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Biotie Announces Completion of Phase 3 Program with Nalmefene in Alcohol Dependence; European Marketing Authorization Application (MAA) expected by the end of 2011

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Biotie Announces Completion of Phase 3 Program with Nalmefene in Alcohol Dependence; European Marketing Authorization Application (MAA) expected by the end of 2011

Biotie's partner, H. Lundbeck A/S (Lundbeck), has today announced the completion of *ESENSE2*, the last study in its Phase 3 program evaluating nalmefene for the treatment of alcohol dependence. Results from this 718 patient, double-blind, placebo controlled trial were consistent with the profile observed in previous clinical studies of nalmefene. Lundbeck plans to file a marketing authorization application (MAA) in Europe by the end of 2011.

Timo Veromaa, President and CEO of Biotie said, *"The conclusion of the Phase 3 program is an important milestone for Biotie and we are excited that Lundbeck is on track to submit this extensive clinical data package to the regulators in Europe by the end of this year. Nalmefene is the first treatment that has been specifically developed to help patients reduce their harmful levels of alcohol consumption, therefore offering patients, physicians and payors a highly differentiated treatment option*".

Nalmefene builds on a novel principle of treating alcohol dependence. Unlike existing therapies, treatment with nalmefene is not aimed at keeping patients from drinking. Instead, nalmefene helps patients control and limit the intake of alcohol. This is supported by specialists as a valuable treatment option to increase willingness among patients to initiate treatment and to promote compliance. In addition, nalmefene distinguishes itself by being available as a tablet formulation to be taken only according to need, whereas existing pharmaceuticals must be taken continuously over a longer period of time and are aimed at maintaining abstinence.

Lundbeck assessed a wide range of primary and secondary endpoints in its Phase 3 program for nalmefene including: number of heavy drinking days per month, total alcohol consumption, proportion of responders based on drinking measures, alcohol dependence symptoms and clinical status, liver function and other laboratory tests, pharmaco-economic outcomes and treatment discontinuation effects. All assessments were consistently in favour of nalmefene compared to placebo, though some were not statistically significant at every single time point. Overall, nalmefene reduced heavy drinking days and total alcohol consumption by more than 50% compared to pre-treatment baseline. The effect was observed already during the first month of treatment and was maintained throughout the study period in the three trials.

Furthermore, data from the 12-month safety study (*SENSE*) confirmed that the treatment effect of nalmefene was maintained and even improved after 1 year of treatment. Approximately two-thirds of the individuals in the studies had previously not been treated for alcohol dependence, despite an ongoing affliction, indicating that reduction of alcohol intake represents an attractive treatment objective compared to current treatments which all require abstinence.

The safety profile of nalmefene was consistent with observations and data provided in earlier studies, including Biotie's previously completed Phase 3 program. The most frequent adverse events in patients taking nalmefene were dizziness, insomnia and nausea. These adverse events were usually mild and transient in nature. The three studies in the Lundbeck Phase 3 clinical program were conducted in Europe and enrolled about 2,000 individuals with alcohol dependence. Including prior studies conducted by Biotie, the total clinical database now contains more than 3,000 patients with alcohol dependence.

Detailed efficacy and safety data is expected to be submitted by Lundbeck for presentation at scientific and medical meetings over the next 12 months.

About the clinical Phase 3 program

Based on the results of previous trials sponsored by Biotie, Lundbeck initiated three Phase 3 clinical studies in Europe in 2008 enrolling a total of approximately 2,000 individuals randomized into two groups receiving nalmefene (20 mg as needed, orally) or placebo, in addition to a brief medical compliance program. Two of the three trials (*ESENSE1* and *ESENSE2*), in which individuals were treated over a period of six months, were primarily aimed to demonstrate the efficacy of nalmefene, whilst the third study (*SENSE*), in which individuals were treated for 12 months, was primarily conducted to confirm the safety and tolerability of the compound.

About Nalmefene

Nalmefene is a small molecule opioid receptor antagonist that inhibits the reward pathway in the brain that reinforces the desire and craving for alcohol and other addictive substances. As a result, nalmefene removes a person's desire to drink.

Biotie has licensed global rights to nalmefene to Lundbeck. Under the terms of the agreement, Biotie is eligible for up to EUR 84 million in upfront and milestone payments plus royalties on sales from Lundbeck. Biotie has already received EUR 12 million from Lundbeck. Further milestone payments are expected on commercial launch of nalmefene and on the product reaching certain predetermined sales. Lundbeck will be responsible for manufacturing and registration of the product.

About alcohol dependence

Alcohol dependence is a disease in which the afflicted person continually craves alcohol, is unable to limit his or her drinking, needs to drink greater amounts to get the same effect and has withdrawal symptoms after stopping alcohol use. Alcohol dependence also has potentially fatal consequences such as liver cirrhosis and cancer, among others. As a result, this disease is one of the most serious health concerns in the western world, both socially and economically, with estimated associated costs to society of at least EUR 200 billion per annum. 10% of deaths and 25% of all emergency room admissions in the western world are directly alcohol related. According to the World Health Organization, there are 60 million people in Europe alone who are 'riskful' consumers of alcohol, which is categorized as alcohol consumption of 40-60 grams (5-6 standard drinks) by females and 60-100 grams (7-8 standard drinks) by males on a single drinking day. Despite this, alcohol dependence tends to be severely under-diagnosed with only approximately 13% of alcohol dependants receiving treatment, characterizing it as a large unmet medical need.

Currently, conventional methods of treating alcohol dependence require abstinence from drinking as a starting point - a high hurdle for an alcohol dependent patient. There are only a few pharmaceutical compounds that have received marketing approval to help alcohol dependent patients maintain abstinence. All these treatments, including psychosocial counseling measures, cannot prevent patients from relapsing and the long term prognosis remains poor. There are no approved therapies on the market yet to proactively help curb a person's urge to drink.

Turku, 15 June 2011

Biotie Therapies Corp.

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About Biotie Therapies

Biotie is a specialized drug development company focused on the development of drugs for neurodegenerative and psychiatric disorders (Parkinson's disease, Alzheimer's disease and other cognitive disorders, bipolar disorder, and alcohol and drug dependence) and inflammatory diseases (rheumatoid arthritis, psoriasis, chronic obstructive pulmonary disease and others). It has 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.

Partnerships with top-tier pharmaceutical partners are in place for several programs as well as a strategic collaboration with UCB Pharma S.A. Biotie's most advanced product, nalmefene for alcohol dependence, has completed Phase 3 clinical development by licensing partner H. Lundbeck A/S.

Biotie shares are listed on NASDAQ OMX Helsinki Ltd.