i for the treatment of type 2 diabetes. DPP-4i is designed to 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. NESINA was approved by the U.S. FDA as a monotherapy and also in fixed-dose combinations with metformin (KAZANO) and pioglitazone (OSENI) in January 2013. These products are available in pharmacies in the U.S. for the treatment of type 2 diabetes in adults as adjuncts to diet and exercise.

About Type 2 Diabetes

Type 2 diabetes is the most common form of diabetes affecting millions of people globally. 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. China is now the country with the largest number of people with diabetes and 92.3 million adults are suffering from the disease. In China, the majority of diabetes is type 2 diabetes, with an estimated 93% - 95% of Chinese diabetes patients having type 2 diabetes.

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 people 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.

Contacts:

Corporate Communications Department
Takeda Pharmaceutical Company Limited
+81-3-3278-2037

Takeda Pharmaceuticals International GmbH
Jane Jin (金莹)
Tel: +41 44 555 15 05
Cell: +41 (0) 79 961 1605
jane.jin@takeda.com

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