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Press release

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New study results demonstrate Brintellix® (vortioxetine) is efficacious in Asian patients suffering from depression

Brintellix® meets primary efficacy end-point in SOLUTION study, treating depression in Asian patients.

H. Lundbeck A/S (Lundbeck) announced results of the SOLUTION trial conducted in Asian patients suffering from Major Depressive Disorder (MDD), more commonly referred to as depression. In this head-to-head study, Brintellix® (vortioxetine) was at least as efficacious as venlafaxine on the primary efficacy endpoint was better tolerated than venlafaxine. The data, one of the 15 Brintellix abstracts accepted for presentation at the Congress of the International College of Neuropsychopharmacology (CINP) have been presented for the first time during a poster session (P-42-33 Depression C) on the 25th of June at 5:15pm PDT.

The study demonstrated that, after 8 weeks of treatment, Brintellix-treated patients (n=209) achieved substantial reductions (improvements) of depressive symptoms: -19.4 points on the Montgomery–Åsberg Depression Rating Scale (abbreviated MADRS) total score. The MADRS is one of the most commonly-used rating scales which psychiatrists use to measure the severity of depressive symptoms in patients suffering from depression.

“We are now pleased to also document the effect of Brintellix in an Asian population suffering from depression, further emphazing Brintellix as an effective antidepressant. In Asia, depression is rapidly increasing. The findings from this study address the needs of Asian adults suffering from depression and will be included in the ongoing regulatory filings for Brintellix in Asia” said Anders Gersel Pedersen, Executive Vice President Research and Development at Lundbeck.

About the study

The objective of this 8 week study was to compare efficacy and tolerability of vortioxetine 10mg/day and venlafaxine XR 150mg/day in patients with Major Depressive Disorder from four Asian countries, China, South Korea, Taiwan and Thailand. A total of 437 adult patients with a MADRS total score ≥26 were treated (211 vortioxetine, 226 venlafaxine).
Non-inferiority was established with a mean difference to venlafaxine of -1.20 points in favor of Brintellix (mean change from baseline in MADRS total score at Week 8, with 95% CI: -3.03 to -0.63). Brintellix and venlafaxine demonstrated similar improvements on the pre-defined secondary end-points, the Hamilton Anxiety rating scale (HAM-A), the Sheehan Disability Scale (SDS) total scores, the Clinical Global Impression (CGI) scale and the Quality of life enjoyment and satisfaction questionnaire (Q-LES-Q) scores, as well as on response and remission rates.
Fewer Brintellix than venlafaxine patients withdrew for any reason (18.0% versus 27.4%) or for adverse events (6.6% vs 13.7%). The most frequent AEs for vortioxetine were nausea, dizziness, dry mouth, and decreased appetite.

The FDA approved Brintellix on September 30, 2013 for the treatment of Major Depressive Disorder in adults. Brintellix was also approved in December 2013 by the European Commission for the treatment of adults with Major Depressive Episode commonly referred to as depression. More recently, the Australian Therapeutic Goods Administration (TGA) approved Brintellix for the treatment of Major Depressive Disorders in April 2014.

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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-HT_3, 5-HT_{1D} and 5-HT_7 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.

Vortioxetine 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.