28 MAY 2024 08:00:00 CEST

Clinical activity and safety of naptumomab and docetaxel to be presented at ASCO 2024

Lund, May 28, 2024 - Active Biotech (NASDAQ STOCKHOLM: ACTI) announces today that NeoTX Therapeutics, exclusive licensee of naptumomab estafenatox (naptumomab, NAP) from Active Biotech, will present initial results from phase IIa trial with NAP and docetaxel in advanced/metastatic Non-Small Cell Lung Cancer (NSCLC) patients, at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting being held May 31- June 4, 2024, at the McCormick Place, Chicago, IL.

The trial enrolled 38 patients, whereof 32 were evaluable for response. All patients had previously received platinum-based chemotherapy and checkpoint inhibitor (CPI). The primary endpoint was overall response rate (ORR) and duration of response (DOR) based on institutional iRECIST review. Secondary objectives included safety, progression free survival (PFS) and overall survival (OS). NAP safety was acceptable and consisted of mostly grade 1-2 infusion related reactions, were generally easily manageable and rapidly reversable in line with previous reports.

Five patients had partial response (PR), 2 of them unconfirmed, and overall response rate (ORR) was 16%. Two patients had prolonged responses: one lasted for 22 months and the second had complete response in target lesions lasting for 24 months despite CNS progression. One patient had initial pseudo-progression in target lesions with a subsequent PR, suggesting a possible immune response. Mean DOR was 7.3 months (1.3 – 20.8). Mean PFS was 4.6 months, 18 pts (56%) had stable disease, disease-control rate was 72%, with mean duration of 5.3 months. Median OS was 8 months with 11 pts (34%) still alive at database lock and 3 patients receiving NAP under individual expanded access protocol.

The results of the combination of NAP and docetaxel show preliminary evidence of activity with acceptable safety in heavily pre-treated NSCLC patients. Further trials of NAP in combination, including CPIs are planned.

Details on the poster presentation:

1. **Abstract Title:** Clinical Activity and Safety of Naptumomab Estafenatox (NAP) and Docetaxel in Patients (pts) with Checkpoint Inhibitor (CPI) Pre-treated Advanced/ Metastatic Non-Small Cell Lung Cancer (NSCLC) - Preliminary Results, P2 Trial
2. **Abstract Number:** 8615
3. **Session Type and Title:** Poster Session – Lung Cancer—Non-Small Cell Metastatic
4. **Session Date & Time:** Monday June 3, 2024 1:30 PM-4:30 PM CDT

For more information on the trial, visit **www.clinicaltrials.gov** NCT04880863 and **www.neotx.com**

For further information, please contact:

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About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that develops first-in-class immunomodulatory treatments for oncology and immunology indications with a high unmet medical need and significant commercial potential. Active Biotech currently holds three projects in its portfolio, of which tasquinimod and laquinimod are wholly owned small molecule immunomodulators with a mode of action that includes modulation of myeloid immune cell function. The projects are in clinical development for hematological malignancies and inflammatory eye disorders, respectively. The company's core focus is on the development of tasquinimod in myelofibrosis, a rare blood cancer, where clinical proof-of-concept studies are being prepared. Also ongoing is a clinical Phase Ib/IIa study in multiple myeloma. Laquinimod is in clinical development for the treatment of non-infectious uveitis. A clinical phase I program with a topical ophthalmic formulation is ongoing to support phase II development together with a partner. The third pipeline project is naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, which 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. 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.

This information is information that Active Biotech is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-05-28 08:00 CEST.

Attachments

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