Vortioxetine demonstrates advantage on daily and social functioning vs. desvenlafaxine in a large head-to-head study

- The study assessed the efficacy of vortioxetine in a head-to-head comparison to desvenlafaxine in patients suffering from Major Depressive Disorder (MDD) who had a partial response to selective serotonin reuptake inhibitors (SSRI) treatment.
- The primary study objective was achieved by demonstrating non-inferiority of vortioxetine to desvenlafaxine on depression symptom reduction (MADRS).
- On secondary endpoints, vortioxetine-treated patients were significantly more likely to reach global clinical remission (CGI-S), experience a significant improvement in their daily and social functioning (FAST), as well as experience significant effect on treatment satisfaction compared to desvenlafaxine as measured by Q-LES-Q.

H. Lundbeck A/S (Lundbeck) recently completed a global Phase IV, randomized, comparative study exploring the role of vortioxetine as a treatment option between SSRIs and serotonin–noradrenaline reuptake inhibitors (SNRIs). The efficacy of vortioxetine was directly compared to one of the latest introduced SNRIs, desvenlafaxine, as monotherapy. The study, called VIVRE, recruited a total of 605 patients across 12 countries at sites in Europe and South America who were suffering from MDD and had a partial response to treatment with an SSRI for at least 6 weeks at approved dose. The VIVRE study took place from mid-2020 to early 2022 and is one of the rare examples of Phase IV head-to-head studies in MDD.

Vortioxetine demonstrated non-inferiority to desvenlafaxine on the primary study endpoint as measured by Montgomery–Åsberg Depression Rating Scale (MADRS) with a treatment difference of -0.47 on the MADRS total score (confidence limit [-1.61, 0.67]) in favor of vortioxetine, meeting a predefined non-inferiority criterion.

Importantly, the VIVRE study demonstrated that vortioxetine provided significant benefits vs desvenlafaxine in the secondary endpoints including remission, daily and social functioning, and satisfaction with medication.

A significantly higher percentage of vortioxetine treated patients were in remission (33% versus 25% for desvenlafaxine, p-value 0.0339) at the end of the study, as measured by the Clinical Global Impression rating for the Severity of Illness (CGI-S) scale. The CGI rating measures the decrease in the severity of depressive symptoms as they relate to patient’s functioning.

This is highly relevant as the VIVRE study identified two domains of overall functioning in which vortioxetine treated patients showed significantly better outcome – daily functioning (also known as autonomy) and social functioning (or interpersonal skills) versus patients.
treated with desvenlafaxine (p-value 0.0092 and 0.0448, respectively). These results were obtained using the Functioning Assessment Short Test (FAST), which is a physician-rated scale assessing the main functioning problems experienced by patients.

Finally, in these patients with partial response to prior SSRI therapy the average treatment satisfaction at baseline was 40.2%. Employing the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q), the study revealed that patients who received vortioxetine reported a significant increase in the Satisfaction with Medication compared to patients treated with desvenlafaxine (27% vs 24% respectively, p-value 0.0438).

On other study outcomes, vortioxetine showed advantage or comparable effects to desvenlafaxine.

Overall, the study was confirming the previously reported tolerability profiles for vortioxetine and desvenlafaxine.

“This study clearly demonstrates that a vulnerable patient subpopulation, namely patients suffering from MDD, but only partially responsive to SSRIs, are offered important clinical benefits when treated with Trintellix/Brintellix® (vortioxetine) compared to SNRI treatment. Using objective assessments, the secondary endpoints in the study show a significantly better efficacy of Trintellix/Brintellix® versus desvenlafaxine on remission, as well as daily and social functioning says Johan Luthman, Executive Vice President for Research and Development at Lundbeck.

The results of the study will be presented at The American Society for Clinical Pathology (ASCP) congress taking place in Arizona, USA from May 31-June 3 this year.

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About the VIVRE study

VIVRE was a global phase IV head-to-head randomized comparative study evaluating the efficacy of vortioxetine versus desvenlafaxine on depressive symptoms, rewards motivation, cognitive performance, and health-related quality of life (HRQoL) in patients with MDD with a partial response to SSRIs treatment in a psychiatric outpatient setting. The study enrolled a total of 605 patients (f/m, aged 18–65 years) at sites in Europe and South America with a primary diagnosis of a major depressive episode (3–12 months in duration). Eligible participants had a Montgomery-Åsberg Depression Rating Scale (MADRS) score ≥24 (moderate to severe depression) at baseline and had previously received SSRI monotherapy at the approved dose for ≥6 weeks. The patients were randomized (1:1) to double-blind vortioxetine or desvenlafaxine treatment for 8 weeks, followed by a 4-week safety follow-up
period. The starting dose of vortioxetine of 10 mg/day for the first week was increased subsequently to 20 mg/day. Dose adjustments were performed up until Week 4, based on investigator judgement at subsequent scheduled or unscheduled visits. Desvenlafaxine was dosed at 50 mg/day. The primary endpoint was improvement in depressive symptoms as assessed by change from baseline to Week 8 in MADRS total score. Secondary endpoints included clinical global impression (Clinical Global Impression - Severity of Illness (CGI-S) scores [change from baseline to Week 8] and Global Improvement (CGI-I) scores, overall functioning (change from baseline to Week 8 in Functioning Assessment Short Test total score and domains), and HRQoL (change from baseline to Week 8 in Quality of Life Enjoyment and Satisfaction Questionnaire Long Form domains). Safety and tolerability were also assessed.

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-HT1A receptors, a partial agonist at 5-HT1B receptors and an antagonist at 5-HT3, 5-HT10 and 5-HT7 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 not fully understood. Vortioxetine was discovered by Lundbeck researchers in Copenhagen, Denmark. Depending on the market, vortioxetine is known as Trintellix® or Brintellix®.

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

Too many people worldwide live with brain diseases – complex conditions often invisible to others that nonetheless take a tremendous toll on individuals, families and societies. 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. Every day, we strive for improved treatment and a better life for people living with brain disease.

We have approximately 5,300 employees in more than 50 countries, and our products are available in more than 100 countries. 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. We have research facilities in Denmark and the United States, and our production facilities are located in Denmark, France, and Italy. Lundbeck generated revenue of DKK 16.3 billion in 2021 (EUR 2.2 billion; USD 2.6 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.