



Valby, 30 September 2013

Lundbeck launches Selincro® in Denmark

The launch of Selincro® – the first and only medicine approved for the reduction of alcohol consumption in alcohol-dependent patients – will commence in Denmark today.

H. Lundbeck A/S (Lundbeck) today commenced its launch of Selincro® in Denmark, making the product available to alcohol-dependent patients in Denmark with a high drinking risk level. It is estimated that 585,000 Danes have a harmful alcohol intake, of whom about 140,000 are alcohol-dependent¹.

The socio-economic costs associated with alcohol abuse in Denmark amount to approximately DKK 10 billion each year². Of this amount, expenses for medical treatment of alcohol consumption amount to only DKK 10.8 million, or close to 0.1% of the total costs. Antabus®, which has been on the market since 1955³, currently account for 95.5% of all pharmaceutical treatments.

"The fact that a very large group of alcohol-dependent patients receive no treatment involves huge human and economic costs. We have been looking forward to making Selincro® available to Danish patients, and we are proud to launch a new treatment regime that offers new possibilities for the treatment of alcohol-dependent patients," said Ole Chrintz, Senior Vice President, International Markets and Europe at Lundbeck.

Selincro® is the first and only medicine approved for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and who do not require immediate detoxification. In clinical trials, Selincro® in conjunction with psychosocial intervention has reduced alcohol consumption by 61% after six months of treatment⁵, and for the recruited patients this corresponded to an average reduction equal to nearly one bottle of wine per day.

Earlier this year, Selincro® was launched in Norway, Finland, Poland, Estonia, Latvia, Lithuania, Portugal, Iceland, Sweden, the UK, Bulgaria, the Czech Republic, Hungary, Slovenia and Italy.

On 24 September 2013, Selincro® won the Confederation of Danish Industry's 2013 product award.

About Selincro®

Selincro is a so-called opioid-receptor modulator. The compound acts by affecting the mechanism in the brain that may cause a continuing and uncontrolled intake of alcohol. This

means that Selincro may be prescribed in conjunction with psychosocial intervention to help control and limit the alcohol intake.

Selincro[®] is approved for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (>60g of pure alcohol a day for men, >40g pure alcohol a day for women, equal to about 5 units of alcohol for men and about 3.5 units of alcohol for women) without physical withdrawal symptoms and who do not require immediate detoxification.

Selincro[®] should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Selincro[®] should be prescribed only to patients who continue to have a high drinking risk level two weeks after the physicians initial assessment⁴.

Selincro[®] is to be taken as-needed; 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. The maximum dose of Selincro[®] is one tablet per day. In the clinical trials Selincro[®] was taken on average every other day. Selincro[®] has shown to be well tolerated. 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 duration⁴.

About alcohol dependence

Alcohol dependence is a brain disorder characterised by the creation of an imbalance in the reward system due to excessive alcohol consumption⁶. Due to changes in the brain's reward system, the alcohol-dependent patient will prioritise alcohol over important things such as health, family and working life. Diagnosis of alcohol dependence requires at least 3 of 6 criteria in the ICD-10 classification from WHO⁷.

Alcohol is a causal factor in more than 60 types of disease and injury, including cancer, cardiovascular diseases, cerebral atrophy, ulcer and cirrhosis of the liver^{8,9}. 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^{10,11}.

Excessive alcohol consumption is common in many parts of the world, especially in Europe where more than 14 million people are alcohol dependent.¹² In Europe the treatment gap is quite significant, with only 8% of patients receiving any form of treatment¹³. Both abstinence and reduction goals should be considered as part of a comprehensive treatment approach for patients with alcohol dependence¹⁴.

Contacts

Mads Kronborg, Media Relations Manager
Telephone (direct): 36 43 28 51

Søren Mikkil Berg, Media Relations
Telephone (direct): 36 43 49 80

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 centers in Denmark, China and the United States and production facilities in Italy, France, Mexico, China and Denmark. Lundbeck generated revenue of DKK 15 billion in 2012. For additional information, we encourage you to visit our corporate site www.lundbeck.com.

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