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Safety and preliminary activity of naptumomab in combination with durvalumab presented at AACR 2023

Lund, April 19 2023 - Active Biotech (NASDAQ STOCKHOLM: ACTI) announces today that NeoTX Therapeutics, exclusive licensee of naptumomab estefanatox (naptumomab, Nap) from Active Biotech presented the following interim results from the phase Ib trial with naptumomab in combination with the checkpoint inhibitor durvalumab in patients with advanced or metastatic solid tumors. The results were presented at a poster presentation at the American Association for Cancer Research (AACR) annual meeting 14 – 19 April, in Orlando, Florida.

The study, enrolled 59 patients with previously treated advanced or metastatic disease and a high likelihood of tumor 5T4 expression. The primary objective was to evaluate the safety, tolerability and determining the maximum tolerated dose (MTD) and recommended phase II dose (RP2D) of naptumomab in combination with checkpoint inhibitor (CPI) durvalumab. Secondary objectives included antitumor activity and duration of response based on RECIST 1.1/iRECIST of the combination. Obinutuzumab pre-treatment was used to inhibit the formation of anti-drug-antibodies (ADAs). The results from the dose-escalation and MTD - expansion part of the study show that naptumomab at the RP2D of 10mcg/kg in combination with durvalumab is generally well tolerated with limited toxicity. Preliminary results show that pre-treatment with obinutuzumab reduces the formation of ADAs and preserves naptumomab plasma levels. Durable responses were seen, including complete responses in patients, where response to single agent CPI was not expected. In the next step cohort expansion in patients with esophageal cancer is planned.

"I am excited about naptumomab's potential to synergize with checkpoint inhibitors ("CPI"). Naptumomab's ability to bring activated T cells to the tumor, remodel the tumor microenvironment, act as a neoantigen mimetic, induce epitope spreading and long-term memory response, along with an acceptable safety profile makes naptumomab a good fit with checkpoint inhibitor therapy, especially for patients whose profile typically do not respond to immunotherapy." Asher Nathan, CEO of NeoTX Therapeutics.

The abstract Safety and Preliminary Activity of Naptumomab Estafenatox (NAP) and Durvalumab in Patients with Advanced or Metastatic Solid Tumors - Interim Results from a Phase 1b Trial is available on the American Association for Cancer Research (AACR) Annual Meeting 2023 webpage https://www.abstractsonline.com/pp8/#!/10828/presentation/10341.

For more information on the trial, visit www.clinicaltrials.gov NCT03983954

For further information, please contact:

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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 NeoTX

NeoTX Therapeutics (NeoTX) is a clinical-stage immuno-oncology company which is developing targeted anticancer immunotherapies utilizing its proprietary Tumor Targeted Superantigen (TTS) platform. TTS binds a genetically engineered bacterial determinant to the tumor surface while simultaneously activating and expanding tumor specific immune cells that are then redirected from the periphery to the tumor to mount an immune response. The company's lead TTS molecule, naptumomab estafenatox is currently in clinical development for advanced solid tumors (clinicaltrials.gov/NCT039883954 and NCT04880863). Please visit www.neotx.com for more information.

Naptumomab was licensed from Active Biotech to NeoTX Therapeutics Ltd in 2016. NeoTX is responsible for the global development and commercialization of naptumomab for the treatment of cancer under the license agreement.

Attachments

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