Clinical study with Biotie's BTT1023 in primary sclerosing cholangitis awarded external grant funding

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Biotie Therapies Corp. will be working in partnership with the University of Birmingham, UK, who have been awarded funding of up to approximately EUR 1.0 million for an investigator-sponsored, Phase 2, proof of concept study with its vascular adhesion protein-1 (VAP-1) antibody, BTT1023, in primary sclerosing cholangitis (PSC). PSC is a chronic and progressive orphan fibrotic disease for which there are currently no approved therapeutic treatments. The study will be conducted in the UK and is expected to start recruiting patients by the end of 2014.

The grant holder and Chief 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 delighted to have been awarded this peer-reviewed grant which will allow us to investigate whether blocking VAP-1 with BTT1023 can offer the first effective therapeutic option for this life-changing disease."

The investigator-sponsored study will be an open label, single arm, multi-centre study enrolling 41 patients which will examine the efficacy, safety and pharmacokinetic properties of BTT1023 in patients with primary sclerosing choloangitis. The duration of drug treatment in the study is 11 weeks and the primary efficacy endpoint will be reduction of elevated levels of alkaline phosphatase, a blood biomarker of bile duct inflammation.

This project was awarded by the NIHR Efficacy and Mechanism Evaluation (EME) Programme* and is funded and managed by the National Institute for Health Research (NIHR) on behalf of the MRC-NIHR partnership. Biotie retains full rights to BTT1023.

Turku, 24 July 2014

Biotie Therapies Corp.

Timo Veromaa
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ABOUT BTT1023

BTT1023 is a fully human monoclonal antibody that specifically binds to vascular adhesion protein-1 (VAP-1) and prevents inflammation. Biotie has previously demonstrated encouraging efficacy and safety for BTT1023 in early clinical studies in rheumatoid arthritis and psoriasis patients and in a range of preclinical models of inflammatory diseases, including COPD. More recently, Biotie has generated data indicating that VAP-1, in addition to its role in inflammatory diseases, has an important role in fibrotic diseases. These data, generated in collaboration with National Institute for Health Research Liver Biomedical Research Unit at the University of Birmingham, UK, reveal significant potential for BTT1023 in fibrotic diseases of the liver.

About the Investigators

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 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 no currently approved drugs 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. 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 BTT1023, 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.

*The EME Programme is funded by the MRC and NIHR, with contributions from the CSO in Scotland and NISCHR in Wales and the HSC R&D Division, Public Health Agency in Northern Ireland. It is managed by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton.