

ACTIVE BIOTECH AND NEOTX ANNOUNCE FDA CLEARANCE OF IND FOR PHASE II CLINICAL TRIAL OF NAPTUMOMAB

Phase IIa trial in non-small cell lung cancer expected to begin enrollment in the US in the second half of 2021

Lund Sweden, April 19, 2021 - Active Biotech AB (publ) (NASDAQ STOCKHOLM: ACTI) and NeoTX today announced that they have received clearance from the U.S. Food and Drug Administration (FDA) for the Investigational New Drug (IND) application of the tumor targeted superantigen naptumomab estafenatox (Naptumomab).

The Phase IIa open label trial will evaluate naptumomab in combination with docetaxel in 35 patients with checkpoint inhibitor pretreated, advanced or metastatic non-small cell lung cancer. The primary endpoint is objective response rate as measured by RECIST 1.1 criteria. The trial will also evaluate safety, duration of response, progression free survival, pharmacokinetics and pharmacodynamics.

Naptumomab treatment regimens have demonstrated preliminary safety and anti-tumor activity in early-stage clinical trials in solid tumors. Naptumomab binds a genetically engineered bacterial determinant to the tumor surface while simultaneously activating and expanding tumor specific immune cells.

"The FDA clearance of the IND for phase II clinical trial of naptumomab in non-small cell lung cancer marks a significant step in the continuing development of naptumomab as well as our collaboration with NeoTX. We are glad to receive the IND clearance and are excited to follow the progress of the development of naptumomab and the upcoming clinical Phase IIa trial" said Helén Tuvesson, CEO, Active Biotech AB.

See also www.neotx.com for NeoTX's communication related to this information.

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 08.30 a.m. CET on April 19, 2021.

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: Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a Phase I/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 phase II for treatment of non-infectious uveitis during second half of 2021. Please visit <u>www.activebiotech.com</u> for more information.

About NeoTX

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 effective response. The company's lead TTS molecule, naptumomab estafenatox is currently in clinical development for advanced solid tumors. For more information, please visit <u>www.neotx.com</u>.

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.