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Corporate Release

Aripiprazole once-monthly shows superior effectiveness to paliperidone palmitate once-monthly on quality of life scale in patients with schizophrenia

- *The head-to-head QUALIFY study compared the effectiveness of aripiprazole once-monthly to paliperidone palmitate once-monthly in adult patients with schizophrenia*
- *Patients treated with aripiprazole once-monthly demonstrated a statistically significant improvement on the primary endpoint, quality-of-life measure, compared to those treated with paliperidone palmitate*
- *Discontinuations due to adverse events occurred in 10.8% of patients in the aripiprazole once-monthly group compared to 18.4% of patients in the paliperidone once-monthly group*

Valby, Denmark and Princeton, N.J., U.S., 3 November 2014 - H. Lundbeck A/S (Lundbeck) and Otsuka America Pharmaceutical Inc. (Otsuka) today announced results from the *QUALIFY* study[i]; the first study of its kind comparing two atypical long-acting injectable anti-psychotic therapies in a close-to-real life setting. The effectiveness of aripiprazole once-monthly (aripiprazole extended-release injectable suspension, for intramuscular use, Abilify Maintena®) and paliperidone palmitate (paliperidone palmitate extended-release injectable suspension, for intramuscular use) in adult patients with schizophrenia was measured by the Heinrichs-Carpenter *Quality of Life Scale* (QLS; primary endpoint). QLS is clinician-rated scale designed to evaluate social functioning and behaviour in patients with schizophrenia.

The QLS is one of the most commonly used quality-of-life scales in schizophrenia clinical trials. The four domains of the QLS evaluate the patient's intrapsychic foundations (sense of purpose, motivation, emotional interaction, etc.); interpersonal relations (social activity, social network, etc.) instrumental role (work functioning, work satisfaction, etc.); and common objects and activities. Higher scores indicate better quality of life[ii]. Additional secondary assessments include the Clinical Global Impressions scales (CGI, which measures symptom severity and treatment response), and the Investigator's Assessment Questionnaire (IAQ, designed to evaluate response to antipsychotics).

In a 28 week trial, patients treated with aripiprazole once-monthly demonstrated a statistically significant improvement in the QLS total score compared to patients treated with paliperidone palmitate once-monthly. The mean difference between treatments of the change from baseline to week 28 in QLS total score was 4.4 (p=0.031) with a respective change of 7.5 for the aripiprazole once-monthly group and 3.1 for the paliperidone palmitate once-monthly group.

A difference between treatments was also confirmed by a change in the Clinical Global Impression-Severity Scale (CGI-S, used by clinicians to evaluate the severity of a patient's illness) from baseline to 28 weeks of treatment (p=0.004). Both treatments were generally well-tolerated, however discontinuation rates due to adverse events were 10.8% (n=16/148) vs. 18.4% (n=27/147), for aripiprazole once-monthly group vs paliperidone once-monthly group, respectively[iii].

About the *QUALIFY* study

QUALIFY is a randomized, open-label rater-blinded, head-to-head comparison of intramuscular aripiprazole once-monthly (400 or 300 mg/month) and intramuscular paliperidone palmitate injection (50 to 150 mg/month (EU) or 78 to 234 mg/month (US and Canada)) over 28 weeks. The study was designed as a non-inferiority study, allowing for subsequent superiority testing, if non-inferiority criterion was met. After a minimum of 3-week oral conversion period where patients received either oral aripiprazole or oral paliperidone, the intramuscular formulations were administered according to the prescribing information for five weeks and continued for 20 weeks. The primary endpoint was the QLS total score change from baseline to week 28. The study randomized 295 patients in Europe and North America of which 281 received study treatment.

The study design was presented at the New Clinical Drug Evaluation Unit (NCDEU) 53rd Annual Meeting in May 2013[iv]. Data from the *QUALIFY* study will be presented at upcoming medical congresses and in scientific publications.

About Abilify Maintena (aripiprazole once-monthly)

Abilify Maintena (aripiprazole once-monthly) is the first and only once-monthly injection of a dopamine D_2 partial agonist. It is available in a number of European countries for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole. Furthermore, it is available in the US for the treatment of schizophrenia. In Canada it is available for the maintenance treatment of schizophrenia in stabilised adult patients and in Australia for maintenance of clinical improvement in the treatment of schizophrenia.

About schizophrenia

Schizophrenia is a disease characterized by a distortion in the process of thinking and of emotional responsiveness. It most commonly manifests as hallucinations, paranoid or bizarre delusions, or disorganized speech and thinking, and is accompanied by significant social or occupational dysfunction. Onset of symptoms typically occurs in young adulthood and the condition is chronic, often requiring life-long treatment to mitigate symptoms. It has been estimated that schizophrenia affects approximately 1% of the adult population in the US, and approximately 24 million people worldwide[v], [vi]. In the US, there are approximately 2.4 million adults with schizophrenia, prevalent equally in both genders[vii],[viii]. While there is no cure for the disease, symptoms and risk of relapse—the re-emergence or worsening of psychotic symptoms[ix] — can be managed in most patients with appropriate antipsychotic treatment.

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About Otsuka America Pharmaceuticals, 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 http://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, based in Japan. The Otsuka Group employs approximately 42,000 people globally and its products are available in more than 80 countries worldwide. Otsuka welcomes you to visit its global website at https://www.otsuka.co.jp/en/.

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).

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol "HLUYY". For additional information, we encourage you to visit our corporate site www.lundbeck.com.

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] Aripiprazole Once-monthly Versus Paliperidone Palmitate in Adult Patients with Schizophrenia. ClinicalTrials.gov. 2014. Available at: https://clinicaltrials.gov/ct2/show/NCT01795547?term=NCT01795547&rank=1. Accessed on Oct. 28, 2014.

[ii] Heinrichs, D., et al. The Quality of Life Scale: An Instrument for Rating the Schizophrenic Deficit Syndrome. Schizophrenia Bulletin. 1984; 10: 388-396.

[iii] Data on File: 14724A – the QUALIFY study.

[iv] Hansen, K., Baker R., Peters-Strickland T., Forray C., Nylander AG., Eramo A.: "Assessing the Effectiveness of Aripiprazole Once-monthly vs. Paliperidone Palmitate for the Long-term Treatment of Schizophrenia". Poster from NCDEU2013

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[viii] Regier, Darrel et al. The de Facto US Mental and Addictive Disorder Service System. Archives of General Psychiatry. 1993; 50: 85-94.

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