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Lundbeck receives positive opinion for approval of Selincro™ (nalmefene) in the European Union

- *The Committee for Medicinal Products for Human Use (CHMP) recommends approval of Selincro for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high level of alcohol consumption*
- *Upon final marketing authorisation from the EU Commission, Selincro will be the first medicine to provide a new treatment option for alcohol dependence that is based on the harm reduction concept*
- *There is a significant unmet need as alcohol dependence is both underdiagnosed and undertreated. In Europe more than 90% of patients with alcohol dependence are currently untreated*[1]
- *In Europe the impact of alcohol is the highest in the world, with 12% of all deaths in the age group of 15-64 attributable to alcohol*[2]

H. Lundbeck A/S (Lundbeck) today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) adopted a positive opinion and recommended marketing authorization of Selincro for the reduction of alcohol consumption in adult patients with alcohol dependence who maintain a high level of alcohol consumption. Once approved, Lundbeck will provide Selincro as part of a new treatment concept that includes continuous psychosocial support focused on the reduction of alcohol consumption and treatment adherence.

For many patients with alcohol dependence, to entirely stop and abstain from drinking is not an acceptable or attainable treatment goal. Selincro will be the first medication specifically developed for the reduction of alcohol consumption in patients with alcohol dependence who maintain a high level of alcohol consumption. Selincro reduces alcohol consumption and thus the consequences of harmful drinking, and offers a new treatment option for patients who may not have sought treatment before.

"Selincro represents the first major innovation in the treatment of alcohol dependence in many years. Selincro reduces the urge to continue drinking and helps patients with alcohol dependence to reduce their alcohol consumption," says Executive Vice President Anders Gersel Pedersen, Head of Research & Development at Lundbeck, and continues: *"The Committee's support of Selincro brings us closer to encouraging more patients with alcohol dependence to potentially seek help and treatment."*

Selincro is an opioid system modulator[3,4] that works on the brain's motivational system, which is dysregulated in patients with alcohol dependence.[5] Selincro is thought to reduce the reinforcing effects of alcohol.[6]

The CHMP opinion was based on the results from three pivotal, randomized, double-blind, placebo controlled clinical trials studying the effects of 18mg Selincro in adults patients with alcohol dependence.

These studies included approximately 2,000 patients diagnosed with alcohol dependence; two-thirds of these patients had never before received treatment for their disease.

For approval, the efficacy of Selincro was assessed in patients with a high drinking risk level (defined by WHO: men >60 gram per day, women >40 gram per day (1 standard drink ~10 grams of alcohol)). Patients enrolled in the studies with high drinking risk level drank on average 10.5 standard drinks per day (equivalent to approximately 1.5 bottles of wine). Patients treated with Selincro showed a more than 40% reduction in total alcohol consumption within the first month, and at study end (6 or 12 months) the alcohol intake was reduced by more than 60%. This corresponds to an average reduction equal to nearly one bottle of wine per day. The reduction of alcohol consumption in patients with high drinking risk level was significantly better than placebo at study end in all three studies and was considered clinically relevant. Data from the 1-year study suggested longer term efficacy of Selincro beyond 6 months and up to 1 year of treatment. There were no major safety concerns identified during the studies, and Selincro was generally well tolerated.

The European Commission usually delivers its final decision within 2-3 months of the CHMP recommendation. The decision will be applicable to all 27 European Union member states plus Iceland and Norway. Subject to the Commission's final approval and completion of pricing and reimbursement discussions, Lundbeck expects to launch Selincro in a number of European markets by mid-2013.

Financial guidance

The content of this release will have no influence on the Lundbeck Group's financial guidance for 2012, which was provided on 8 February 2012 in connection with the release of the financial results for 2011, and further specified in connection with the announcement of the restructuring plan on 14 June 2012.

About Selincro (nalmefene)

Once approved, Selincro will be 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.

Lundbeck licensed the rights to Selincro from Finnish Biotie Therapies Corp. (Biotie). Under the terms of the agreement, Biotie received an execution fee of EUR 12 million. In total, Biotie is eligible for up to EUR 89 million in upfront and milestone payments plus royalty on sales. Lundbeck holds the global rights to the compound and is responsible for the registration, manufacturing and marketing of the product.

About alcohol dependence

Alcohol dependence is a brain disease with a high probability of following a progressive course.[7,8] 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.[9] Alcohol is a causal factor in more than 60 types of disease and injury.[10] 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.[11] 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.[12]

Excessive alcohol consumption is common in many parts of the world, especially in Europe where more than 14 million people are alcohol dependent.[9,13] In Europe the treatment gap is very large, with only 8% of patients receiving any treatment.[1] Both abstinence and reduction goals should be considered as part of a comprehensive treatment approach for patients with alcohol dependence.[14]

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About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is an international pharmaceutical company highly committed to improving the quality of life for people suffering from brain disorders. For this purpose, Lundbeck is engaged in the research, development, production, marketing and sale of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy and Huntington's, Alzheimer's and Parkinson's diseases.

Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark. Today Lundbeck employs approximately 6,000 people worldwide. Lundbeck is one of the world's leading pharmaceutical companies working with brain disorders. In 2011, the company's revenue was DKK 16.0 billion (approximately EUR 2.1 billion or USD 3.0 billion). For more information, please visit www.lundbeck.com.

References:

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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.