



Biotie: Selincro receives positive draft guidance from UK's NICE

Biotie Therapies (Biotie) announces that the National Institute for Health and Care Excellence (NICE), the United Kingdom's health technology assessment authority, has issued draft guidance recommending the use of Selincro (nalmefene) within the conditions of its marketing authorization in the National Health Service (NHS) in England. The draft guidance is open for comments until July 29, and final guidance is expected in November 2014.

Selincro (nalmefene) is a dual-acting opioid system modulator and the first therapy approved in Europe for the reduction of alcohol consumption in alcohol dependent individuals. Biotie has licensed global rights to Selincro to H.Lundbeck A/S (Lundbeck). Lundbeck received European marketing authorization for Selincro in February 2013 and has to date introduced the product in over 20 European markets.

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Biotie Therapies Corp.

Timo Veromaa
President and CEO

Further information:

For further information, please contact:

Virve Nurmi, Investor Relations Manager
tel. +358 2 274 8900, e-mail: virve.nurmi@biotie.com

Distribution:

NASDAQ OMX Helsinki Ltd
Main media
www.biotie.com

About Nalmefene (sold under the brand name Selincro in Europe)

In Europe, nalmefene is 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. Nalmefene 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. Nalmefene 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 nalmefene to 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 nalmefene. To date, Biotie has received EUR 16 million in milestone payments from Lundbeck. Further payments of EUR 2 million are expected on commercial launch of Selincro in each of France, Germany and Spain, and further potential milestone payments on launches in certain other markets and if the product reaches certain predetermined sales. In addition, Biotie will continue to receive

royalties on sales in all launched markets and make a contribution to Lundbeck towards post approval commitments studies. Lundbeck is responsible for the registration, manufacturing and marketing of the product.

About Biotie

Biotie is a specialized drug development company focused on products for neurodegenerative and psychiatric disorders. For the past years, Biotie has successfully operated a strategy built around search, profile and partner. This has delivered Selincro (nalmefene) for alcohol dependence, which received European marketing authorization in February 2013 and is currently being rolled out across Europe by partner H. Lundbeck A/S, and tozadenant, a novel A2a antagonist which is transitioning into Phase 3 development for Parkinson's disease and for which Biotie holds exclusive, global rights. Biotie is actively developing its pipeline assets, including SYN120, a unique potent 5-HT₆/5-HT_{2a} dual antagonist for which Biotie initially expects to conduct a Phase 2 study in Parkinson's disease dementia that is largely funded by the Michael J Fox Foundation; nepicastat, a selective inhibitor of dopamine beta hydroxylase which is currently in a Phase 2 study, fully funded by NIDA, for treatment seeking cocaine addicts; and BTT-1023, a monoclonal antibody targeting Vascular Adhesion Protein 1 for which Biotie intends to conduct a Phase 2 study in primary sclerosing cholangitis, a rare fibrotic disease of the liver. Biotie's shares are listed on NASDAQ OMX Helsinki.