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Biotie: nepicastat study in cocaine dependence completes enrollment ahead of schedule - top-line data expected around end 2014

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Biotie Therapies today announced that patient enrollment into the Phase 2 study investigating nepicastat for cocaine dependence has been completed ahead of schedule. The 11-week, 179-patient study is being conducted at 10 US clinics under a Collaborative Research and Development Agreement (CRADA) with the National Institute on Drug Abuse (NIDA) at the US National Institutes of Health. Top-line results from the study are expected around the end of 2014.

"The extraordinary commitment that both NIDA and the trial investigators have shown for this program has helped the study exceed the already ambitious enrollment targets", commented Dr. Stephen Bandak, CMO of Biotie. "We look forward to completion of the clinical treatment phase and await the top-line results, scheduled to be available around year end, with great interest."

Turku, 27 May 2014

Biotie Therapies Corp.

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About nepicastat (SYN117)

Nepicastat is an orally administered, potent and selective inhibitor of the enzyme dopamine beta-hydroxylase (DBH) which converts dopamine into norepinephrine. Like many other addictions, cocaine dependence is driven by dysregulation in the dopamine-reward system. Inhibition of DBH by nepicastat increases levels of dopamine, which may reduce craving for cocaine, and reduces the levels of norepinephrine, which may decrease the pleasurable responses to cocaine and the potential for stress-induced relapse following withdrawal.

Nepicastat is currently in Phase 2 development for cocaine dependence. A previously completed placebo-controlled Phase 2a study in non-treatment seeking cocaine addicts showed that nepicastat

had a favourable safety profile and was well tolerated when administered with cocaine. An 11-week Phase 2 safety and efficacy trial in 179 treatment seeking cocaine addicted patients, funded by the U.S. National Institute on Drug Abuse under a Collaborative Research and Development Agreement, has completed patient enrollment, and top-line results are expected around the end of 2014.

Biotie retains full rights to nepicastat and will be able to use data from studies conducted with NIDA to support future potential regulatory submissions.

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-HT2a dual antagonist for which Biotie expects to conduct a Phase 2 study in Alzheimer's disease; 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.