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Biotie announces start of tozadenant Phase 3 Study in Parkinson's disease

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Biotie (Nasdaq Helsinki BTH1V; NASDAQ: BITI) announces the start of the Phase 3 clinical study of tozadenant, an investigational adenosine A2a receptor antagonist, in patients with Parkinson's disease (PD) experiencing levodopa related end-of-dose "wearing-off".

The Phase 3 study (TOZ-PD) is a randomized, double-blind, placebo controlled trial that will evaluate efficacy and safety of tozadenant compared to placebo in 450 PD patients experiencing end-of-dose wearing off episodes. Participants will be randomized to receive twice daily doses of 60 mg or 120 mg of tozadenant or placebo, in addition to their standard anti-PD medications, for 24 weeks. The primary endpoint will be reduction in time spent in the "off" state in patients taking tozadenant as compared to placebo between baseline and week 24. The placebo-controlled period will be followed by a 52 week open label treatment period to collect additional safety data. As previously announced, Biotie Therapies reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) of this study.

A successful outcome to the study will confirm the safety and efficacy observed in the previously completed Phase 2b study of tozadenant in this indication and provide a second pivotal study to support submission of an New Drug Application (NDA) for the use of tozadenant as adjunctive treatment to levodopa in patients experiencing end-of-dose wearing off.

Based on current estimates, top-line data from the double-blind portion of the study is expected to be available by the end of 2017.

Timo Veromaa, President and CEO of Biotie, commented: "A significant number of patients with Parkinson's disease continue to suffer debilitating "off" episodes, despite therapy with existing PD drugs. Tozadenant promises to bring the first new mechanism of action in the treatment of PD for nearly twenty years and we are excited to commence this Phase 3 trial. Thanks to the existing and new shareholders who participated in our recent capital increase, we are in a strong financial position to advance tozadenant through the regulatory process and make it available to patients to address this significant unmet medical need".

Turku, 21 July 2015

Biotie Therapies Corp.

Timo Veromaa
President and CEO

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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 significant effects in Parkinson's disease, across multiple pre-specified endpoints, in a 420 patient Phase 2b study. Full data from the study were published in Lancet Neurology in July 2014, and it is expected that the study will be accepted as one of the two pivotal studies required for registration in the United States.

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 in 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.