24 FEBRUARY 2025 10:00:00 CET

First patient enrolled in the HO172 clinical study of tasquinimod in myelofibrosis

Lund Sweden, February 24, 2025 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced that the first patient has been included in the phase Ib/II clinical study of tasquinimod in patients with myelofibrosis refractory or ineligible to JAK2 inhibitor treatment.

"We are pleased to have enrolled the first patient into the study where tasquinimod will be evaluated in a patient population with high unmet medical need for new treatment options with a different mechanism of action. I am excited to follow the study progress," said Dr. Erik Vahtola, CMO of Active Biotech.

The single-arm, multi-center open-label study will evaluate the safety and efficacy of tasquinimod given as monotherapy. The run-in safety part (phase I) will determine dose-limiting toxicity during 28 days of treatment in the first patients whereafter enrolment into the efficacy phase II part will begin. The primary efficacy endpoint is the proportion of patients who achieve at least a 35% reduction in spleen volume after six 4-week cycles of tasquinimod. Further, the study will determine the effect of tasquinimod on changes in bone marrow fibrosis, myelofibrosis-related symptoms, changes in variant allele frequency and overall survival.

The study will be conducted at the Stichting Haemato-Oncologie Volwassenen Netherland (HOVON) network of study centers in the Netherlands and Germany and HOVON is the legal sponsor of the study.

Active Biotech has a global patent license agreement with Oncode Institute for tasquinimod in myelofibrosis since February 2022. Oncode Institute will be the main financier of the study.

For more information on the study, see **clinicaltrials.gov** (NCT06605586), the HOVON website **www.hovon.nl** and the previously recorded interview with lead principal investigator Rebekka Schneider, connected to Oncode Institute and Erasmus MC **https://ir.financialhearings.com/active-biotech-2023**.

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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 has been initiated. 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.

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 approximately 1.5 cases per 100,000 people in EU, US, UK, and Japan. 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.

Attachments

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