

## H. Lundbeck A/S

Ottiliavej 9  
DK-2500 Valby, Copenhagen  
CVR number: 56759913

Tel +45 36 30 13 11  
Fax +45 36 43 82 62

E-mail investor@lundbeck.com  
www.lundbeck.com

## Corporate Release

### Lundbeck and Otsuka to co-develop a vaccine, Lu AF20513, their third collaborative development project to tackle Alzheimer's disease

- *Lu AF20513 is an anti-beta-amyloid (anti-A $\beta$ ) active vaccine that is expected to enter phase I clinical testing in 2014*
- *The two companies' collaboration on Lu AF20513 represents a different approach from most other drug research to date on Alzheimer's disease*
- *Alzheimer's disease affects more than 30 million people worldwide<sup>i</sup>. The cost to society from dementia has been reported as USD ~600 billion per year<sup>ii</sup>*
- *Lu AF20513 is the third joint investigational project by the two companies that seeks to address a dimension of Alzheimer's disease*

**Valby, Denmark and Tokyo, Japan, 11 December 2013** - H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) today announced that they will further expand their collaboration to include the development of Lu AF20513, an investigational vaccine candidate against Alzheimer's disease.

Lu AF20513 is an active anti-A $\beta$  vaccine candidate against Alzheimer's disease which currently is in preclinical development. It is designed towards an optimal immunogenic response in the elderly, based on the hypothesis that cognitive function would be preserved through the early inhibition of amyloid beta depositions.

The agreement covers the development of Lu AF20513 through clinical phase I. Following completion of the clinical phase I study the parties have an option to enter into a co-commercialisation and co-development agreement under terms to be agreed upon.

Lundbeck will receive from Otsuka an initial payment of EUR 4 million (approximately DKK 30 million) upon signing and Lundbeck will finance the phase I development costs. Additional specific financial terms of the agreement remain undisclosed.

It is expected that the phase I study will be initiated during 2014.

In addition to the vaccine candidate Lu AF20513, the two companies are pursuing the clinical development of two other potential treatments for different symptoms that can occur in patients with Alzheimer's disease - Lu AE58054, a 5HT<sub>6</sub> receptor antagonist for adjunctive treatment of Alzheimer's disease and brexpiprazole, an investigational agent with high affinity to multiple serotonin, dopamine



and norepinephrine receptors for the treatment of agitation in patients with Alzheimer's disease. Both projects are currently in clinical phase III.

These programs illustrate the depth and breadth of experience and resources the two firms can draw on in neuroscience research and development. The two companies' collective revenues in the central nervous system (CNS) area rank the alliance number one in this field<sup>iii</sup>.

### Financial guidance

The content of this release will have no influence on the Lundbeck Group's financial guidance for 2013, which was provided on 6 November.

### About Lu AF20513

Lu AF20513 is an active vaccine inducing high affinity polyclonal antibodies that target beta-amyloid (A $\beta$ ), a protein that can exert toxic effects in the brain and is believed to play a central role in the pathology of Alzheimer's disease. Lu AF20513 is expected to provide an enhanced and heterogeneous immunogenic response towards A $\beta$  peptides in comparison to mono-clonal antibody treatment strategies.

### About Alzheimer's disease

Alzheimer's disease is a progressive brain disorder in which the brain gradually degenerates. It most frequently occurs in people above 65 years of age. People with Alzheimer's disease develop distressing changes in memory, thought, function and behaviour, which worsen over time. These changes increasingly impact the person's daily life and reduce their independence until ultimately these patients are entirely dependent on others<sup>iv</sup>.

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

Worldwide, it is estimated that about 44 million people have dementia. 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, 135 million people will have the condition<sup>ii</sup>. Alzheimer's disease is the most common cause of dementia, accounting for 50 to 80% of these patients<sup>vi</sup>.

The worldwide costs of dementia (estimated at around USD 600 billion in 2010) amount to more than 1% of the global gross domestic product (GDP).



## Lundbeck contacts

### Investors:

Palle Holm Olesen  
Chief Specialist, Head of Investor Relations  
PALO@lundbeck.com  
+45 36 43 24 26

Jens Høyer  
Investor Relations Officer  
JSHR@lundbeck.com  
+45 36 43 33 86

### Media:

Mads Kronborg  
Media Relations Manager  
MAVK@lundbeck.com  
+45 36 43 30 00

## Otsuka contacts:

### Media in Europe:

Alison Ross  
Otsuka Pharmaceutical Europe Ltd.  
[aross@otsuka-europe.com](mailto:aross@otsuka-europe.com)  
+44 7768 337128

### Media in Japan / Asia:

Jeffrey Gilbert  
Otsuka Pharmaceutical Co., Ltd.  
[gilbert.jeffrey@otsuka.co.jp](mailto:gilbert.jeffrey@otsuka.co.jp)  
+81 3 6361 7379, +81 80 8728 6039

### Media in North America:

Kevin Wiggins  
Otsuka America Pharmaceutical, Inc.  
[kevin.wiggins@otsuka-us.com](mailto:kevin.wiggins@otsuka-us.com)  
+1 609 249 7292

## About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUY) 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 development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our 5,800 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more than 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of approximately DKK 15 billion in 2012 (EUR 2 billion; USD 2.6 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 "HLUY". For additional information, we encourage you to visit our corporate site [www.lundbeck.com](http://www.lundbeck.com).



## 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.

In pharmaceuticals, Otsuka is a leading firm in the challenging area of mental health and also has 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 is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group. The chairman Akihiko Otsuka is the third generation of Otsuka family members to lead the business, whose origins date from 1921. The Otsuka Group employs approximately 42,000 people globally and its products are available in more than 80 countries worldwide. Consolidated sales were approximately EUR 10 billion or USD 13 billion for fiscal year 2012 (4/1/2012-3/31/2013). Otsuka Pharmaceutical welcomes you to visit its global website at <https://www.otsuka.co.jp/en/>

### 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.**

---

<sup>i</sup> Barnes DE, Yaffe K. The projected effect of risk factor reduction on Alzheimer's disease prevalence. *Lancet Neurology*. 2011; (9):819-28.

---

<sup>ii</sup> Alzheimer's Disease International. The global impact of dementia 2013-2050; 2013.

<sup>iii</sup> Based on IMS data (MATQ2.2013)

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

<sup>v</sup> Mohamed S. et al. Am J Geriatr Psychiatry. 2010 Oct;18(10):917-27 and Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE)-AD study

<sup>vi</sup> Alzheimer's Association. "Alzheimer's changes the whole brain" Brain Tour. 2011. Document accessible at: [http://www.alz.org/braintour/alzheimers\\_changes.asp](http://www.alz.org/braintour/alzheimers_changes.asp).