The study was a multi-national, randomized, double-blind, placebo-controlled, active-reference, fixed-dose study in elderly patients (n=452) with recurrent MDD, assessing the efficacy and tolerability of Lu AA21004 5 mg/day. The primary endpoint was mean change from baseline in the 24-item Hamilton Depression Rating Scale (HAM-D24) total score, a measure of the severity of MDD. These patients, aged 65 years or older, with a current major depressive episode (MDE) of at least 4-week duration, at least one previous MDE before the age of 60 years, a MADRS total score of 26 or more and a Mini Mental State Examination score of <24, were randomly assigned (1:1:1) to Lu AA21004 5 mg/day, duloxetine 60mg/day (active reference), or placebo for 8 weeks.
Withdrawal rates due to adverse events were 5.8% (Lu AA21004) and 2.8% (placebo). Nausea was reported with a significantly higher incidence for Lu AA21004 (21.8%) than for placebo (8.3%).

**About Lu AA21004**
Lu AA21004 is under investigation as a multimodal anti-depressant that is thought to work through a combination of two complementary mechanisms of actions: receptor activity modulation and reuptake inhibition.

In vitro studies indicate that LuAA21004 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 SERT. In vivo non-clinical studies have demonstrated that LuAA21004 modulates neuronal firing and neurotransmitter release in multiple systems, resulting in enhanced levels of serotonin, noradrenaline, dopamine, acetylcholine and histamine in specific areas of the brain.

**About depression**
Depression is a very common, debilitating illness affecting around 121 million people worldwide, according to the World Health Organization (WHO). Depression was the leading cause of disability and the fourth leading contributor to the global burden of disease in 2000. According to the National Alliance on Mental Illness (NAMI), depression affects more than 6.5 million of the 35 million Americans aged 65 years or older.

The symptoms of depression can be chronic or recurrent, and impact patients both mentally and physically. Symptoms can include feelings of sadness, anxiety, loss of interest in activities, decreased energy, impaired sleep, impaired concentration or indecisiveness, hopelessness, guilt, persistent physical symptoms such as pain and digestive disorders, and in more severe cases, suicidal thoughts and suicide attempts.

**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 the treatment of 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, Lu AA21004 and Lu AA24530. If approved, the companies will 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](http://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.tpna.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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