

Active Biotech receives positive feedback on its clinical study with tasquinimod in myelofibrosis

Lund, Sweden – February 10, 2026 – Active Biotech (NASDAQ Stockholm: ACTI) today received positive feedback on its clinical proof-of-concept trial with tasquinimod in myelofibrosis. The study will now resume recruitment.

“We are very happy with the response to our protocol amendments, and we expect to report interim results from the study in 2026 and study results towards the end of 2027,” said Active Biotech CEO Helén Tuveßon.

Lucia Masarova, M.D., associate professor of Leukemia at The University of Texas MD Anderson Cancer Center is the study’s principal investigator.

A protocol amendment was submitted to the US Food and Drug Administration (FDA) and the MD Anderson Institutional Review Board. The amendment aims to increase the flexibility in the dosing regimen of tasquinimod and broaden the patient population in the combination cohort of the study. The protocol amendment has now been approved, and the study will resume recruitment. The first patient was recruited in 2025.

The clinical study consists of two cohorts: tasquinimod as monotherapy in JAK2 inhibitor refractory or intolerant patients and tasquinimod in combination with a JAK2 inhibitor in patients with a suboptimal response to a JAK inhibitor alone. In the approved protocol amendment, the dosing schedule of tasquinimod closely reflects the schedule used in the previous phase III prostate cancer studies.

Furthermore, the amendment allows the combination of tasquinimod with either the JAK2 inhibitor ruxolitinib or the newly approved JAK2/ACVR1 inhibitor momelotinib.

For more information regarding the clinical study, see www.clinicaltrials.gov NCT06327100.

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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. The company's core focus is on the development of tasquinimod in myelofibrosis, a rare blood cancer, where clinical proof-of-concept studies have been initiated. Laquinimod is in development for the treatment of non-infectious uveitis. A clinical phase I program with a topical ophthalmic formulation has been performed to support phase II development together with a partner. 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.

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 for the treatment of blood cancers, with focus on myelofibrosis. Tasquinimod has previously been studied in patients with solid cancers, including a phase II-III program in patients with metastatic prostate cancer. The safety profile of tasquinimod is well-characterized based on these previous clinical studies. Tasquinimod reduces myeloproliferation, splenomegaly, and fibrosis in preclinical models of myelofibrosis, and demonstrates efficacy both as monotherapy and in combination with approved therapies. Clinical proof-of-concept studies have been initiated in Europe and in the US.

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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