

Active Biotech's clinical trial of tasquinimod in myelofibrosis approved in Europe

Lund, Sweden, October 30, 2024 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced that the clinical phase I/II study of Tasquinimod in Patients with Myelofibrosis Refractory to or Intolerant for JAK2 Inhibition (HOVON 172 MF) has received full approval from the European Medicines Agency (EMA) and the Institutional Ethics Committees.

“With all the approvals in place, we expect the study to start enrolment shortly. The study is supported by strong preclinical data indicating disease-modifying potential of tasquinimod. I look forward to the enrollment of the first patient and I am excited to follow the study progress”, said Dr. Erik Vahtola, CMO of Active Biotech.

The single-arm, multicenter open-label study will evaluate the safety and efficacy of tasquinimod given as mono therapy to patients with myelofibrosis who have previously been treated with a JAK2 inhibitor or who are ineligible to JAK2 inhibitor treatment. 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.

The study will be conducted at the Stichting Haemato-Oncologie Volwassenen Nederland (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 <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 malignancies. 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

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