Biotie: Tozadenant Phase 2b Parkinson's disease study published in Lancet Neurology

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Biotie announces that full data from the positive Phase 2b study evaluating tozadenant, an adenosine A2a antagonist, in Parkinson's disease patients experiencing end of dose wearing off have been published in Lancet Neurology (Hauser RA, Olanow CW, Kieburtz KD, et al. Tozadenant (SYN115) in patients with Parkinson's disease who have motor fluctuations on levodopa: a phase 2b, double-blind, randomised trial. Lancet Neurol 2014; published online July 7. http://dx.doi.org/10.1016/S1474-4422(14)70148-6). The Phase 2b study was an international, randomised, double blind, placebo-controlled, parallel group, dose finding study in 420 levodopa-treated patients with end of dose wearing off (i.e at least 2.5 hours off time per day). Patients received either 60mg, 120mg, 180mg or 240mg tozadenant or matching placebo twice daily for 12 weeks. The primary outcome was a change from baseline to week 12 in hours per day spent in the off-state, assessed from patient diaries. As previously disclosed, the study demonstrated that tozadenant, when compared to placebo, decreased levodopa related motor fluctuations.

Previously released topline results for this study included clinically relevant and highly statistically improvements in 'off' time, 'on' time, UPDRS part III and UPDRS parts I-III. In addition to providing more details on these endpoints, further data published in Lancet Neurology include highly significant improvements in the clinician global impression of severity and clinician global impression of improvement in all tozadenant groups compared with placebo and patient global impression of improvement in the 120 mg BID group. Results of sensitivity analyses of the primary efficacy outcome using multiple methods were consistent with the improvements of the primary analysis.

Many patients with Parkinson's disease experience motor fluctuations despite treatment with available drugs. During this "off-state" the symptoms of Parkinson's, including rigidity, tremors and difficulty in movement, come back and can have a significant impact on daily living. There is a great need for new drugs that can maintain robust benefits for patients throughout the day or that can be added to

existing treatments to smooth the response without exacerbating dyskinesias that develop with long term therapy with existing treatments.

"This phase 2 study identified doses of tozadenant that were well tolerated and demonstrated efficacy to reduce off time without increasing troublesome dyskinesia," noted Robert A. Hauser M.D., Director of the Parkinson's disease and Movement Disorders Center at the University of South Florida and lead investigator of the trial. "Tozadenant has the potential to provide benefit for Parkinson patients who are experiencing fluctuations on levodopa and would be a welcome addition to our treatment armamentarium. I look forward to similarly well-executed phase 3 trials."

"We are excited that this study has been published in Lancet Neurology, the highest ranked clinical neurology journal", said Timo Veromaa, President and CEO of Biotie Therapies Corp. "We are greatly encouraged by the robust data set and continue to plan aggressively for Phase 3 that will begin in the first half of 2015."

Turku, 8 July 2014

Biotie Therapies Corp.

Timo Veromaa
President and CEO

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About tozadenant

Tozadenant is an oral, potent and selective adenosine A2a receptor antagonist being developed for the treatment of Parkinson's disease. Tozadenant has displayed clinically relevant and statistically highly significant effects in Parkinson's disease, across multiple pre-specified evaluation metrics, in a 420 patient Phase 2b study completed in December 2012, and it is currently transitioning into Phase 3 development.

The preparations for the tozadenant Phase 3 program in Parkinson's disease have progressed well. These activities include CMC and non-clinical work, and certain Phase 3 enabling clinical pharmacology studies.

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 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