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Tasquinimod successfully completes dose optimization in patients with multiple myeloma and advances into the pre-planned expansion cohort

Lund Sweden, September 11, 2023 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announces the successful completion of the dose escalation of tasquinimod in combination with the orally administered antimyeloma agents ixazomib, lenalidomide, and dexamethasone (IRd) in patients with relapsed or refractory multiple myeloma. 6 patients have been treated with increasing doses of tasquinimod in combination with IRd and the combination was well tolerated with no protocol-defined dose limiting toxicities. The optimal dose and the treatment schedule of tasquinimod, when used in combination with IRd in patients with multiple myeloma was established at 1 mg per day after a one-week run in of 0.5 mg daily. This is similar to the treatment schedule established for tasquinimod used in monotherapy in patients with multiple myeloma. At present, two patients are ongoing in the combination part of the study.

The study, which is conducted with Dr. Dan Vogl as principal investigator in a partnership with the Abramson Cancer Center of the University of Pennsylvania, is now enrolling into an expansion cohort to further document the biological activity of tasquinimod+IRd in myeloma patients. The cohort will include patients previously refractory to commonly used anti-myeloma agents including proteasome inhibitors and immunomodulatory IMiDs to assess the preliminary efficacy of adding tasquinimod to the combination.

For more information about the study please visit clinicaltrials.gov (NCT04405167).

"With the optimal dose of the oral combination of tasquinimod and IRd established, I now look forward to expanding the study with additional patients to investigate further tasquinimod's antimyeloma effect. I remain enthusiastic about targeting the myeloma bone marrow microenvironment with tasquinimod to overcome therapeutic resistance to effective myeloma agents. Especially since we have a patient with a durable response from this combination who previously progressed on similar regimens and therefore was not expected to respond to IRd alone" says Dr. Dan Vogl, Principal Investigator.

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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 clinical development for treatment of non-infectious uveitis and a clinical phase I study with a topical ophthalmic formulation has been concluded. 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 2024.

Attachments

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