

Active Biotech announces positive interim data from an ongoing study with tasquinimod in heavily pre-treated patients with relapsed and refractory multiple myeloma

Lund, May 26 2023 – Active Biotech (NASDAQ Stockholm; ACTI) announces today that tasquinimod, when given as monotherapy or in combination with ixazomib, lenalidomide and dexamethasone (IRd), has a favourable safety profile in heavily pre-treated patients with a median of 8 previous lines. All 15 patients included in this interim readout were previously refractory to IMiDs, Proteasome Inhibitors (PIs) and CD38 mAbs.

With single agent tasquinimod three patients with progressive disease at study entry had stabilization of disease while on study. Of 5 patients treated with tasquinimod in combination with IRd, one patient (20%) has a durable partial response ongoing since April 2022, despite being previously refractory to ixazomib-pomalidomide and carfilzomib-pomalidomide combinations. No dose limiting toxicity was seen in the combination with tasquinimod at 1mg daily after a one week run in at 0.5 mg daily.

“These are promising early safety and efficacy results for tasquinimod in patients with multiple myeloma. We are especially encouraged by our patient with a durable partial response to tasquinimod in combination with IRd. This patient’s myeloma was previously refractory to two PI /IMiD combinations and was therefore very unlikely to respond to the IRd backbone, suggesting that the response is attributable to the addition of tasquinimod. We also have not observed any increased toxicity or new safety concerns when combining tasquinimod with IRd. We are enthusiastic to accrue additional patients to the combination therapy cohort,” says Dr. Dan Vogl, Principal Investigator.

The results will be presented in a poster session at the upcoming American Society of Clinical Oncology (ASCO) 2023 Annual Meeting in Chicago, 2-6 June.

The study (NCT04405167) which is conducted at Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA is ongoing in the dose-escalation cohort investigating the safety, tolerability, and maximum tolerated dose (MTD) of tasquinimod in combination with (IRd). Enrolment into the study continues and an expansion cohort will start once the MTD is established.

The abstract is available online on <https://meetings.asco.org/> from May 25 at 5:00 PM (ET).

Details on the presentation:

- **Abstract Title:** Phase 1 study of tasquinimod, an S100A9 inhibitor, alone and in combination with IRd for relapsed and refractory multiple myeloma (RRMM)
- **Session Title:** Hematologic Malignancies - Plasma Cell Dyscrasia
- **Abstract Number:** 8042
- **Session Date and Time:** June 5, 2023, 8:00 AM-11:00 AM (ET)

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About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that deploys its extensive knowledge base and portfolio of compounds to develop first-in-class immunomodulatory treatments for specialist oncology and immunology indications with a high unmet medical need and significant commercial potential. Following a portfolio refocus, the business model of Active Biotech aims to advance projects to the clinical development phase and then further develop the programs internally or pursue in partnership. Active Biotech currently holds three projects in its portfolio: The wholly owned small molecule immunomodulators, tasquinimod and laquinimod, both having a mode of actions that includes modulation of myeloid immune cell function, are targeted towards hematological malignancies and inflammatory eye disorders, respectively. Tasquinimod, is in clinical phase Ib/IIa for treatment of multiple myeloma. Laquinimod is in a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II-study for treatment of non-infectious uveitis. 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 oral immunomodulatory and anti-angiogenic investigational treatment, that affects the tumor's ability to grow and metastasize. Tasquinimod is developed as a new immunomodulatory treatment for hematological malignances, in the first step multiple myeloma. 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 license agreement with Oncode Institute, acting on behalf of Erasmus Universiteit Medisch Centrum (Erasmus MC) to develop and commercialize tasquinimod worldwide in myelofibrosis. A clinical study with tasquinimod in patients with myelofibrosis is planned to start in 2023.

Attachments

Active Biotech announces positive interim data from an ongoing study with tasquinimod in heavily pre-treated patients with relapsed and refractory multiple myeloma