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E-mail [investor@lundbeck.com](mailto:investor@lundbeck.com)[www.lundbeck.com](http://www.lundbeck.com)**Corporate Release No 497****26 March 2013****Lundbeck and Otsuka further expand their alliance and enter into collaboration for the development and commercialization of Lu AE58054 in development for Alzheimer's disease**

- *Clinical phase II data will be presented at the AAIC in Boston in July 2013*
- *A phase-III program of more than 2,500 patients will commence during 2013*
- *Lundbeck receives from Otsuka USD 150 million upon signing of the deal*
- *Within the two companies' global agreement this is the first of the projects that will ultimately involve co-development and co-promotion of three Lundbeck drug candidates*

H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) today announced a license and development agreement for Lu AE58054, a selective 5HT<sub>6</sub> receptor antagonist currently in development for the treatment of Alzheimer's disease. Under the terms of the agreement, Lundbeck will grant Otsuka co-development and co-commercialization rights to Lu AE58054 in the U.S., Canada, East Asia including Japan, major European countries and Nordic countries.

Under the terms of the agreement, Lundbeck will receive from Otsuka an initial payment of USD 150 million (approximately DKK 855 million) upon signing. Both companies will share the sales, development, and commercialization costs based on the agreement. Lundbeck is also entitled to up to USD 675 million (approximately DKK 3.9 billion) in regulatory and sales milestones. Additional specific financial terms of the agreement remain undisclosed.

Taro Iwamoto, President and Representative Director of Otsuka Pharmaceutical Co., Ltd., noted with respect to Lu AE58054 "*The global collaboration between Otsuka and Lundbeck continues to grow stronger with the addition of Lu AE58054. Not only does the product further enhance the synergy between the companies as we work together to bring to the market solutions for better health, Lu AE58054 is a potentially promising development in a very difficult disease area.*"

Ulf Wiinberg, President & Chief Executive Officer of Lundbeck commented "*There is a serious, global, unmet medical need regarding treatments for Alzheimer's disease in aging populations. Together, Otsuka and Lundbeck with their development capabilities, commercial experience and geographical reach will provide a solid foundation in the development of Lu AE58054.*"

The pivotal clinical program with Lu AE58054 is planned to be initiated later in 2013. The global program will consist of several studies and include more than 2,500 patients. The first phase III study will enroll

patients with mild-to-moderate Alzheimer's disease. Lu AE58054 will be tested as adjunct treatment to donepezil. Subsequent studies are expected to be initiated towards the end of 2013.

In May 2012, it was announced that Lu AE58054 had met its primary endpoint in a fixed dose, randomized, placebo-controlled, 24-week clinical study in 278 patients. The study was conducted in patients suffering from moderate Alzheimer's disease, with Lu AE58054 administered as an add-on to donepezil, a commonly used acetylcholinesterase inhibitor<sup>i</sup>. The clinical data from the phase II study is planned to be presented at the annual Alzheimer's Association International Conference (AAIC) in Boston on 13-18 July 2013.

### About Lu AE58054<sup>ii</sup>

Lu AE58054 is a selective 5-HT<sub>6</sub>-receptor antagonist. The 5-HT<sub>6</sub>-receptor is primarily found in areas of the brain involved in cognition. A number of early trials have demonstrated that a 5-HT<sub>6</sub>-receptor antagonist could offer potential benefits in the treatment of disorders such as Alzheimer's disease and in November 2009 Lundbeck initiated the above described 24 week clinical phase II trial with Lu AE58054 as augmentation therapy in Alzheimer's disease.

### About Alzheimer's disease

Alzheimer's disease is a progressive brain disorder, in which the brain gradually degenerates. It most frequently occurs in people aged above 65—70 years. People with Alzheimer's disease develop distressing changes in memory, thought, function and behavior, which worsen over time. These changes increasingly impact upon the person's daily life, reducing their independence, until ultimately they are entirely dependent on others.

Alzheimer's disease also has an enormous impact on the patient's caregiver. Most caregivers are close relatives who provide care in the home — a demanding and exhausting role that represents an emotional and physical burden<sup>ii</sup>.

Alzheimer's disease is associated with damages and death of brain cells, leading to significant brain shrinkage and neurotransmitter imbalances. As the brain cells degenerate, characteristic waste accumulates in the brain, known as 'plaques' and 'tangles'.

