Takeda and Lundbeck Announce the U.S. Submission of a New Drug Application for Vortioxetine, an Investigational Drug for the Treatment of Major Depressive Disorder

Osaka, Japan and Copenhagen, Denmark – October 1, 2012 – Takeda Pharmaceutical Company Limited (Takeda) and H. Lundbeck A/S (Lundbeck) jointly announced today the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the investigational agent vortioxetine (Lu AA21004) for the treatment of major depressive disorder (MDD) in adult patients.

Vortioxetine is under investigation as an antidepressant with multimodal activity that is thought to work through a combination of two complementary mechanisms of actions: receptor activity modulation and reuptake inhibition. The NDA includes data from six short-term placebo controlled studies, including one dedicated study in the elderly, which have been conducted in regions throughout the world and support statistically significant efficacy of vortioxetine in a dose range of 5 to 20 mg per day. Efficacy of vortioxetine was also demonstrated in a long-term relapse-prevention study in MDD. The vortioxetine global clinical development program included more than 7,500 individuals exposed to the drug.

MDD, commonly referred to as major depression, is a very common, debilitating illness affecting around 121 million people worldwide, according to the World Health Organization (WHO). Results from a landmark, long-term U.S. government study evaluating depression treatment (STAR*D) revealed that only a third of patients with MDD achieve remission at the first stage of treatment. Each additional unsuccessful course of therapy is associated with a progressively lower likelihood of remission and higher relapse rates.

“The prevalence and complexity of major depressive disorder remains a growing concern for physicians and those living with the condition. This NDA submission is a critical milestone for Takeda and our partner Lundbeck, demonstrating our commitment to those living with and treating this condition,” said Azmi Nabulsi, M.D., M.P.H., president of Takeda Global Research & Development Center, Inc. “Together, we are focused on patients’ needs and believe that the profile of vortioxetine may translate into therapeutic benefits that help in the treatment of depression.”

“We are encouraged by the data results that indicate the potential for vortioxetine, if approved, to help address the needs of people suffering from major depressive disorder who are seeking additional therapeutic options,” said Anders Gersel Pedersen, executive vice president and head of Research & Development at Lundbeck. “The vortioxetine NDA represents an important step in the evaluation of a potentially new treatment option for this debilitating disease. We look forward to working with the FDA as they review the data package.”

Depression was the third leading contributor to the global burden of disease in 2004, and is projected by WHO to be the leading contributor to the worldwide burden of disease by 2030. MDD can be described as a complex syndrome of emotional, cognitive and somatic symptoms, which can be chronic or recurrent, and impact people both mentally and physically. Symptoms can include feelings of sadness, anxiety, loss of interest in activities, decreased energy, impaired sleep, impaired concentration, forgetfulness and indecisiveness, hopelessness, guilt, persistent physical symptoms such as digestive disorders, and in more severe cases, suicidal thoughts and suicide attempts.
About vortioxetine (Lu AA21004)

Vortioxetine is under investigation as a multimodal antidepressant that is thought to work through a combination of two mechanisms of action: receptor activity modulations and reuptake inhibition. In vitro studies indicate that vortioxetine is a 5-HT_3 and 5-HT_7 receptor antagonist, 5-HT_1B receptor partial agonist, 5-HT_1A receptor agonist and inhibitor of the serotonin transporter (SERT). In vivo non-clinical studies have demonstrated that vortioxetine enhances levels of the neurotransmitters serotonin, noradrenaline, dopamine, acetylcholine and histamine in specific areas of the brain.

Across the doses of 5-20mg, the most commonly observed adverse reactions in MDD patients treated with vortioxetine in placebo-controlled studies (incidence ≥5%) were: nausea, constipation and vomiting. Overall, 6.5% of the patients who received vortioxetine discontinued treatment due to an adverse reaction, compared with 3.8% of placebo-treated patients in these studies. Nausea was the most common adverse reaction reported as a reason for discontinuation and considered to be drug-related.

Takeda and Lundbeck alliance
In September 2007, Lundbeck and Takeda formed a strategic alliance for the exclusive co-development and co-commercialization in the United States and Japan of several compounds in Lundbeck's pipeline for mood and anxiety disorders. The partnership initially focuses on co-development and co-commercialization of the two most advanced compounds in Lundbeck's pipeline for mood and anxiety disorders, vortioxetine and tedatioxetine (Lu AA24530). If approved, the companies plan to co-promote the products in the United States and Japan.

About Lundbeck
H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company highly committed to improving the quality of life for people suffering from brain disorders. For this purpose, Lundbeck is engaged in the research, development, production, marketing and sale of pharmaceuticals across the world. The company’s products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy and Huntington’s, Alzheimer’s and Parkinson’s diseases. Lundbeck’s U.S. business is based in Deerfield, Illinois. To learn more about Lundbeck in the U.S., visit www.lundbeckus.com.

Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark. Today Lundbeck employs approximately 6,000 people worldwide. Lundbeck is one of the world’s leading pharmaceutical companies working with brain disorders. In 2011, the company's revenue was DKK 16.0 billion (approximately EUR 2.2 billion or USD 3.0 billion). For more information, please visit www.lundbeck.com.

About 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 disease treatments and seek to bring innovative products to patients through a pipeline that includes compounds in development for diabetes, 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.

Contacts

Sally Benjamin Young
Public Affairs
Lundbeck LLC
947-282-5770

Palle Holm Olesen
Chief Specialist, Head of Investor Relations
H. Lundbeck A/S
palo@lundbeck.com
+45 36 43 24 26

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

Josephine Zammuto
Corporate Communications
Takeda Global Research & Development Center, Inc.
224-554-2795

###