TASQUINIMOD CLINICAL DEVELOPMENT IN MULTIPLE MYELOMA ADVANCES INTO COMBINATION THERAPY FOLLOWING COMPLETION OF THE INITIAL PHASE OF THE ONGOING TRIAL IN THE US

Lund, October 3, 2021 - Active Biotech AB (publ) (NASDAQ STOCKHOLM: ACTI) today announces that the ongoing trial of tasquinimod in multiple myeloma has reached an important milestone. Ten patients have been treated with increasing doses of tasquinimod, which was generally well tolerated. The optimal dose and schedule of tasquinimod, when used as a single agent in patients with multiple myeloma has been established at 1 mg per day after a one-week run in of 0.5 mg daily. This is similar to the treatment schedule used in previous studies of tasquinimod.

The trial will now advance to a previously planned combination part, in which treatment with tasquinimod will be tested in patients with multiple myeloma together with the orally administered antimyeloma agents ixazomib, lenalidomide, and dexamethasone (IRd). Once an optimal dose and schedule of tasquinimod for the IRd combination is established, an expansion cohort will be recruited to further document the biological activity of tasquinimod in myeloma patients. Key secondary endpoints will include antimyeloma activity using the response criteria of the International Myeloma Working Group.

The study is conducted in a partnership with the Abramson Cancer Center of the University of Pennsylvania, with Dr. Dan Vogl as principal investigator. For more information about the study please visit clinicaltrials.gov (NCT04405167).

”We are pleased to have concluded the first part of this trial, confirming the previous safety profile of tasquinimod in patients with multiple myeloma and defining an optimal dose and schedule for tasquinimod in this patient population. The patients included in this study phase were heavily pretreated, with a median of 8 prior lines of therapy; 8 of the 10 patients were triple-class refractory to Imids, proteasome inhibitors, and anti-CD38 monoclonal antibodies. While none of the patients formally achieved a partial response, two patients with progressive myeloma at study entry achieved significant periods of stable disease on single-agent tasquinimod therapy. This suggests that tasquinimod has anti-myeloma activity in patients with advanced disease that is resistant to established therapies. These results enable us to advance into the combination part of the study, in which tasquinimod will be combined with a standard anti-myeloma treatment regimen. Our preclinical laboratory models suggest that this combination strategy may be a particularly effective way to utilize tasquinimod in myeloma therapy.” says Dr. Dan Vogl, Principal Investigator.

"We are enthusiastic to have reached this milestone and can conclude the first phase of this study. Based on the established safety data together with the encouraging anti-myeloma activities observed, we look forward to the continuation of the study. In the coming phase, tasquinimod will be evaluated in combination with ixazomib, lenalidomide, and dexamethasone (IRd), which already are established in the clinical practice. The use of tasquinimod, as a novel class of treatment for multiple myeloma, in combination with treatments used for earlier stage patients, is aligned with our current understanding of the mechanism of action of tasquinimod in these patients. " says Helén Tuvesson, CEO, Active Biotech AB.

For further information, please contact:
Helén Tuvesson, *CEO*, +46 46 19 21 56, helen.tuvesson@activebiotech.com
Hans Kolam, *CFO*, +46 46 19 20 44, hans.kolam@activebiotech.com

This information is information that Active Biotech AB is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of the contact person set out above, at 21:30 p.m. CET on October 3, 2021.

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 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.

About multiple myeloma
Multiple myeloma is an incurable blood cancer in which abnormal plasma cells in the bone marrow grow uncontrollably while other blood forming cells such as white and red blood cells and blood platelets are suppressed. This leads to anemia, infections, destruction of bone tissue and progressive loss of renal function. Despite new treatments have greatly improved survival of multiple myeloma patients, the biological heterogeneity of the disease and the emergence of drug resistance is a major challenge, and the medical need of innovative treatment modalities remains high. In 2017, 81000 new cases of multiple myeloma were diagnosed in the eight major markets. The global sales of drugs for multiple myeloma totaled USD 16 billion in 2017 and sales are expected to increase 48% by 2026 (ref Global Data 2019).

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: Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a phase Ib/II clinical program in patients with advanced solid tumors. The 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 advancing to a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II for treatment of non-infectious uveitis. Please visit www.activebiotech.com for more information.