



Press release

Valby, 17 June 2014

## **Brintellix<sup>®</sup> demonstrated a statistically significantly superior improvement compared to escitalopram in improving sexual functioning in well treated patients suffering from depression and experiencing treatment-emergent sexual dysfunction**

### **Lundbeck announces results at American Society of Clinical Psychopharmacology Annual Meeting**

H. Lundbeck A/S (Lundbeck) today will present results about sexual functioning from a head-to-head study of Brintellix<sup>®</sup> (vortioxetine) vs. escitalopram in patients with well treated Major Depressive Disorder (MDD, commonly referred to as “depression”) experiencing treatment-emergent sexual dysfunction (TESD). The data, accepted as a late-breaker, will be shared in a poster presentation (#41) today at 11:15 a.m. EDT.

Sexual dysfunction, induced by treatment affects the patient’s quality of life and is a common reason people taking antidepressants may choose to be less compliant with their treatments and then potentially experience relapse of depressive symptoms<sup>1</sup>. The results demonstrated that patients treated with Brintellix (n=169) experienced a statistically significant improvement, with a mean treatment difference of 2.2 points (95% CI: 0.48–4.02) in the CSFQ-14 total score after eight weeks of treatment ( $P=0.013$ ; MMRM) compared to escitalopram (n=179). The CSFQ-14 is a recognized clinical and research instrument identifying five dimensions of sexual functioning and yields scores for three phases of the sexual response cycle.

Prior to initiating the study medication, the patients were already in partial or full remission from their depression, and they maintained or slightly improved their depressive symptoms in both treatment groups after eight weeks, as measured by the Montgomery-Åsberg Depression Rating Scale (MADRS) total score and the Clinical Global Impression Severity and Improvement scales (CGI – S/I). The adverse event profile for Brintellix<sup>®</sup> was similar to that seen in previous trials, with nausea, headache, and dizziness being the most common side effects observed.

447 patients with recent major depressive episode who had responded to SSRI monotherapy - citalopram, paroxetine and sertraline (single treatment medication) but were experiencing treatment-induced sexual dysfunction were randomized to the study. Their previous treatment was discontinued and patients were switched to flexible doses of Brintellix 10-20 mg/day or escitalopram 10-20 mg/day for eight weeks (although the dose was fixed as 10 mg for week one and 20 mg for week 2 of treatment). The dose of Brintellix or escitalopram could be adjusted after week two, four, or six, as judged by the investigator. The primary endpoint was change from baseline to week 8 in the Changes in Sexual Functioning Questionnaire Short-Form (CSFQ-14) total score using mixed-effects model repeated measures approach (MMRM).

The FDA approved Brintellix on September 30, 2013 for the treatment of Major Depressive Disorder in adults. Brintellix is also approved since 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.

### **Contacts**

Mads Kronborg, Director, Media Relations  
Telephone (direct): +45 36 43 28 51

### **About Brintellix® (vortioxetine)**

Brintellix is an inhibitor of serotonin (5-HT) reuptake and is also an agonist at 5-HT<sub>1A</sub> receptors, a partial agonist at 5-HT<sub>1B</sub> receptors and an antagonist at 5-HT<sub>3</sub>, 5-HT<sub>1D</sub> and 5-HT<sub>7</sub> 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 than 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](http://www.lundbeck.com).

### **REFERENCES**

---

<sup>i</sup> Montejo AL, Llorca G, Izquierdo JA, Rico-Villademoros F. Incidence of sexual dysfunction associated with antidepressant agents: a prospective multicenter study of 1022 outpatients. Spanish Working Group for the Study of Psychotropic-Related Sexual Dysfunction. *J Clin Psychiatry* 2001;62 Suppl 3:10-21.

Roose SP. Tolerability and patient compliance. *J Clin Psychiatry* 1999;60 Suppl 17:14-7; discussion 46-8.

Rothschild AJ. Sexual side effects of antidepressants. *J Clin Psychiatry* 2000;61 Suppl 11:28-36.

Zajecka JM. Clinical issues in long-term treatment with antidepressants. *J Clin Psychiatry* 2000;61 Suppl 2:20-5.