

Corporate Release No 494

28 February 2013

**Lundbeck receives European marketing authorization for Selincro as the first therapy approved for the reduction of alcohol consumption**

- *Selincro® offers a new approach for the treatment of adults with alcohol dependence who have a high drinking risk level.<sup>1</sup> In clinical trials, Selincro reduced alcohol consumption by approximately 60% after six months treatment.*
- *Alcohol dependence is considered a major public health concern with harmful physical, mental and social consequences.<sup>2</sup>*
- *There is a significant unmet need as alcohol dependence is both underdiagnosed and undertreated. In Europe more than 90% of the 14 million patients with alcohol dependence are currently untreated.<sup>3,4</sup>*

H. Lundbeck A/S (Lundbeck) today announced that the European Commission granted marketing authorization for Selincro® (nalmefene) for the reduction of alcohol consumption in adult patients with alcohol dependence.

*"Selincro represents the first major innovation in the treatment of alcohol dependence in many years,"* said Executive Vice President Anders Gersel Pedersen, Head of Research & Development at Lundbeck, and continued: *"The approval of Selincro is exciting news for the many patients with alcohol dependence who otherwise may not seek treatment."*

Selincro is a unique dual-acting opioid system modulator,<sup>5,6</sup> and acts on the brain's motivational system, which is dysregulated in patients with alcohol dependence.<sup>7</sup> Selincro is thought to reduce the reinforcing effects of alcohol, and thereby reduces the urge to drink alcohol.<sup>8,9</sup> Lundbeck will provide Selincro as part of a novel treatment concept that includes continuous psychosocial support focused on the reduction of alcohol consumption and treatment adherence. It has been developed for use on an as-needed basis, with one tablet taken each day when the patient feels a risk of drinking.

*"For a large proportion of patients with alcohol dependence, reduction of alcohol consumption is a more acceptable and realistic treatment goal"*, commented Professor Dr. Karl F. Mann, Head of the Department of Addictive Behavior and Addiction Medicine at the Central Institute of Mental Health in Mannheim, Germany. *"Offering this treatment option opens a new chapter in the treatment of alcohol dependence."*

The marketing authorisation of Selincro is based on the results of three pivotal, randomized, double-blind, placebo-controlled trials that evaluated the efficacy and safety of Selincro in approximately 2,000 alcohol dependent patients.

Selincro has been shown to be effective in reducing alcohol consumption in patients with high drinking risk level. Patients treated with Selincro showed a 40% reduction in total alcohol consumption within the first month, and after six months the alcohol intake was reduced by approximately 60%. This corresponds to an average reduction equal to nearly one bottle of wine per day. Data from the 1-year study suggested longer-term efficacy of Selincro beyond 6 months. Selincro is generally well tolerated and adverse events were mostly mild to moderate and transient.

The approval of Selincro applies to all 27 European Union (EU) member states. Subject to the completion of pricing and reimbursement discussions, Lundbeck expects to launch Selincro in its first markets in mid-2013.

### 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 February 2013 in connection with the release of the financial results for 2012.

### About Selincro® (nalmefene)

Selincro is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (>60g/day for men, >40g/day for women) without physical withdrawal symptoms and who do not require immediate detoxification. Selincro should be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and the reduction of alcohol consumption. Treatment should be initiated only in patients who continue to have a high drinking risk level two weeks after an initial assessment. Selincro is to be taken as-needed; that is, on each day the patient perceives a risk of drinking alcohol, one tablet should be taken, preferably 1-2 hours prior to the anticipated time of drinking.

### About alcohol dependence

Alcohol dependence is a brain disease with a high probability of following a progressive course.<sup>10,11</sup> Alcohol is toxic to most organs of the body, and the level of consumption is strongly correlated with the risk for long-term morbidity and mortality.<sup>12</sup> Alcohol is a causal factor in more than 60 types of disease and injury.<sup>13</sup> Genetic and environmental factors are important in the development of alcohol dependence; genetic factors account for an estimated 60% of the risk of developing the disease.<sup>14</sup> A central characteristic of alcohol dependence is the often overpowering desire to consume alcohol. Patients experience difficulties in controlling the consumption of alcohol and continue consuming alcohol despite harmful consequences. Diagnosis of alcohol dependence requires at least 3 of 6 criteria in the ICD-10 classification from WHO.<sup>15</sup>

Excessive alcohol consumption is common in many parts of the world, especially in Europe where more than 14 million people are alcohol dependent.<sup>4</sup> In Europe the treatment gap is quite significant, with only 8% of patients receiving any form of treatment.<sup>3</sup> Both abstinence and reduction goals should be considered as part of a comprehensive treatment approach for patients with alcohol dependence.<sup>16</sup>

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## About Lundbeck

Lundbeck 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 5800 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).

### References:

- <sup>1</sup>WHO 2000: International guide for monitoring alcohol consumption and related harm
- <sup>2</sup>Rehm et al. CAMH. Alcohol consumption, alcohol dependence and attributable burden of disease in Europe [http://www.camh.ca/en/research/news\\_and\\_publications/reports\\_and\\_books/Pages/default.aspx](http://www.camh.ca/en/research/news_and_publications/reports_and_books/Pages/default.aspx)
- <sup>3</sup>Kohn et al. Bull World Health Organ 2004; 82(11):858-866
- <sup>4</sup>Wittchen et al. Eur Neuropsychopharmacol 2011;21(9): 655-679
- <sup>5</sup>Michel et al. Meth Find Exp Clin Pharmacol 1985; 7: 175-177
- <sup>6</sup>Hillemacher et al. Expert Opin. Investig. Drugs 2011; 20(8): 1073-1086
- <sup>7</sup>Heinz et al. Addict Biol 2009; 14(1): 108-118
- <sup>8</sup>Spanagel & Valentini. Curr Topics Behav Neurosci 2013; 13: 583–609
- <sup>9</sup>Drobes et al. Alcohol Clin Exp Res 2004; 28(9): 1362-70
- <sup>10</sup>Burge et al. Am Fam Physician 1999; 59(2): 361-370
- <sup>11</sup>Leshner. Science 1997; 278: 45-47
- <sup>12</sup>Rehm et al. Eur Addict Res 2003; 9: 147-156
- <sup>13</sup>WHO. Global status report on alcohol and health, 2011
- <sup>14</sup>Schuckit. Ch. 98. In: Davis et al (eds). Neuropsychopharmacol: The Fifth Generation of Progress 2002
- <sup>15</sup>WHO, ICD-10, F10-19
- <sup>16</sup>Ambrogne. J Subst Abuse Treat 2002; 22(1): 45-53



#### **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.