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Press release

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Lundbeck introduces Selincro® as the first and only medicine for the reduction of alcohol consumption in alcohol dependent patients

Lundbeck launches Selincro® in Norway, Finland, Poland and the Baltic countries.

H. Lundbeck A/S (Lundbeck) announced that the company shipped Selincro® in its first markets and made the product available for alcohol dependent patients with high-risk drinking levels in Norway, Finland, Poland and the Baltic countries. The launch marks the first introduction of a new treatment of alcohol dependence in Europe for more than a decade.[1,2,3,4] Additional launches in other countries will follow later in 2013 and 2014.

Selincro is the first and only medicine approved for the reduction of alcohol consumption in patients with alcohol dependence.[5] In clinical trials, Selincro reduced alcohol consumption by approximately 60% after six months treatment.[6,7]

“We are proud to make Selincro available to patients suffering from alcohol dependence. This is an area with significant unmet medical needs, and we are excited about introducing an innovative treatment concept that provides a new and different option for patients who may otherwise not seek treatment”, said Ole Chrintz, Senior Vice President, International Markets and Europe at Lundbeck.

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. Selincro was generally well tolerated in clinical studies. The most common adverse reactions were nausea, dizziness, insomnia and headache. The majority of these reactions were mild or moderate, associated with treatment initiation, and of short duration.[8]

About alcohol dependence

Alcohol dependence is a brain disease with a high probability of following a progressive course.[9,10] 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.[11] Alcohol is a causal factor in more than 60 types of disease and injury.[12,13] 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.[14] 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.[15]

Excessive alcohol consumption is common in many parts of the world, especially in Europe where more than 14 million people are alcohol dependent.[16] In Europe the treatment gap is quite significant, with only 8% of patients receiving any form of treatment.[17] Both abstinence and reduction goals should be considered as part of a comprehensive treatment approach for patients with alcohol dependence.[18]

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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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