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Lundbeck submits a European Marketing Authorization Application (MAA) for Selincro™ (nalmefene) for the treatment of alcohol dependence

- *Lundbeck submits an MAA via centralized procedure for regulatory approval of Selincro™ in Europe*
- *Selincro™ has a significant potential for helping individuals with alcohol dependence in reducing their alcohol consumption*
- *The reduction in heavy drinking days and total alcohol consumption has been seen within the first month of treatment in all three studies and was maintained throughout the 12-months safety study*
- *Selincro™ has been shown to be well tolerated*
- *Selincro™ is the first medicine aimed at regulatory approval in Europe for the reduction of alcohol consumption in patients with alcohol dependence*

H. Lundbeck A/S (Lundbeck) today announced that it has submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for Selincro™ (nalmefene), the company's novel opioid receptor ligand in development for alcohol dependence and the dossier has been accepted for review by EMA.

"*Alcohol dependence is a significant burden for both individuals and society with only limited medical treatment options. We are very pleased that we now are at a stage where we can start the regulatory review and approval process for Selincro™ in Europe*" says Executive Vice President Anders Gersel Pedersen, Head of Research & Development at Lundbeck, and continues: "*Clinical studies have shown that Selincro™ is well-tolerated and with a demonstrated clinical benefit in reducing heavy drinking days and overall alcohol consumption".*

Lundbeck plans to present efficacy and safety data from its clinical phase III programme at the 20th European Congress of Psychiatry (EPA) in Prague, Czech Republic, 3-6 March 2012.

About the clinical phase III programme

Based on the results of earlier trials, Lundbeck initiated three phase III clinical studies in Europe in 2008 enrolling a total of approximately 2,000 individuals with alcohol dependence who were randomised into two groups receiving Selincro™ (18 mg tablets as needed) or placebo in addition to appropriate advice and support designed to increase motivation and adherence. Two of the three trials (ESENSE1 and ESENSE2), in which individuals were treated over a period of six months, were primarily aimed at demonstrating the efficacy of Selincro™. The primary objective of the third study (SENSE), in which individuals were treated for 12 months, was to confirm the safety and tolerability of the compound.

During the clinical programme a wide range of primary and secondary endpoints were assessed, including number of heavy drinking days (HDD) per month, total alcohol consumption (TAC) per day, proportion of responders based on drinking measures, alcohol dependence symptoms and clinical status, liver function and other laboratory tests, pharmacoeconomic outcomes and treatment discontinuation effects. All assessments were consistently in favour of Selincro™ compared to placebo, and it was further observed that the medical intervention with Selincro™ had a strong effect that was seen within the first month and led to a reduction in alcohol consumption of more than 50%, which was maintained throughout the study periods.

The three studies in the overall phase III clinical programme were conducted in Europe and enrolled about 2,000 individuals with alcohol dependence. Medical advice and support to enhance motivation and adherence were included in all treatment arms in the studies. No abstinence treatment goal was imposed. In all three clinical studies the overall safety profile of Selincro™ was consistent with observations and data provided in previous studies, resulting in a total clinical database of more than 3,000 individuals. The most frequent adverse events included dizziness, insomnia and nausea and were mild and transient upon stopping treatment.

Heavy drinking level is defined as five or more drinks per day for men and four or more drinks per day for women. After 6 months of treatment, individuals taking 18 mg Selincro™ (equivalent to 20 mg nalmefene, HCl) had a decrease of heavy drinking days by more than 50%. Furthermore, data from the 12 month safety study (SENSE) confirmed that this effect is maintained or even improved after 1 year of treatment, leading to more than 60% overall reduction in total alcohol consumption. Approximately 2/3 of the individuals in the studies had not been previously treated for alcohol dependence, indicating that reduction of alcohol intake is an attractive alternative treatment objective compared to current treatments which all require abstinence.

About Selincro™ (nalmefene)

Selincro™ is a distinct opioid system modulator that reduces the urge to continue drinking when alcohol is consumed.

Lundbeck licensed the rights to Selincro™ from Biotie Therapeutics Corp. (Biotie) in Finland. Under the terms of the agreement, Biotie received an execution fee of EUR 12 million. In total, Biotie is eligible for up to EUR 84 million in upfront and milestone payments plus royalty on sales. Lundbeck will be responsible for manufacturing and registration of the product.

Lundbeck holds the global rights to the compound.

About alcohol dependence

Alcohol dependence is a disorder of the central nervous system with a high risk of a chronic, relapsing, and often progressive course. It is characterised by structural and neurochemical changes in the brain, and disturbances in behaviour. Patients with alcohol dependence continue to drink due to alcohol's rewarding effects and to avoid or relieve unpleasant emotional and physiological states. Research suggests that genetic and environmental factors contribute about equally to the risk of developing alcohol dependence.

Alcohol is toxic to most organs, and its use is linked to several diseases including cancer and cardiovascular diseases. Alcohol is a significant threat to public health, social welfare and economic development. It is estimated that in any given year approximately 3.4% of EU citizens over 15 years of age suffer from alcohol dependence, corresponding to more than 14 million people.

Financial guidance

The content of this release will have no influence on the Lundbeck Group's financial guidance for 2011 which was provided on 24 February 2011 in connection with the release of the financial results for 2010.

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About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) is an international pharmaceutical company highly committed to improving the quality of life for people suffering from central nervous system (CNS) 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, schizophrenia, insomnia, 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 5,900 people worldwide. Lundbeck is one of the world’s leading pharmaceutical companies working with CNS disorders. In 2010, the company's revenue was DKK 14.8 billion (approximately EUR 2.0 billion or USD 2.6 billion). For more information, please visit www.lundbeck.com.