

NeoTX Announces FDA Clearance of IND for Phase 2 Clinical Trial of Naptumomab Estafenatox (NAP), its lead Tumor Targeted Superantigen Candidate

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REHOVOT, Israel

REHOVOT, Israel — April 19, 2021 – NeoTX Therapeutics (NeoTX), a clinical-stage immuno-oncology company, announced today that it received clearance from the U.S. Food and Drug Administration (FDA) for the Company's Investigational New Drug (IND) application for naptumomab estafenatox (NAP). NeoTX is developing targeted anticancer immunotherapies utilizing its proprietary Tumor Targeted Superantigen (TTS) platform. NAP, the company's lead TTS molecule, binds a genetically engineered bacterial determinant to the tumor surface while simultaneously activating and expanding tumor specific immune cells. NAP has demonstrated preliminary safety and anti-tumor activity in early-stage clinical trials in solid tumors.

"This FDA clearance is an exciting milestone for NeoTX," said Asher Nathan, Ph.D., chief executive officer of NeoTX. "Preclinical and preliminary clinical studies have demonstrated that NAP has potential in combination with other treatment modalities. Non-small cell lung cancer is one of the deadliest cancers, and we are looking forward to assessing NAP in the clinic in combination with chemotherapy as a potential new treatment option after failure of current standards of care."

The Phase 2a open label trial will evaluate NAP 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, overall survival, pharmacokinetics and pharmacodynamics.

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 (NAP) is currently in clinical development for advanced solid tumors. For more information,

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