Published: 09:15 CEST 23-04-2015 /GlobeNewswire /Source: Biotie Therapies Oyj / : BTH1V /ISIN: FI0009011571

Biotie provides update on tozadenant Phase 3 program

BIOTIE THERAPIES CORP. STOCK EXCHANGE RELEASE 23 April 2015 at 10.15 a.m.

Biotie provides update on tozadenant Phase 3 program

Biotie has further refined its plans for the design and conduct of Phase 3 trials in Parkinson's disease (PD) patients experiencing levodopa related end-of-dose 'wearing-off' (motor fluctuations). The phase 3 program will consist of a double- blind trial with an open-label extension and, providing this demonstrates safety and efficacy, will be followed by a separate open-label trial to generate further clinical safety data.

The refinement in the trial design does not impact the expected overall timeline to submission of a U.S. New Drug Application for tozadenant, but allows top-line results from the double-blind portion to be available by the end of 2017, approximately one year earlier than previously planned, while maintaining adequate statistical power in the study.

In the double-blind portion, 450 participants will be randomized to receive twice daily doses of 60mg or 120mg of tozadenant or placebo in addition to their standard anti-PD medications, for 24 weeks. The primary endpoint will be time spent in the "off" state in patients taking tozadenant as compared to placebo between baseline and week 24. Secondary endpoints will include "on" time without troublesome dyskinesia, the Unified Parkinson's Disease Rating Scale, Clinical Global Impression of Change and Patient Global Impression of Change. The placebo-controlled period will be followed by a 52 week open label treatment period to collect additional clinical safety data. The study is expected to start recruiting patients in the United States, Canada and selected European countries in the middle of 2015.Based on current estimates and the number of patients being enrolled into the study, top-line data is expected to be available by the end of 2017.

Providing the double-blind portion of the trial meets its primary efficacy endpoint, another open-label trial will be initiated in a separate population of 450 PD patients to establish the requisite number of unique patient exposures required for approval. The open label trial will evaluate safety over a year and is also expected to be conducted in North America and selected European countries. Patients will be dosed with 120 mg of tozadenant twice/day, although the investigator may adjust the dose to 60 mg twice/day based on individual response.

Turku, 23 April 2015

Biotie Therapies Corp.

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About tozadenant (SYN115)

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.

About Biotie

Biotie is a specialized drug development company focused on products for neurodegenerative and psychiatric disorders. Biotie's development has delivered Selincro (nalmefene) for alcohol dependence, which received European marketing authorization in 2013 and is currently being rolled out across Europe by partner Lundbeck. The current development products include tozadenant for Parkinson's disease, which is transitioning into Phase 3 development, and two additional compounds which are in Phase 2 development for cognitive disorders including Parkinson's disease dementia, and primary sclerosing cholangitis (PSC), a rare fibrotic disease of the liver.