Press release

Valby, 22 April 2021

Vortioxetine significantly improves overall functioning in a global real-world study in Major Depressive Disorder

In a new real-world study, the ability of Trintellix/Brintellix® (vortioxetine) to improve functioning in family, social, and work life for people living with Major Depressive Disorder was assessed. The trial included 994 patients and shows a significant improvement in overall functioning after three months and sustained and further improved over a six-month period.

H. Lundbeck A/S (Lundbeck) announces positive results from the RELIEVE (real world effectiveness of vortioxetine) study, demonstrating the ability of Trintellix/Brintellix® (vortioxetine) to improve the daily life of people living with Major Depressive Disorder (MDD) when measured using the Sheehan Disability Scale (SDS). The SDS measures the impairment patients see in their life in areas of family, social life, home responsibilities, and work or school.

RELIEVE is a global, prospective, observational study conducted in patients with MDD prescribed vortioxetine aiming to assess the real-life effectiveness of vortioxetine. Data were collected at routine clinical visits at baseline, 3 months and 6 months. A total of 994 patients were recruited into the study.

Key results from RELIEVE show significant and meaningful improvements by 6.9 points and 8.6 points respectively after 3 and 6 months on the SDS compared to prior antidepressant treatment. An improvement equal to or greater than 4 points on the SDS total score is considered to represent a meaningful improvement for patients[i].
The study provides novel insights by focusing on patient's own assessment of their functioning in daily life and their experienced improvement after being treated with Trintellix/Brintellix®.

"The strong results from this trial show that patients treated with Trintellix/Brintellix experience a significant improvement in overall functioning over a substantial period of six months. I think it is an interesting aspect that this study specifically shows an effect of Trintellix/Brintellix on family, work and social life functioning. At the end of the day, we want to be able to restore brain health, so people can be at their best," says Johan Luthman, Executive Vice President for Research and Development at Lundbeck.

A Real-World Evidence study like RELIEVE represents a patient centric way of assessing MDD-treatments. Real-World Evidence is increasingly important in determining effectiveness outside of the strict conditions of Randomized Controlled Trials and may provide an

alternative source of data to help contextualize the value of medicine from the patient's perspective.

Secondary and exploratory endpoints also met

The trial also met its secondary endpoints measuring effect on health-related quality of life, depressive symptoms, and cognitive symptoms. There was a significant improvement in health-related quality of life for patients on vortioxetine as measured by the EQ-5D utility score. The improvement on the EQ-5D utility score was 0.13. The EQ-5D score ranges between 0-1.

Depressive symptoms were also reduced with a 7.4 decrease from baseline in depressive symptoms as measured by the PHQ-9 (Patient Health Questionnaire-9) scale.
When measuring cognitive symptoms using the PDQ-D-5 (Perceived Deficit Questionnaire – Depression) scale, there was 4.6 points decrease from baseline. Improvement in cognitive performance was also observed with 6.1 points increase using the neuropsychological test Digital Symbol Substitution Test (DSST).

The study also met its exploratory endpoints, focusing on productivity. When looking at workdays lost due to MDD, treatment with vortioxetine led to a decrease in 1.1 lost workdays from 2.2 days per week at baseline and 2.2 decrease in unproductive days from 4.0 days per week at baseline over six months.

In addition, safety data was consistent with data collected in clinical trials, confirming the tolerability profile of vortioxetine in a real-world setting. The full results will be published in a peer-reviewed scientific journal in 2021 and will also be presented at future medical conferences.

Contacts

Mikkel Ballegaard Pedersen
Media Relations Specialist, Corp. Communication
mbap@lundbeck.com
+45 30 83 20 44

Thomas Mikkel Mortensen
Media Relations Lead, Corp. Communication
thmr@lundbeck.com
+45 30 83 30 24

About the RELIEVE study

RELIEVE was a global, prospective, single-arm, observational study conducted in patients with Major Depressive Disorders (MDD) prescribed vortioxetine aiming to assess the real-life effectiveness of vortioxetine. Eligible subjects for the study were MDD patients initiating treatment with vortioxetine or switching from another antidepressant for the current major depressive episode. The primary endpoints were changes from baseline to Week 12 and Week 24 in the total score in Sheehan Disability Scale (SDS). Other key endpoints included changes from baseline to Week 12 and 24 in the PHQ-9 (Patient Health Questionnaire-9), PDQ-D-5 (Perceived Deficits Questionnaire-Depression), DSST (Digit Symbol Substitution Test) questionnaires. Data were collected at routine clinical visits at baseline, 3 months and 6

months. A total of 994 patients were recruited in the study in Canada, United States, France, and Italy, with 737 patients completing at least one assessment. Comparable improvements were observed in all countries where the study was conducted. The RELIEVE study represents one of the largest international real-world evidence studies being conducted in recent times within Major Depressive Disorder.

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. It is considered to be the first and only compound with this combination of pharmacodynamic activity. The clinical relevance of this is unknown. Vortioxetine was discovered by Lundbeck researchers in Copenhagen, Denmark. Depending on the market, vortioxetine is known as Trintellix® or Brintellix®.

About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) 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.

Millions of people worldwide live with brain diseases and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary consequences. Every day, we strive for improved treatment and a better life for people living with brain diseases – we call this Progress in Mind.

Our approximately 5,600 employees in more than 50 countries are engaged in the entire value chain throughout research, development, production, marketing and sales. Our pipeline consists of several R&D programs and our products are available in more than 100 countries. We have research centers in Denmark and the US, and our production facilities are located in Denmark, France and Italy. Lundbeck generated revenue of DKK 17.7 billion in 2020 (EUR 2.4 billion; USD 2.7 billion).

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.

---

[i] Sheehan KH, Sheehan DV. Assessing treatment effects in clinical trials with the discan metric of the Sheehan Disability Scale. Int Clin Psychopharmacol. 2008 Mar;23(2):70-83.