



Press release

For international media only

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Lundbeck to present clinical and pre-clinical data on Brintellix® (vortioxetine) at the American Psychiatric Association (APA) 167th Annual Meeting

- 13 posters presentations of pre-clinical and clinical data for vortioxetine (Brintellix®)
- The clinical data represent outcome from over 4,000 total patients
- The Annual Meeting will be held in New York City, USA on 3-7 May 2014
- Brintellix® (vortioxetine) was approved by the FDA in October 2013 and the European Commission in December 2013; the product has been launched in the U.S.

H. Lundbeck A/S (Lundbeck) announced today that clinical and pre-clinical data highlighting the company's ongoing commitment to advancing the science and treatment of depression will be presented at the American Psychiatric Association (APA) 167th Annual Meeting in New York City, USA on 3-7 May 2014. In total, there will be 13 poster presentations on pre-clinical and clinical data of vortioxetine (Brintellix®), and covering efficacy and tolerability results, both in long term studies as well as across distinct patient populations. The abstracts are embargoed until Saturday, 3 May at 8 AM (EST) and will be posted on the APA website at <http://annualmeeting.psychiatry.org/scientific-program/scientific-program>.

Brintellix® was approved by the U.S. Food and Drug Administration (FDA) for the treatment of Major Depressive Disorders in adults and by the European Commission for the treatment of adults with Major Depressive Episodes, commonly referred to as depression. More recently, the Australian Therapeutic Goods Administration (TGA) approved Brintellix® for the treatment Major Depressive Disorders in April 2014.

Clinical data:

Poster NR6-106: A Phase 3, Long-Term, Open-Label Extension Study Evaluating the Safety and Tolerability of vortioxetine in Subjects with Major Depressive Disorder

Authors: Jacobsen PL, Harper L, Serenko M, Chan S, Mahableshwarkar AR.

Poster NR6-105: Which Cognitive Domains are Improved by Treatment with vortioxetine?

Authors: Harrison JE, Lophaven S, Olsen CK.

Poster NR6-112: A Meta-Analysis of the Efficacy of vortioxetine in Patients with Major Depressive Disorder (MDD) and High Levels of Anxiety Symptoms

Authors: Baldwin DS, Ménard F, Loft H, Chen Y, Mahableshwarkar AR.

Poster NR6-130: Efficacy of vortioxetine vs Placebo in Adults with Major Depressive Disorder: Meta-Analyses of MADRS Single Items from 9 Short-Term Studies

Authors: Thase ME, Mahableshwarkar AR, Dragheim M, Loft H.

Poster NR6-114: Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy of vortioxetine in Adult Patients with Major Depressive Disorder (MDD)

Authors: McIntyre RS, Lophaven S, Olsen CK.

Poster NR6-118: Efficacy and Tolerability of vortioxetine vs agomelatine is independent of Previous Treatment in MDD Patients Switched After an Inadequate Response

Authors: Papakostas G, Nielsen RZ, Dragheim M.

Pre-clinical data:

Poster NR6-086: Vortioxetine: Exploratory Analysis of the Relation Between Target Engagement and Integrated Clinical Database Analysis of Single MADRS Scale Items

Authors: Areberg A, Mahableshwarkar AR, Sánchez C.

Poster NR6-111: Vortioxetine-Induced Recovery of Memory Impairment in Old Mice is Associated with Activation of Synaptic Plasticity Genes But Not Neurogenesis

Authors: Li Y, Abdourahman A, Tamm JA, Sánchez C, Gulinello M.

Poster NR6-132: Role of the Novel Multimodal-Acting Antidepressant vortioxetine in Regulation of Synaptic Marker Expression and Dendritic Branching

Authors: Waller J, Li Y, du Jardin KG, Wegener G, David DJ, Sánchez

Poster NR6-122: Vortioxetine Produces Acute and Sustained Enhancement of Monoaminergic Neurotransmission through 5-HT Receptor Modulation and 5-HT Transporter Inhibition

Authors: Pehrson A, Sánchez C.

Poster NR6-127: Histamine and Cognition: Chronic Treatment with the Multimodal Acting Antidepressant vortioxetine Activates the Central Histaminergic System in Rats

Authors: Smagin GN, Song D, Budac DP, Pehrson A, Li Y, Sánchez, C.

Poster NR6-125: Vortioxetine, a Multimodal-Acting Antidepressant with Distinct Pharmacological

Properties – A Comparative Preclinical Study vs. SRIs

Authors: Sánchez C, Dale E, Li Y, Leiser SC, Gulinello M.

Poster NR8-101: Vortioxetine Produces Acute and Sustained Enhancement of Monoaminergic Neurotransmission through 5-HT Receptor Modulation and 5-HT Transporter Inhibition

Authors: Mørk A, Pehrson A, Bétry C, Haddjeri H, Sánchez C.

Contacts

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About Brintellix® (vortioxetine)

Brintellix® is an inhibitor of serotonin (5-HT) reuptake and is also an agonist at 5-HT_{1A} receptors, a partial agonist at 5-HT_{1B} receptors and an antagonist at 5-HT₃, 5-HT_{1D} and 5-HT₇ receptors. Brintellix® is considered to be the first and only compound with this combination of pharmacodynamic activity, although the mechanism of the antidepressant effect of Brintellix® is not fully understood and has not been established.

Brintellix® was discovered by Lundbeck researchers in Copenhagen, Denmark. The clinical trial program in the U.S. was conducted jointly by Lundbeck and Takeda, and Takeda holds marketing authorization for the U.S. market. Brintellix® is a trademark of H. Lundbeck A/S and is used under license by Takeda Pharmaceuticals America, Inc.

The World Health Organization has issued an Anatomical Therapeutic Chemical (ATC) code for Brintellix® that places it in the category of "Other" antidepressants.

About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of approximately DKK 15 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

For further information please visit www.lundbeck.com.