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Biotie announces start of patient enrolment into Phase 2a clinical study with BTT1023 in primary sclerosing cholangitis

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Biotie announces start of patient enrolment into Phase 2a clinical study with BTT1023 in primary sclerosing cholangitis

Biotie Therapies Corp ("Biotie") announces the start of patient enrolment into the Phase 2a clinical study evaluating BTT1023, Biotie's fully human monoclonal antibody targeting Vascular Adhesion Protein-1, in primary sclerosing cholangitis (PSC). PSC is a progressive immune mediated biliary disease characterised by bile duct inflammation and fibrosis, and accompanying hepatic fibrosis, that frequently results in the need for liver transplantation. The study is being funded through the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership*.

The BUTEO study (**B**TT1023, a human monoclonal antibody targeting vasc**u**lar adhesion pro**t**ein (VAP-1), in the tr**e**atment of patients with primary sclerosing ch**o**langitis) is an investigator-sponsored open label, single arm, multi-centre study that will evaluate efficacy, safety and pharmacokinetic properties of BTT1023 in 41 patients with PSC. Patients will receive BTT1023 via intravenous infusion every two weeks over an 11 week treatment period. The primary efficacy endpoint is a reduction of elevated levels of alkaline phosphatase, a blood biomarker of bile duct inflammation; secondary endpoints include various measures of liver injury and fibrosis.

The grant holder and Co-Investigator for the study, Professor David Adams, Director of the National Institute for Health Research (NIHR) Biomedical Research Unit in Liver Disease and Centre for Liver Research at the University of Birmingham, UK, said "We have demonstrated that PSC is driven by aberrant lymphocyte homing and were the first to report a role for VAP-1 in mediating liver inflammation and fibrosis. We are excited to be working with Biotie to investigate whether blocking VAP-1 with BTT1023 can offer the first effective therapeutic option for this life-changing disease."

The two-stage study design includes a pre-planned futility analysis. Based on current estimates, it is expected that the requisite number of patients will have been treated by the end of 2016 to enable the futility analysis to be completed.

Clinicaltrials.gov identifier: NCT02239211.

Turku, 31 March 2015

Biotie Therapies Corp.

Timo Veromaa
President and CEO

For further information, please contact:

Virve Nurmi, Biotie Therapies Corp.
tel. +358 2 274 8900
e-mail: virve.nurmi@biotie.com

DISTRIBUTION
NASDAQ OMX Helsinki Ltd
Main Media
www.biotie.com

ABOUT BTT1023

BTT1023 is a fully human monoclonal antibody that specifically binds to vascular adhesion protein-1 (VAP-1). BTT1023 has demonstrated encouraging efficacy and safety in early clinical studies in rheumatoid arthritis and psoriasis patients and in a range of preclinical models of inflammatory diseases, including COPD. More recently, an important role for VAP-1 has also been demonstrated in fibrotic diseases.

BTT1023 is in Phase 2 clinical development for the treatment of primary sclerosing cholangitis (PSC), a chronic and progressive fibrotic liver disease for which there are currently no effective therapeutic treatments. BTT1023 has received Orphan Drug Designation in the EU for the treatment of PSC. Biotie retains full rights to BTT1023.

ABOUT THE INVESTIGATORS

The grant holder and Co-Investigator for the study is Professor David Adams, Director of the National Institute for Health Research (NIHR) Biomedical Research Unit in Liver Disease and Centre for Liver Research at the University of Birmingham, UK.

The University of Birmingham delivers excellence in liver research and has access to a large, well-defined, cohort of patients with PSC. Professor Adams at Birmingham developed the concept of PSC as a disease driven by aberrant lymphocyte homing and first reported a role for VAP-1 in the liver in mediating liver inflammation and fibrosis. Together with Chief Investigator Dr Gideon Hirschfield he runs the PSC translational programme in Birmingham from where patients will be recruited for the trial.

ABOUT PRIMARY SCLEROSING CHOLANGITIS

PSC is an orphan disease featuring chronic and progressive inflammation of the liver and is characterised by bile duct fibrosis and progression to cirrhosis. It most commonly affects men of working age and more than 50% of patients require liver transplantation within 10-15 years of symptomatic presentation. In the later stages of the disease patients feel severely unwell, with abdominal pain, itching, jaundice, poor appetite, deep fatigue and signs of malnourishment and eventually liver failure and death. There are currently no effective treatments to treat PSC and there is a high unmet medical need for new treatment options.

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.

ABOUT EME

*The project is managed by the Efficacy and Mechanism Evaluation Programme, a Medical Research Council and NIHR partnership in the UK, that supports later-phase "science-driven" clinical trials and evaluative studies, which seek to determine whether a health intervention (e.g. a drug, diagnostic technique or device) works and in some cases how or why it works. The programme is funded by the MRC and NIHR (www.nihr.ac.uk), with contributions from the CSO in Scotland, NISCHR in Wales and the HSC R&D Division, Public Health Agency in Northern Ireland.
www.nets.nihr.ac.uk/programmes/eme