Published: 08:00 CET 11-12-2012 /Thomson Reuters /Source: Biotie Therapies Oyj /XHEL: BTH1V /ISIN: FI0009011571

Biotie's tozadenant (SYN115) meets primary and multiple secondary endpoints in phase 2b study in Parkinson's disease

BIOTIE THERAPIES CORP. STOCK EXCHANGE RELEASE 11 DECEMBER 2012 at 9:00 a.m.

Biotie's tozadenant (SYN115) meets primary and multiple secondary endpoints in phase 2b study in Parkinson's disease

Biotie today reported top-line data from a Phase 2b study evaluating its adenosine A2a antagonist tozadenant (SYN115) in Parkinson's disease (PD) patients experiencing levodopa related end of dose wearing off. The study met its primary endpoint of a statistically highly significant decrease in 'off' time vs. placebo, as well as demonstrating efficacy across multiple secondary endpoints. Full data from the study will be disclosed at upcoming medical conferences and in scientific publications.

In the 420 patient study, tozadenant displayed clinically relevant and statistically highly significant effects on PD across multiple pre-specified evaluation metrics including: a decrease vs. placebo in 'off' time, an increase in 'on' time, an improved score on UPDRS part III and UPDRS parts I-III combined, as well as improvements on clinician- and patient-assessed global impression scores. Additionally, the study identified the minimally efficacious and maximum feasible dose levels, as well as clinically useful target doses for Phase 3. Tozadenant was generally well tolerated in the study. "This trial met all the objectives to be expected of a Phase 2 study", said Dr. Stephen Bandak, CMO of Biotie Therapies Corp.

Dr. C Warren Olanow, Professor of Neurology and Neuroscience at the Mount Sinai School of Medicine stated "This important study demonstrated that the A2a antagonist tozadenant reduced 'off' time in advanced PD patients. This agent, which does not act directly on the dopamine system, represents a new class of therapeutic agent that could be used to aid in the management of patients with this potentially disabling disorder."

Dr. Robert Hauser, Professor of Neurology, Molecular Pharmacology and Physiology at the University of South Florida stated "The patient reported outcomes indicate that the overall effect of tozadenant was clinically relevant and provided a meaningful improvement for patients. These results suggest that tozadenant promises to be a useful treatment for Parkinson's disease patients experiencing wearing off fluctuations on levodopa."

Dr. Karl Kieburtz, Professor of Neurology, Environmental Medicine, and Community & Preventive Medicine at the University of Rochester added, "To see such consistent, dose-responsive results in a Phase 2 study, with both patient-reported and physician-based scales showing meaningful beneficial effects, is both striking and gratifying."

"We are extremely pleased with the results of this study", said Timo Veromaa, President and CEO of Biotie Therapies Corp. "The rigor with which the study was conducted also makes us optimistic that it may be considered a pivotal study within the envisioned development program. We look forward to analyzing the results in detail with our license partner UCB and expect a decision from UCB in the first quarter of 2013 regarding the next steps."

Turku, 11 December, 2012

Biotie Therapies Corp.

Timo Veromaa
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Distribution:
NASDAQ OMX Helsinki Ltd
Main Media

About the study (ClinicalTrials.gov identifier: NCT01283594)

The completed Phase 2b study was a randomized, placebo-controlled, double-blind dose-finding study conducted in the US, Canada, Chile, Argentina, Ukraine and Romania. Altogether 420 PD patients experiencing levodopa related end of dose wearing off were enrolled into the study. In these patients, treatment with levodopa is insufficient to control PD symptoms until their next dose, resulting in an 'off' period when symptoms reappear.

The subjects were randomized in an even ratio to receive either one of four dose levels of tozadenant or matching placebo for 12 weeks, in addition to their standard anti-PD medications. The primary goal of the study was to determine the efficacy of tozadenant in reducing the mean number of hours per day spent in the 'off' state. The trial also

assessed the safety of tozadenant and its impact on various measures of motor symptom severity, dyskinesia and non-motor symptoms.

About tozadenant (SYN115)

Tozadenant is an oral, potent and selective adenosine A2a receptor antagonist, which enters the brain and modulates regions associated with motor and non-motor function. Biotie holds a license from Roche for development and commercialization of tozadenant in all indications.

Biotie has granted UCB Pharma S.A. a license for exclusive, worldwide rights to tozadenant. Pending evaluation of the results of the now completed Phase 2b study, UCB will be responsible for conducting the Phase 3 program and commercializing tozadenant. UCB is expected to take a decision about this in the first quarter of 2013.

About Parkinson's disease

Parkinson's disease is the second most common neurodegenerative disorder, after Alzheimer's disease. It affects about one percent of people ages 65-69, rising to up to three percent of people who are 80 years and older. The symptoms of Parkinson's disease result from decreased dopamine production in regions of the brain controlling movement.

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 has a strategic collaboration with UCB Pharma S.A. covering tozadenant for Parkinson's disease. The Marketing Authorization Application for Biotie's most advanced product, SelincroTM (nalmefene) for alcohol dependence was filed in the EU by our partner H. Lundbeck A/S and was accepted for review by the European Medicines Agency in December 2011. Biotie shares are listed on NASDAQ OMX Helsinki Ltd.