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Corporate Release

US FDA accepts for review Otsuka and Lundbeck's sNDA filing for labeling update of Rexulti® (brexpiprazole) for maintenance treatment of schizophrenia

- *The safety and efficacy of Rexulti® (brexpiprazole) as maintenance treatment in adults with schizophrenia aged 18 to 65 years was demonstrated in a 52-week randomized withdrawal trial*
- *The anticipated date for the FDA to complete its review of the proposed expanded labeling is 23 September 2016*
- *Rexulti was approved by the FDA in July 2015 as a treatment for adults with schizophrenia and as an adjunctive treatment for adults with major depressive disorder (MDD)*
- *There are approximately 2.4 million adults in the US[i] with schizophrenia and around 75% of patients experience relapses where their symptoms come back or in some cases, worsen[ii]*

Valby, Denmark and Princeton, New Jersey, 8 February 2016 - H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) for the proposed labeling update of Rexulti (brexpiprazole) for the maintenance treatment of adults with schizophrenia. Under the Prescription Drug User Fee Act (PDUFA), the PDUFA date is 23 September 2016.

The sNDA is supported by results from a 52-week randomized withdrawal trial in adults with schizophrenia aged 18 to 65 years. In the trial, patients were stabilized on Rexulti and were then randomized to continued therapy with Rexulti (n=96) or placebo (n=104). The primary endpoint of the study was time from randomization to relapse. At a pre-specified interim analysis, the study demonstrated a statistically significantly longer time to relapse in patients randomized to the Rexulti group (1 mg/day to 4 mg/day) compared to placebo-treated patients and the trial was terminated early because maintenance of efficacy had been demonstrated ($p < 0.0001$, final analysis). During the randomized maintenance phase, adverse reactions were similar to those reported in the short-term schizophrenia trials.

About Rexulti (brexpiprazole)

Rexulti is a molecule discovered by Otsuka and co-developed by Otsuka and Lundbeck. The mechanism of action for Rexulti in the adjunctive treatment of major depressive disorder or schizophrenia is unknown. However, the efficacy of Rexulti may be mediated through a combination of

partial agonist activity at serotonin 5-HT_{1A} and dopamine D_2 receptors, and antagonist activity at serotonin 5-HT_{2A} receptors. Rexulti exhibits high affinity (subnanomolar) for these receptors as well as for noradrenaline alpha1B/2C receptors. The drug was approved in the US on 10 July 2015, as an adjunctive therapy to antidepressants in adults with major depressive disorder and as a treatment in adults with schizophrenia.

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About H. Lundbeck A/S

Lundbeck (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 research within neuroscience. The key areas of focus are Alzheimer's disease, depression, Parkinson's disease and psychosis.

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*.

Our approximately 5,500 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 programs and our products are available in more than 100 countries. We have research centres in China and Denmark and production facilities in China, Denmark, France and Italy. Lundbeck generated core revenue of DKK 13.5 billion in 2014 (EUR 1.8 billion; USD 2.4 billion).

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

About Otsuka America Pharmaceutical, Inc.

Otsuka America Pharmaceutical, Inc. (OAPI) is an innovative, fast-growing healthcare company that commercializes Otsuka-discovered and in-licensed products in the U.S., with a strong focus on neuroscience, oncology, cardio-renal, and medical devices. For more information, visit www.otsuka-us.com. OAPI is a subsidiary of Otsuka America, Inc. (OAI), a holding company established in the U.S. in 1989. OAI is wholly owned by Otsuka Pharmaceutical Co., Ltd., a global healthcare company with the corporate philosophy: 'Otsuka-people creating new products for better health worldwide.' Otsuka Pharmaceutical is a leading firm in the challenging area of mental health and also has products and research programs for several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate more powerfully than words how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does. Otsuka Pharmaceutical and its affiliates employ approximately 30,000 people globally, and the company welcomes you to visit its global website at: http://www.otsuka.co.jp/en/index.php.

Safe Harbor/Forward-Looking Statements

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

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[i] The National Alliance of Mental Illness, Mental Illness Facts and Numbers. March 2013

[ii] Smith TE1, Weston CA, Lieberman JA.: Schizophrenia (maintenance treatment); BMJ Clin Evid. 2009 Apr 16;2009