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Corporate Release

Lundbeck and Otsuka announce U.S. Food and Drug Administration (FDA) approval of supplemental New Drug Application (sNDA) for Rexulti® (brexpiprazole) for the treatment of agitation associated with dementia due to Alzheimer's Disease

- *Rexulti is the first and only pharmacological treatment approved in the U.S. for agitation associated with dementia due to Alzheimer's disease*

Valby, Denmark, May 11, 2023 - H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical, Co. Ltd. (Otsuka) announce the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) of Rexulti® (brexpiprazole) for use in the treatment of agitation associated with dementia due to Alzheimer's disease.

This approval makes Rexulti the first and only pharmacological treatment approved in the U.S. for agitation associated with dementia due to Alzheimer's disease. Agitation is a common neuropsychiatric symptom in Alzheimer's dementia and one of the most complex and stressful aspects of caring for people living with the condition. It is reported in approximately half of people with Alzheimer's dementia and is associated with earlier nursing home placement. Rexulti is not indicated as an as needed ("prn") treatment for agitation associated with dementia due to Alzheimer's disease.

Deborah Dunsire, CEO and president, Lundbeck, said, "*This approval is a testament to our commitment and unwavering support of patients and caregivers to lessen the symptoms of agitation associated with dementia due to Alzheimer's disease. We look forward to offering this first FDA-approved treatment option to address this significant unmet need for patients. We are grateful to the patients and caregivers who participated in these important trials.*"

Makoto Inoue, president and representative director of Otsuka, commented, "*Today marks a major milestone for patients, caregivers, and families navigating the complexities of agitation associated with dementia due to Alzheimer's disease. Otsuka Pharmaceutical will continue its efforts to engage and provide options for those impacted by this devastating condition.*"

The FDA previously granted priority review for the sNDA, a designation for a drug application that represents a significant improvement in the safety and/or effectiveness of the treatment, diagnosis, or prevention of a serious medical condition.

The submission was based on two phase III, 12-week, randomized, double-blind, placebo-controlled fixed-dose studies that evaluated the frequency of agitation symptoms in patients with dementia due to Alzheimer's disease based on the Cohen-Mansfield Agitation Inventory (CMAI) total score. The primary

endpoint was a change in agitation symptom frequency (CMAI total score) from baseline at Week 12 in both studies. Brexpiprazole patients with agitation associated with dementia due to Alzheimer's disease achieved a 31% greater reduction from baseline in frequency of agitation symptoms vs. placebo.

Overall, the data showed brexpiprazole as being well-tolerated with a low incidence of discontinuations, and with a safety profile consistent with the known safety profile of brexpiprazole in other indications[3].

About agitation associated with dementia due to Alzheimer's disease

Agitation associated with dementia due to Alzheimer's disease is a common neuropsychiatric symptom that is reported in approximately half of all patients with Alzheimer's dementia. The condition has a large impact on the quality of life for the patients, family members, and caregivers[1,3].

Agitation associated with dementia covers a large group of behaviors occurring in patients with Alzheimer's disease, such as pacing, gesturing, profanity, shouting, shoving, and hitting[4]. Symptoms of agitation are also a consistent predictor of nursing home admission in patients with dementia, including those with Alzheimer's disease[5,6,7].

About Brexpiprazole

Brexpiprazole was approved in the U.S. in 2015, as an adjunctive therapy to antidepressants in adults with major depressive disorder (MDD) and as a treatment for schizophrenia in adults. Brexpiprazole was also approved by Health Canada for schizophrenia and adjunctive treatment of MDD in 2017 and 2019, respectively. It was approved by the Ministry of Health, Labour and Welfare in Japan and by the European Medicines Agency (EMA) in 2018 for the treatment of schizophrenia.

Brexpiprazole was discovered by Otsuka and is being co-developed by Otsuka and Lundbeck. The mechanism of action of brexpiprazole is unknown, 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.[8]

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About H. Lundbeck A/S

Lundbeck 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. We are committed to fighting stigma and discrimination against people living with brain diseases and advocating for broader social acceptance of people with brain health conditions. Our research programs tackle some of the most complex challenges in neuroscience, and our pipeline is focused on bringing forward transformative treatments for brain diseases for which there are few, if any therapeutic options.

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

About Otsuka

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 established a presence in the U.S. in 1973 and today its U.S. affiliates include Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) and Otsuka America Pharmaceutical, Inc. (OAPI). These two companies’ 2,000 employees in the U.S. develop and commercialize medicines in the areas of mental health and nephrology, using cutting-edge technology to address unmet healthcare needs.

OPDC and OAPI are indirect subsidiaries of Otsuka Pharmaceutical Company, Ltd., which 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 13.1 billion in 2022.

All Otsuka stories start by taking the road less traveled. Learn more about Otsuka in the U.S. at www.otsuka-us.com and connect with us on LinkedIn and Twitter at @OtsukaUS. Otsuka Pharmaceutical Co., Ltd.'s global website is accessible at https://www.otsuka.co.jp/en/.

Citations:

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Safe Harbor/Forward-Looking Statements

This corporate release contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance. Forward looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and may contain words like "believe", "anticipate", "expect", "estimate", "intend", "plan", "project", "will be", "will continue", "will result", "could", "may", "might", or any variations of such words or other words with similar meanings. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements.

Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements. Factors that may affect future results include, among others, interest rate and currency exchange rate fluctuations, delay or failure of development projects, production or distribution 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.

The forward-looking statements in this document and oral presentations made on behalf of Lundbeck speak only as at the date of this presentation. Lundbeck does not undertake any obligation to update or revise forward-looking statements in this presentation or oral presentations made on behalf of Lundbeck, nor to confirm such statements to reflect subsequent events or circumstances after the date of the presentation or in relation to actual results, unless otherwise required by applicable law or applicable stock exchange regulations.