Worldwide, 36 million people have dementia. Perhaps as many as 28 million of the world's 36 million people with dementia have yet to receive a diagnosis and, therefore, do not have access to treatment, information and care. Every year, an estimated 4.6 million new cases are identified<sup>iii</sup>. With the shift towards an increasingly elderly population, it is predicted that the number of people affected by dementia will almost double every 20 years, and by the year 2050, 115 million people will have the condition<sup>iv</sup>.

Alzheimer's disease is the most common cause of dementia, accounting for 50—70% of cases<sup>v</sup>.

The worldwide costs of dementia (USD 604 billion in 2010) amount to more than 1% of gross domestic product (GDP).

## Lundbeck's financial guidance for 2013

The content of this release will have some impact on the Lundbeck Group's financial guidance for 2013, which was provided on 6 February 2013 in connection with the release of the financial results for 2012.

The initial payment of USD 150 million (approximately DKK 855 million) is a non-refundable cash payment which will be split and USD 50 million (approximately DKK 285 million) will be booked under Other revenue for the first quarter of 2013 and the additional non-refundable cash payment of USD 100 million (approximately DKK 570 million) will be booked in the P&L in the period 2013-2015. Therefore, Lundbeck now expects revenue in the range DKK 14.4-15 billion. EBIT is now expected to reach DKK 1.9-2.4 billion for 2013.

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## About Otsuka Pharmaceutical Co., Ltd.

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 and original products, with a focus on pharmaceutical products for the treatment



of diseases and nutraceutical products for the maintenance of everyday health. We are a "big venture" company at heart, applying a youthful spirit of creativity in everything we do.

In pharmaceuticals, Otsuka is a leading firm in the challenging area of psychiatric disorders and our drug ABILIFY® (aripiprazole) recently became the number-one selling drug in the U.S.<sup>vi</sup>. Tuberculosis, a global public health issue, is another research area that we have been active in for several decades. These commitments illustrate more powerfully than words how we are a "big venture" company at heart, applying a youthful spirit of creativity in everything we do.

Otsuka is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group. Our chairman Akihiko Otsuka is the third generation of Otsuka family members to lead the business, whose origins date from 1921. The Otsuka Group has business operations in 25 countries and regions around the world, with consolidated sales of approximately USD 14.7 billion for fiscal year 2011 (4/1/2011-3/31/2012.) We welcome you to visit our 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 highly committed to improving the quality of life of people living with brain diseases. For this purpose, Lundbeck is engaged in the entire value chain throughout research, development, production, marketing and sales of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy, Huntington's, Alzheimer's and Parkinson's diseases. Lundbeck's pipeline consists of several mid- to late- stage development programs.

Lundbeck employs more than 5,800 people worldwide, 2,000 of whom are based in Denmark. We have employees in 57 countries, and our products are registered in more than 100 countries. We have research centers in Denmark, China and the United States and production facilities in Italy, France, Mexico, China and Denmark. Lundbeck generated revenue of approximately DKK 15 billion in 2012. For additional information, we encourage you to visit our corporate site [www.lundbeck.com](http://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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<sup>i</sup> H. Lundbeck A/S. (29 May 2012). Lundbeck's Lu AE58054 meets primary endpoint in large placebo-controlled clinical proof of concept study in people with Alzheimer's disease [corporate release]. Available at <http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=677436>

<sup>ii</sup> Georges J, Jansen S, Jackson J, et al. Alzheimer's disease in real life — the dementia carer's survey. *Int J Geriatr Psychiatry* 2008; 23 (5): 546—551.

<sup>iii</sup> Ferri CP, Prince M, Brayne C, et al. Global prevalence of dementia: a Delphi consensus study. *Lancet* 2005; 366 (9503): 2112—2117.

<sup>iv</sup> Alzheimer Disease International. *World Alzheimer Report 2011. The benefits of early diagnosis and intervention.* Published by Alzheimer's Disease International (ADI), September 2011.

<sup>v</sup> Alzheimer's Association. *Basics of Alzheimer's disease: what it is and what you can do.* 2010. [http://www.alz.org/national/documents/brochure\\_basicsofalz\\_low.pdf](http://www.alz.org/national/documents/brochure_basicsofalz_low.pdf). Accessed 30/09/11.

<sup>vi</sup> ABILIFY sales rank in the overall U.S. market based on IMS data for the fourth quarter of 2012