



Press release

Valby, 8 April 2013

Lundbeck presents new data on Selincro from three phase III studies that consistently show a significant reduction in alcohol consumption in alcohol dependent patients with high risk drinking level

- *Patients treated with Selincro® (nalmefene) showed a reduction in total alcohol consumption after 6 months of 57% in study 1 (ESENSE 1)¹ and 62% in study 2 (ESENSE 2)² and after 12 months of 67% in study 3 (SENSE)³ among high risk drinking alcohol dependent patients.*
- *Selincro is the first and only medicine approved for the reduction of alcohol consumption in patients with alcohol dependence.⁴*
- *There is a significant unmet need as alcohol dependence is both underdiagnosed and undertreated. In Europe more than 90% of the patients with alcohol dependence are currently untreated.^{5,6}*

H. Lundbeck A/S (Lundbeck) announced today the results of the revised analysis of the Phase III programme that formed the basis for the approval of Selincro® (nalmefene) in the EU on February 25, 2013. Alcohol dependent patients with high risk drinking level (>60g/day for men, >40g/day for women) treated with Selincro showed a significant reduction in total alcohol consumption after 6 months of 57% in study 1 (ESENSE 1)¹ and 62% in study 2 (ESENSE 2),² and after 12 months of 67% in study 3 (SENSE).³ The analyses from these randomized, double-blind, placebo-controlled Phase III studies were presented at the 21st European Congress of Psychiatry (EPA) in Nice, France.

“The clinical data in patients with alcohol dependence with a high risk drinking level are very robust and consistent across the three studies,” said Executive Vice President Anders Gersel Pedersen, Head of Research & Development at Lundbeck. “As the first medicine approved for the reduction of alcohol consumption, Selincro provides a new and innovative option for patients who may otherwise not seek treatment.”

Selincro is thought to reduce the reinforcing effects of alcohol, and thereby reduces the urge to drink alcohol.^{7,8} Selincro is a unique dual-acting opioid system modulator^{9,10} and works on the brain's motivational system, which is dysregulated in patients with alcohol dependence.¹¹ Lundbeck will provide Selincro as part of a novel treatment concept and it 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, taken on days when the patient feels a risk of drinking.¹²

The presented results are from a subgroup analysis in approximately 850 patients who continued to have a high risk drinking level after an initial assessment in the three pivotal clinical trials ESENSE 1, ESENSE 2 and SENSE.^{1,2,3}

- In ESENSE 1 the patients enrolled in the study with a high risk drinking level drank on average 102 grams of alcohol (equivalent to approximately 1.5 bottles of wine) per day. Patients treated with Selincro showed a 40% reduction in total alcohol consumption within the first month, and after 6 months the total alcohol consumption decreased to 44 g/day which is equivalent to a 57% reduction.¹
- In ESENSE 2 the patients enrolled in the study with a high risk drinking level drank on average 113 grams of alcohol per day. Patients treated with Selincro showed a 49% reduction in total alcohol consumption within the first month, and after 6 months the total alcohol consumption decreased to 43 g/day which is equivalent to a 62% reduction.²
- In SENSE the patients enrolled in the study with a high risk drinking level drank on average 100 grams of alcohol per day. Patients treated with Selincro showed a 36% reduction in total alcohol consumption within the first month, 56% after 6 months and after 12 months the total alcohol consumption decreased to 33 g/day which is equivalent to a 67% reduction.³

All three studies showed a consistent reduction in alcohol consumption, and Selincro was superior to placebo at study end in all three trials. The two identical 6-months studies showed that patients treated with Selincro on average reduced their total alcohol consumption by more than 40% within the first month and by approximately 60% after 6 months, and this was statistically significant from placebo. In addition, data from the 1-year study confirmed that the positive effects of Selincro are maintained and even improved after one year of treatment, leading to a 67% reduction in total alcohol consumption – equivalent to nearly one bottle of wine per day. In all three studies Selincro was generally well tolerated, and adverse events were mostly mild to moderate and transient.^{1,2,3}

“To stop drinking completely is not an achievable or acceptable goal for many patients with alcohol dependence, and therefore Selincro is an important addition to the current treatment options which aim to support sustained abstinence,” commented Wim van den Brink, MD PhD from the Institute for Addiction Research at the University of Amsterdam, Netherlands. “The reduction of alcohol consumption supported by Selincro may have benefits not only for patients and their families, but also at their workplace and for society as a whole.”

Alcohol dependence is a medical and behavioural disorder with a high probability of a chronic, relapsing and progressive course.^{13,14} 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.^{5,6}

Selincro was approved by the European Commission for the reduction of alcohol consumption in patients with alcohol dependence on the 25th of February 2013, and Lundbeck expects to launch Selincro in its first markets in Q2-2013.

About Selincro® (nalmefene)

Selincro is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high risk drinking 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 risk drinking level two weeks after an initial assessment. Selincro is to be taken as-needed; that is, on days the patient perceives a risk of drinking alcohol, maximum one tablet should be taken, preferably 1-2 hours prior to the anticipated time of drinking. In the clinical trials Selincro was taken on approximately half of the days.¹²

About alcohol dependence

Alcohol dependence is a brain disease with a high probability of following a progressive course.^{13,14} 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.¹⁵ Alcohol is a causal factor in more than 60 types of disease and injury.¹⁶ 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.¹⁷ 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.¹⁸

Excessive alcohol consumption is common in many parts of the world, especially in Europe where more than 14 million people are alcohol dependent.⁶ In Europe the treatment gap is quite significant, with only 8% of patients receiving any form of treatment.⁵ Both abstinence and reduction goals should be considered as part of a comprehensive treatment approach for patients with alcohol dependence.¹⁹

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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 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 centres 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.

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