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Active Biotech enters into clinical trial collaboration agreement for a clinical study with tasquinimod in myelofibrosis

Lund, July 31 2023 - Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced it has entered into a clinical trial collaboration agreement with Stichting Haemato-Oncologie Volwassenen Netherland (HOVON) and Stichting Oncode Institute (Oncode) for the upcoming clinical proof-of-concept trial of tasquinimod in myelofibrosis. HOVON will be the legal sponsor of the trial, Oncode the main financier and Active Biotech will provide tasquinimod study drug to the study. Active Biotech has a global patent license agreement with Oncode for tasquinimod in myelofibrosis since February 2022.

The planned study will investigate tasquinimod given as monotherapy to patients with myelofibrosis who have previously been treated with a JAK inhibitor or who are ineligible for JAK inhibitor treatment. The trial will be conducted at sites in the Netherlands and in Germany.

The study is supported by strong preclinical data showing that tasquinimod ameliorates myelofibrosis in an experimental mouse model (Leimkuhler et al., Cell Stem Cell. 2021 Apr 1;28(4): 637-652). The data presented in the publication further demonstrate that treatment with tasquinimod results in normalization of the spleen size and blood counts and reduction of fibrosis in the bone marrow.

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About tasquinimod

Tasquinimod is an oral immunomodulatory and anti-angiogenic investigational treatment, that affects the tumor's ability to grow and metastasize. Tasquinimod is developed as a new immunomodulatory treatment for hematological malignances, in the first step multiple myeloma. Tasquinimod has previously been studied as an anti-cancer agent in patients with solid cancers, including a phase III randomized trial in patients with metastatic prostate cancer. The tolerability of tasquinimod is well-characterized based on these previous experiences. Tasquinimod has demonstrated a clear therapeutic potential in preclinical models of multiple myeloma, when used as a single agent and in combination with standard multiple myeloma therapy. A clinical Phase Ib/IIa study is ongoing with tasquinimod in relapsed and refractory multiple myeloma. Tasquinimod ameliorates disease development in preclinical models for myelofibrosis. In February 2022 Active Biotech entered into an exclusive license agreement with Oncode Institute, acting on behalf of Erasmus Universiteit Medisch Centrum (Erasmus MC) to develop and commercialize tasquinimod worldwide in myelofibrosis. A clinical study with tasquinimod in patients with myelofibrosis is planned to start in 2023.

About myelofibrosis

Myelofibrosis (MF) is a rare blood cancer belonging to a group of disorders called myeloproliferative neoplasms. The underlying cause of MF is unknown. The estimated annual incidence of MF is 0.4 - 1.3 cases per 100 000 people in Europe. Patients with MF have an abnormal production of blood-forming cells leading to the replacement of healthy bone marrow with scar tissue (fibrosis). Due to the lack of normal blood cell production patients typically present with laboratory value abnormalities such as anemia and changes in white blood cell counts and blood cell-differentiation. Later symptoms include enlargement of the spleen, an increased risk for infections, night sweats and fever. MF is associated with shortened survival and causes of death include bone marrow failure and transformation into acute leukemia. MF can be treated with bone marrow transplantation for eligible individuals, erythropoietin to manage anemia and JAK inhibitors to reduce spleen size. At present there are no approved therapies that would reverse bone marrow fibrosis in MF.

About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that deploys its extensive knowledge base and portfolio of compounds to develop first-in-class immunomodulatory treatments for specialist oncology and immunology indications with a high unmet medical need and significant commercial potential. Following a portfolio refocus, the business model of Active Biotech aims to advance projects to the clinical development phase and then further develop the programs internally or pursue in partnership. Active Biotech currently holds three projects in its portfolio: The wholly owned small molecule immunomodulators, tasquinimod and laquinimod, both having a mode of actions that includes modulation of myeloid immune cell function, are targeted towards hematological malignancies and inflammatory eye disorders, respectively. Tasquinimod, is in clinical phase Ib/IIa for treatment of multiple myeloma. Laquinimod is in clinical development for treatment of non-infectious uveitis and a clinical phase I study with a topical ophthalmic formulation has been concluded. Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a phase Ib/II clinical program in patients with advanced solid tumors. Please visit **www.activebiotech.com** for more information.

Attachments

Active Biotech enters into clinical trial collaboration agreement for a clinical study with tasquinimod in myelofibrosis