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Lu AA24530 shows positive results in major depressive disorder phase II study

H. Lundbeck A/S (Lundbeck) today announced positive headline results from a dose finding clinical trial with the compound Lu AA24530 for the treatment of major depressive disorder (MDD).

The primary objective of the study was to compare the efficacy of three doses of Lu AA24530, 5, 10 and 20 mg, to that of placebo in terms of change from baseline on the Montgomery- Åsberg Depression Rating Scale (MADRS) total score after six weeks of treatment in patients with MDD. Duloxetine was included as an active reference compound in the trial.

Lu AA24530 consistently produced statistically significant improvements on the primary efficacy endpoint and on key secondary endpoints. The active reference compound, duloxetine, also produced significant improvement compared to placebo, thereby validating the study. This trial also demonstrated that Lu AA24530 was well-tolerated. Drop-out rates due to serious adverse events were low in groups treated with Lu AA24530 and were similar to those of duloxetine.

"These findings demonstrate the potential value of Lu AA24530 in the treatment of major depressive disorders", says Executive Vice President Anders Gersel Pedersen, Head of Drug Development at Lundbeck. "We are pleased with the combination of efficacy and good tolerability for Lu AA24530 which clearly supports the development of the compound as a future treatment option for physicians and patients."

About the study

The clinical trial was the first study to test the efficacy of the drug in patients with MDD. It was designed as a multicenter, double-blinded, dose-finding trial and included 652 patients with major depression. Three doses of Lu AA24530 that were predicted to be efficacious based on pre-clinical and phase I data were used in the trial (5, 10 and 20 mg) and 60 mg duloxetine was used as active reference.

The primary endpoint was the difference in change from baseline to end of treatment on the MADRS total score after six weeks of daily treatment. The secondary endpoints included response rate, remission rate, HAM-D₁₇, Clinical Global Impression (CGI), quality of life and safety and tolerability.

Financial guidance

The content of this release will have no influence on the Lundbeck Group's financial result for 2009.



About Lu AA24530

In pre-clinical studies, Lu AA24530 has demonstrated activities as a monoamine enhancer with reuptake inhibition at monoamine transporters, and antagonist activity at 5-HT₃ and 5-HT_{2c} receptors. In vivo rat studies have demonstrated that treatment with Lu AA24530 leads to increases in acetylcholine (ACh), noradrenaline (NA), dopamine (DA) and 5-HT levels in brain regions that play a key role in the regulation of mood.

About depression

Depression is a very common, debilitating illness affecting around 121 million people worldwide. Major depression is not at all recognised by society as the serious disorder it actually is. The symptoms of depression can be chronic or recurrent, and impact patients both mentally and physically. Depression has a significant impact on patient quality of life and imposes a considerable burden on society, yet it is still under-recognised and under-treated.

Symptoms include feelings of sadness, anxiety, loss of interest in activities, decreased energy, impaired sleep, impaired concentration, 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, H. Lundbeck A/S and Takeda Pharmaceutical Company Limited 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. Once approved, the companies will co-promote the products in the United States and Japan.



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About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company highly committed to improve the quality of life for people suffering from central nervous system (CNS) disorders. For this purpose Lundbeck is engaged in the research and development, production, marketing and sale of pharmaceuticals across the world, targeted at disorders like depression and anxiety, schizophrenia, insomnia, Huntington's, Alzheimer's and Parkinson's diseases.

Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark, and employs today over 5,500 people worldwide. Lundbeck is one of the world's leading pharmaceutical companies working with CNS disorders. In 2008, the company's revenue was DKK 11.3 billion (approximately EUR 1.5 billion or USD 2.2 billion). For more information, please visit www.lundbeck.com.