



Press release

Valby, 16 September 2014

European launch of Brintellix commences in Denmark

Brintellix is launched as the first new antidepressant drug in five years in Denmark and will be introduced in several other European and International Markets during 2014 and 2015.

H. Lundbeck A/S (Lundbeck) has now started the launch of its novel antidepressant Brintellix (vortioxetine) in Denmark. This marks the first European launch and thereby the next step in the global introduction of Brintellix, which was commercially launched in the US in January 2014. Following the Danish launch, Brintellix, which is approved for treatment of major depressive episodes (MDE, hereafter referred to as “depression”) in adults, will be introduced in several other European and International Markets during 2014 and 2015.

This is the first time in five years that a new antidepressant drug becomes available in Denmark where 150,000 people suffer from depressionⁱ. Brintellix will be available and reimbursed in Denmark as second line treatment for depression, in line with the reimbursement dossier submitted and approved by Danish health authorities.

Brintellix is a novel multimodal antidepressant, which has demonstrated significant efficacy in adult patients with depression as measured by traditional scales like MADRS or HAMD. It has also demonstrated improvement of cognitive performance in adult patients with depression, as measured with neuropsychological tests, as e.g. DSST or RAVLTⁱⁱ. Cognitive symptoms are part of the diagnostic criteria for depression, and include the ability to concentrate, make decisions and the ability to rememberⁱⁱⁱ. Cognitive symptoms are both part of the acute depressive episode as well as often being a residual symptom of depression^{iv}. This means that patients with depression may have difficulties performing their duties at work. As a lot of people with depression are working, this loss of productivity is very costly for the society^v.

“When someone suffers from depression, the daily life of that person is severely affected, at home and in the workplace. Depression is a complex disease that involves mood, physical and cognitive symptoms. We are pleased to be able to offer a new treatment option to patients with depression,” says Ole Chrintz, Group Senior Vice President of International Markets and Europe at Lundbeck.

About Brintellix (vortioxetine)

Brintellix is an inhibitor of serotonin (5-HT) reuptake and is also an agonist at 5-HT1A receptors, a partial agonist at 5-HT1B receptors and an antagonist at 5-HT3, 5-HT1D and 5-HT7 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.

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 key areas of focus are alcohol dependence, Alzheimer's disease, bipolar disorder, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia, stroke and symptomatic neurogenic orthostatic hypotension (NOH).

An estimated 700 million people worldwide are living with brain disease 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 disease – we call this Progress in Mind.

Read more at www.lundbeck.com/global/about-us/progress-in-mind.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales. Our pipeline consists of several late-stage development programmes and our products are available in more 100 countries. We have research centres in China, Denmark and the United States and production facilities in China, Denmark, France and Italy. Lundbeck generated revenue of approximately DKK15.3 billion in 2013 (EUR2.1 billion; USD2.7 billion).

For additional information, we encourage you to visit our corporate site www.lundbeck.com.^{vi}

Contacts

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

Lars Otto Andersen-Lange, Media Relations
Telephone (direct): +45 36 43 26 57

ⁱ Danish Health and Medicines Authority, 2012.

ⁱⁱ EPAR and McIntyre R.S., Lophaven S and Olsen C. K. (2014) A randomized, double-blind, placebo-controlled study of vortioxetine on cognitive function in depressed adults. *Intl J Neuropsychopharmacol* 17 (10): 1557 - 1567.

ⁱⁱⁱ Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5).

^{iv} McClintock SM et al. (2011) Residual symptoms in depressed outpatients who respond by 50% but do not remit to antidepressant medication. *J Clin Psychopharmacol*. 31(2):180–186.

^v McIntyre R.S. et al. (2013) Cognitive deficits and functional outcomes in Major Depressive Disorder: Determinants, substrates, and treatment interventions. *Depress. Anxiety*, 30: 515–527.