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Active Biotech enters agreement for a clinical study of tasquinimod in myelofibrosis

Lund, July 1, 2024 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced it has entered into a clinical study agreement for a Phase II investigator-initiated clinical study investigating the use of tasquinimod in myelofibrosis. The study will be led by Lucia Masarova, M.D., assistant professor of Leukemia at The University of Texas MD Anderson Cancer Center. Active Biotech will support the study with the Investigational Medicinal Product and related costs.

The clinical study, entitled *Open Label Phase 2 Study of Tasquinimod in Patients with Primary Myelofibrosis (PMF), Post-Polycythemia Vera Myelofibrosis (Post-PV MF), or Post-Essential Thrombocytosis Myelofibrosis (Post-ET MF)*, will evaluate the efficacy and safety of tasquinimod in patients with myelofibrosis.

The primary objective of the study is to determine the anti-tumor activity of tasquinimod as monotherapy and in combination with a stable dose of ruxolitinib based on the measurement of objective response rate (ORR) after six cycles of treatment. Secondary objectives include safety and tolerability, symptom burden, duration of response and bone marrow fibrosis grade.

More information about the study is available at **ClinicalTrials.gov** NCT06327100.

“This is the first time tasquinimod will be evaluated in patients with myelofibrosis. With a well-known safety profile from previous clinical studies and strong preclinical myelofibrosis data, we will now test the hypothesis that tasquinimod can act as a disease modifying treatment in this group of patients with a high unmet medical need. At present, JAK inhibitors is the only approved drug class in myelofibrosis, and there is an urgent need for effective and safe compounds with a new mechanism of action,” said Erik Vahtola, Chief Medical Officer at Active Biotech.

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About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that develops first-in-class immunomodulatory treatments for oncology and immunology indications with a high unmet medical need and significant commercial potential. Active Biotech currently holds three projects in its portfolio, of which tasquinimod and laquinimod are wholly owned small molecule immunomodulators with a mode of action that includes modulation of myeloid immune cell function. The projects are in clinical development for hematological malignancies and inflammatory eye disorders, respectively. The company's core focus is on the development of tasquinimod in myelofibrosis, a rare blood cancer, where clinical proof-of-concept studies are being prepared. Also ongoing is a clinical Phase Ib/IIa study in multiple myeloma. Laquinimod is in clinical development for the treatment of non-infectious uveitis. A clinical phase I program with a topical ophthalmic formulation is ongoing to support phase II development together with a partner. The third pipeline project is naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, which is in a phase Ib/II clinical program in patients with advanced solid tumors. Please visit **www.activebiotech.com** for more information.

About tasquinimod

Tasquinimod is an orally active small molecule immunomodulator with a novel mode of action, blocking tumor supporting pathways in the bone marrow microenvironment. Tasquinimod is being developed as a new immunomodulatory treatment for hematological malignances. 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 patent license agreement with Oncode Institute, a foundation acting on behalf of Erasmus Universiteit Medisch Centrum (Erasmus MC) to develop and commercialize tasquinimod in myelofibrosis. Clinical studies with tasquinimod in patients with myelofibrosis are planned to start in 2024.

Attachments

Active Biotech enters agreement for a clinical study of tasquinimod in myelofibrosis