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Biotie: Selincro(TM) (nalmefene) receives positive opinion for approval in the European Union

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

Biotie today announced that its partner H.Lundbeck A/S (Lundbeck) has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization of Selincro(TM) (nalmefene; an opioid system modulator) for the reduction of alcohol consumption in adult patients with alcohol dependence who have 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.

The European Commission usually delivers its final decision on approval 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.

"*This is a historic occasion for Biotie. We are extremely pleased that the CHMP has recommended Selincro for approval and we look forward to the final decision from the European Commission in the coming months*." said Timo Veromaa, President & CEO of Biotie. He continued, "*There are limited options available for patients who need to reduce their harmful levels of alcohol intake and, for many, stopping drinking is not an acceptable or achievable treatment goal. Selincro will be the first product specifically developed to reduce alcohol consumption without the need to completely abstain from drinking. In Europe alone, over 10% of all deaths in adults are attributable to alcohol - this represents a huge medical burden and one we hope Selincro will help to address by providing physicians and patients with a fresh approach to treatment*".

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

Turku, 14 December 2012

Biotie Therapies Corp.

Timo Veromaa
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ABOUT THE CLINICAL STUDIES:

For the approval of Selincro, efficacy 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 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.

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 (>60 g/day for men, >40 g/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.

Biotie has licensed global rights to Selincroto Lundbeck. Under the terms of the agreement, Biotie is eligible for up to EUR 89 million in upfront and milestone payments plus royalties on sales of Selincro. Biotie has previously received EUR 12 million of such milestone payments from Lundbeck. Further milestone payments are expected on potential commercial launch of nalmefene and on the product potentially reaching certain predetermined sales. Lundbeck 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[1,2]. 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[3]. Alcohol is a causal factor in more than 60 types of disease and injury[4]. 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[5]. 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 consequence[6].

Excessive alcohol consumption is common in many parts of the world, especially in Europe where more than 14 million people are alcohol dependent[3,7]. In Europe the treatment gap is very large, with only 8% of patients receiving any treatment.[8] Both abstinence and reduction goals should be considered as part of a comprehensive treatment approach for patients with alcohol dependence[9].

ABOUT BIOTIE

Biotie is a specialized drug development company focused on the development of drugs for neurodegenerative and psychiatric disorders (e.g. Parkinson's disease, Alzheimer's disease and other cognitive disorders, alcohol and drug dependence (addiction) and post-traumatic stress disorder), and inflammatory and fibrotic liver disease. The company has a strong and balanced development portfolio with several innovative small molecule and biological drug candidates at different stages of clinical development. Biotie's products address diseases with high unmet medical need and significant market potential.

Biotie's most advanced product, SelincroTM (nalmefene), licensed to Lundbeck A/S, has on 14 December 2012 received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization of Selincro(TM) for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high level of alcohol consumption. In addition, Biotie has a strategic collaboration with UCB Pharma S.A. covering tozadenant which has successfully completed a Phase 2b study in 420 patients with advanced Parkinson's disease. Biotie shares are listed on NASDAQ OMX Helsinki Ltd.

References:

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