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Corporate Release

Lundbeck and Otsuka announce decision to continue phase III clinical trial evaluating brexpiprazole for treatment of agitation in patients with Alzheimer's-type dementia

Valby, Denmark and Tokyo, Japan, 13 April 2021 - H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) announce the decision to continue the recruitment of patients in the phase III clinical trial of brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer's type (NCT03548584). The decision to continue the trial is based on the results of an independent interim analysis, supporting to progress the trial to the planned full enrollment of 330 patients.

The continuation of the study enables Lundbeck and Otsuka to further explore the efficacy of brexpiprazole to address the high medical need in patients suffering from agitation in Alzheimer's type dementia. Completion of the trial is expected in the first half of 2022.

About the study

Trial 331-14-213 (NCT03548584; Trial 213) was designed to assess the safety, tolerability and efficacy of brexpiprazole in the treatment of patients with agitation in Alzheimer's dementia. The trial consists of a continuous 12-week double-blind treatment period with a 30-day follow-up. The trial population is planned to include 330 male and female patients, aged 55–90 years, with a diagnosis of probable Alzheimer's disease.

The primary outcome is change in the Cohen-Mansfield Agitation Inventory (CMAI) Total score. The key secondary outcome measure is change in the Clinical Global Impression – Severity of Illness (CGI-S) score, as related to symptoms of agitation. Participating countries include Bulgaria, Hungary, Serbia, Slovakia, Spain, Ukraine and the U.S. Approximately half of the patients in the trial are living at home and the rest are institutionalized.

As agreed with the U.S. Food and Drug Administration (FDA), an interim analysis conducted by an independent Data Monitoring Committee was planned to assess both efficacy and futility, in accordance to pre-specified criteria, when 255 subjects had completed the trial.

About brexpiprazole

Rexulti/Rxulti (brexpiprazole) is approved as an adjunctive therapy for the treatment of adults with major depressive disorder and as a treatment for adults with schizophrenia in markets such as the U.S. and Canada. In Europe and Japan, the product is approved for schizophrenia. In addition, brexpiprazole has been approved in over 20 other countries and regions across the world. Brexpiprazole is distributed and marketed under the brand name Rexulti®. In Europe, brexpiprazole is distributed and marketed under the brand name Rxulti®.

Brexpiprazole was discovered by Otsuka and is being co-developed by Otsuka and Lundbeck. The mechanism of action for brexpiprazole in the adjunctive treatment of major depressive disorder or schizophrenia is not fully understood. However, the efficacy of brexpiprazole 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. Brexpiprazole exhibits high affinity (sub-nanomolar) for these receptors as well as for noradrenaline $alpha_{1B/2C}$ receptors.

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About H. Lundbeck A/S

H. Lundbeck A/S (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 neuroscience research. We are tirelessly dedicated to restoring brain health, so every person can be their best.

Millions of people worldwide live with brain diseases, 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 diseases – we call this *Progress in Mind*.

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

Our approximately 5,600 employees in more than 50 countries are engaged in the entire value chain throughout research, development, production, marketing, and sales. Our pipeline consists of several R&D projects, and our products are available in more than 100 countries. We have research facilities in

Denmark and the U.S., and our production facilities are located in Denmark, France, and Italy. Lundbeck generated revenue of DKK 17.7 billion in 2020 (EUR 2.4 billion; USD 2.7 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.

About Otsuka Pharmaceutical

Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: "Otsuka–people creating new products for better health worldwide." Otsuka researches, develops, manufactures, and markets innovative products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging areas of mental, renal and cardiovascular health and has additional research programs in oncology and on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka Pharmaceutical is a subsidiary of Otsuka Holdings Co., Ltd. headquartered in Tokyo, Japan. The Otsuka group of companies employed 47,000 people worldwide and had consolidated sales of approximately USD 13.3 billion in 2020.

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 considering 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.