Press release

Valby, 18 October 2022

New study presented at ECPN 2022 finds that vortioxetine improves depressive symptoms and cognitive function in patients with Major Depressive Disorder and co-morbid dementia

H. Lundbeck A/S (Lundbeck) announced positive data showing Trintellix/Brintellix® (vortioxetine) significantly reduced depressive symptoms and improved cognitive performance in people living with Major Depressive Disorder (MDD) and co-morbid dementia. This data was presented at the 35th European College of Neuropsychopharmacology (ECNP) Congress, October 15-18, 2022, in Vienna, Austria.

"MDD is a risk factor for developing dementia, and dementia is an aggravating factor for MDD. Both are clinical conditions with high unmet need and commonly occur as co-morbidities[1]," says Johan Luthman, Executive Vice President, Research and Development at Lundbeck. "We are pleased to share data which reinforces the safety and efficacy of vortioxetine on depressive symptoms and sheds new light on its potential to improve cognitive performance in adults aged 55 and older living with MDD and co-morbid early dementia."

MEMORY study results met the primary endpoint, showing significant improvement in symptoms of depression as measured by the Montgomery-Åsberg Depression Rating Scale (MADRS). MEMORY study results demonstrated a clinically meaningful[2] reduction of 12.4 points from the baseline to week 12 ($p<0.0001$).

Secondary endpoints in the study measuring cognitive performance were also met, as shown by significant and clinically relevant improvements in the Digit Symbol Substitution Test (DSST); a measure of attention, working memory, learning ability, and processing speed, and the Rey Auditory Verbal Learning Test (RAVLT); a measure verbal memory. The specific improvement as measured from baseline in standardized effect sizes were:

- Digit Symbol Substitution Test (DSST): Week 4=0.52 ($p<0.0001$) and Week 12=0.65, $p<0.0001$
- Rey Auditory Verbal Learning Test (RAVLT) immediate recall: Week 4=0.26, $p=0.0361$; Week 12=0.28, $p=0.0176$
- RAVLT delayed recall: Week 4=0.32, $p=0.0047$; Week 12=0.33, $p=0.0062$

Significant improvement in patients' health-related quality of life as measured by the Bath Assessment of Subjective Quality of Life in Dementia (BASQID) was also observed from week four (change from baseline in total score = 4.4; $p<0.0001$) and increasing in effect until week 12 (change from baseline = 10.2; $p<0.0001$).

Safety and tolerability data reported in the study were consistent with data from the pivotal development program of vortioxetine, confirming the tolerability profile of the compound.

Depression and dementia commonly co-occur. Depression occurs in approximately 20–30% of patients with Alzheimer's disease and is even more prevalent in patients with vascular dementia and dementia with Lewy bodies[1]. Patients with depressive symptoms have a 1.2–2.4x higher risk of developing dementia than those without depressive symptoms[2-6]. The presence of depressive symptoms in dementia worsens patient outcomes, resulting in increased mortality rates,[7] greater functional impairment,[8] worse health-related quality of life,[8] decreased cognitive function[9] and increased Behavioural and Psychological Symptoms of Dementia[10].

More information about the study and Lundbeck at ECNP 2022 can be viewed here.

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About the MEMORY study

The study was a 12-week interventional, open-label effectiveness study of flexible doses of vortioxetine (5-20 mg) with a primary objective to investigate the effect on depressive symptoms in patients with MDD comorbid with early dementia. The study was conducted at 24 sites in a psychiatric outpatient setting across five countries: Estonia, France, Italy, Poland, and Spain. In total, 83 patients were enrolled in the MEMORY study and had a primary diagnosis of recurrent MDD (with onset before the age of 55) and comorbid diagnosis of early dementia (with onset at least 6 months before screening and after already being diagnosed with MDD). Patients were treated open-label with 5 mg vortioxetine once daily for the first week, and then up-titrated to 10 mg/day at week one. Thereafter the dose could be adjusted to according to the patient's response. From week eight till week 12, 43% of the patients were treated with 10 mg and 51% with 20 mg.

About vortioxetine

The mechanism of the antidepressant effect of vortioxetine is not fully understood. It is an inhibitor of serotonin (5-HT) reuptake and that is thought to be a mechanism of its action. It 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. The contribution of each of these activities to vortioxetine's antidepressant effect has not been established. Vortioxetine is considered to be the first and only compound with this combination of pharmacodynamic activity. The clinical relevance of this is not fully understood. Vortioxetine was discovered by Lundbeck researchers in Copenhagen, Denmark. Depending on the market, vortioxetine is known as Trintellix® or Brintellix®.

About Lundbeck

Lundbeck is a global pharmaceutical company specialized in brain diseases. For more than 70 years, we have been at the forefront of neuroscience research. We are tirelessly dedicated to restoring brain health, so every person can be their best.

We are committed to fighting stigma and discrimination against people living with brain diseases and advocating for broader social acceptance of people with brain health conditions. Our research programs tackle some of the most complex challenges in neuroscience, and our pipeline is focused on bringing forward transformative treatments for brain diseases for which there are few, if any therapeutic options.

For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us on Twitter at @Lundbeck and via LinkedIn.

Citations

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