



Release No 314

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## **Lu AA21004 for the treatment of mood and anxiety disorders enters into clinical phase III**

H. Lundbeck A/S and Takeda Pharmaceutical Company Limited today announced the advancement of Lu AA21004 for the treatment of mood and anxiety disorders into clinical phase III. Based on the positive clinical phase II data, the first patient in a phase III study in major depressive disorder has been enrolled.

The clinical phase III program will consist of several clinical studies that will be conducted at investigational sites around the world. More than 2,000 patients are expected to be enrolled in the clinical phase III program.

Lu AA21004, discovered by Lundbeck and being jointly developed by Lundbeck and Takeda, belongs to a new chemical class having a mode of action that is different from currently marketed antidepressants. In the clinical phase II study, Lu AA21004 showed highly significant improvements on the primary efficacy endpoints for both 5 and 10 mg doses compared to placebo and had an attractive safety profile.

"Lu AA21004 is the most advanced project in our portfolio of new and innovative compounds for the treatment of mood and anxiety disorders, all of which have the potential to treat unmet patient needs", said Senior Vice President Anders Gersel Pedersen, head of Development at Lundbeck. "Our collaboration with Takeda is working very well and we look forward to advancing the development of Lu AA21004 with Takeda."

Lundbeck and Takeda formed an alliance in September 2007 to develop and commercialize a portfolio of novel compounds in the US and Japan for the treatment of mood and anxiety disorders, including Lu AA21004 and Lu AA24530, which is in clinical phase II development.

"We are pleased with the continued positive results from the Lu AA21004 development program which is under collaboration with Lundbeck," said Dr. Masaomi Miyamoto, General Manager of the Pharmaceutical Development Division of Takeda. "Advancing this compound for the treatment of mood and anxiety disorders to Phase III represents a



significant achievement in Takeda's enhancement of our R&D pipeline in the central nervous system field."

Lundbeck will receive a milestone payment from Takeda of USD 40 million in connection with the advancement of Lu AA21004 into clinical phase III. The payment will be booked by Lundbeck as other revenue in the fourth quarter of 2007.

Excluding non-recurring items like the payment from Takeda the content of this release will have no influence on the Lundbeck Group's financial forecast for 2007.

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### **About Takeda**

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. Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com).

### **About Lundbeck**

H. Lundbeck A/S is an international pharmaceutical company engaged in the research and development, production, marketing and sale of drugs for the treatment of psychiatric and neurological disorders. In 2006, the company's revenue was DKK 9.2 billion (approximately EUR 1.2 billion or USD 1.6 billion). The number of employees is approximately 5,300 globally. For further information, please visit [www.lundbeck.com](http://www.lundbeck.com)