10 MARCH 2025 08:30:00 CET

First patient dosed in the phase II study of tasquinimod in myelofibrosis in the US

Lund, Sweden, March 10, 2025 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced the first patient has been dosed in the phase II clinical study of tasquinimod in myelofibrosis in the US. The clinical study, entitled Open Label Phase 2 Study of Tasquinimod in Patients with Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis or Post-Essential Thrombocytosis Myelofibrosis, evaluates the efficacy and safety of tasquinimod as monotherapy and in combination with standard JAK2 inhibitor (JAKi) treatment in patients with myelofibrosis.

The primary objective of the study is to determine the anti-tumor activity of tasquinimod as monotherapy in JAKi-relapsed or ineligible patients, and separately in combination with the JAKi ruxolitinib in patients with a suboptimal response to ruxolitinib alone, 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.

The study is being conducted at The University of Texas MD Anderson Cancer Center (Houston, TX, and the principal investigator is Lucia Masarova, M.D., assistant professor of Leukemia at MD Anderson. Active Biotech will support the study with the Investigational Medicinal Product and related costs. Detailed information about the study is available on **clinicaltrials.gov** NCT06327100.

“The use of tasquinimod as a single agent in relapsed/refractory myelofibrosis patients as well as in combination with a JAK2 inhibitor is aligned with our current understanding of its potential capabilities of positively modulating the suppressive bone marrow microenvironment. We are enthusiastic to follow the progress of the study,” said Dr Erik Vahtola, Chief Medical Officer at Active Biotech.

For further information, please contact:

Helén Tuvesson, *CEO*, +46 46 19 21 56, **helen.tuvesson@activebiotech.com**
Hans Kolam, *CFO*, +46 46 19 20 44, **hans.kolam@activebiotech.com**

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

First patient dosed in the phase II study of tasquinimod in myelofibrosis in the US