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European regulatory approval obtained to resume enrolment in the HOVON 172 MF study evaluating tasquinimod in myelofibrosis and conducted in collaboration between Active Biotech, Oncode and HOVON

Lund, Sweden – May 13, 2026 Active Biotech (NASDAQ Stockholm: ACTI) today announced positive feedback from the European regulatory authorities and ethics committee regarding the clinical proof-of-concept study of tasquinimod in myelofibrosis (HOVON 172 MF, NCT06327100). The study is conducted within the HOVON network of leading clinics in the Netherlands and Germany is now cleared to resume patient recruitment.

"We are very pleased with the favorable and supportive response from the authorities to our protocol amendment. This is an important step forward for our proof-of-concept study evaluating tasquinimod in patients with myelofibrosis," said Active Biotech's CMO Erik Vahtola.

"Bringing our research to the clinic has always been my ambition. With the HO172 tasquinimod study, we are translating years of fundamental research into a clinical setting for patients with myelofibrosis. Through the strong support of Oncode Institute and our collaboration with HOVON and Active Biotech, we are accelerating the development of a potential new treatment option for patients with limited therapeutic alternatives," said Rebekka Schneider, Oncode Investigator and haematologist at Erasmus MC.

"The approval of this amendment allows us to safely and responsibly continue this study within the HOVON framework. It reflects our commitment to high-quality investigator-initiated research and enables the careful evaluation of promising scientific insights through close collaboration with academic and industry partners, for patients with myelofibrosis who have limited treatment options," said Marleen Breems, CEO, HOVON.

A protocol amendment was submitted to the authorities and ethics committee, with the aim to increase the flexibility in the dosing regimen of tasquinimod, closely reflecting the schedule of tasquinimod previously used in the phase III prostate cancer study. With the amendment now approved, the study is well positioned to move forward, and recruitment will resume shortly.

The clinical study evaluates tasquinimod as a monotherapy in patients with myelofibrosis who are refractory or ineligible to JAK2 inhibitors. The study is conducted within the Stichting Haemato-Oncologie Volwassenen Netherland (HOVON) network of study centers in the Netherlands and Germany, with HOVON as the legal sponsor.

Active Biotech entered into a global patent license agreement with Oncode Institute for tasquinimod in myelofibrosis in February 2022. The current study is supported through Oncode Institute's Clinical Proof-of-Concept (CPoC) programme, which aims to accelerate the translation of promising cancer research into clinical applications for patients through close collaboration between academia, clinical centres and industry partners.

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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