TILT Biotherapeutics Announces Positive Clinical Data in Checkpoint Resistant Metastatic Melanoma Phase I Trial at ESMO Immuno-Oncology 2023

Promising Signs of Efficacy Achieved with TILT-123 in Combination with Tumor Infiltrating Lymphocytes Therapy (TILT-T215)

Helsinki, Finland – 8 December 2023: TILT Biotherapeutics (TILT), a clinical-stage biotechnology company at the forefront of developing cancer immunotherapies, presented safety and efficacy data from its international Phase I trial in patients with metastatic melanoma (NTC04217473), in an oral presentation at the ESMO Immuno-Oncology Congress (ESMO-IO) in Geneva, Switzerland (6-8 December).

The data (1) from clinical work in close collaboration with Denmark’s National Center for Cancer Immune Therapy (CCIT-DK) and France’s Department of Dermatology at CHU Nantes, shows the combination of TILT-123 and Tumor Infiltrating Lymphocytes (TIL) cell therapy (TILT-T215) is safe and effective in patients with metastatic melanoma. Notably, as TILT’s therapeutic approach does not require pre or post conditioning, the safety data was markedly better than in those patients treated with regular TIL therapy, as that does require conditioning.

TILT Biotherapeutics’ founder and CEO, Akseli Hemminki, a cancer clinician who has personally treated hundreds of cancer patients with oncolytic viruses, said: “Following on from positive results with our TILT-123 monotherapy (TUNIMO) trial, recently presented at SITC, this data shows that the combination of TILT-123 and TIL therapy is safe and shows promising efficacy in patients with checkpoint inhibitor resistant metastatic melanoma. This is the first-time clinical data with an oncolytic virus in combination with tumor infiltrating lymphocyte therapy has been presented. We are focused on achieving the best possible patient outcomes by using innovative cancer immunotherapy treatment strategies including combination therapies.”

Copenhagen University Hospital’s Professor Inge Marie Svane, M.D., corresponding author on the abstract, key opinion leader on cancer immunotherapy, and co-author of over 275 scientific publications, said: “There’s significant unmet medical need in metastatic melanoma, with around 300,000 news cases a year globally, with no treatment options after progressing on immune checkpoint inhibitors. This latest clinical data is good news for the potential treatment of patients with check point inhibitor resistant progressive metastatic melanoma.”

TILT-123 (igrelimogene litadenorepvec) is an oncolytic adenovirus encoding for interleukin-2 and tumor necrosis factor alpha, designed for recruiting, propagating, and stimulating T-cells for re-invigoration of the tumor microenvironment. TILT’s approach uses oncolytic viruses to selectively replicate in and lyse cancer cells, while simultaneously stimulating immune responses towards the tumor. The data announcement at ESMO-IO relates to 16 patients with checkpoint inhibitor (CPI) resistant progressive metastatic melanoma, who were treated with multiple intravenous and intratumoral injections of TILT-123 and a one- or two- time
treatment with TILs. Responders include one with an ongoing partial response, one with a durable complete response, and two with long term (over ten months) stable disease.

The company has several trials currently underway, reflecting its commitment to pushing the boundaries of cancer treatment (NCT04217473, NCT05271318, NCT05222932).

Reference

(1) Safety and Efficacy of Combined Treatment with Tumor Infiltrating Lymphocytes (TILs) and Oncolytic Adenovirus TILT-123 for Patients with Metastatic Melanoma – Results from a Phase I Trial

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Notes to Editors

About TILT Biotherapeutics

TILT Biotherapeutics is a clinical-stage biotechnology company developing cancer therapeutics based on its proprietary oncolytic adenoviruses armed with molecules including cytokines that can activate T cells and destroy cancer cells.

The company’s patented TILT® technology can be delivered intravenously, locoregionally, or intratumorally. It modifies the tumor microenvironment and has a broader systemic effect. By making cold tumors hot, it eliminates cancer’s ability to evade immune responses, thereby enhancing T-cell therapies such as immune checkpoint inhibitors, tumor infiltrating lymphocyte (TIL) therapy, and CAR T therapies.

TILT’s lead asset, TILT-123, is a 5/3 chimeric serotype adenovirus armed with two human cytokines: TNF alpha and IL-2. About fifty patients have been treated in four international trials sponsored by the company with promising initial efficacy responses observed in some of the patients. In 2023 further clinical trials are planned, including Phase Ib trials in ovarian and lung cancers.

The company’s pioneering approach has been recognized by industry leaders. It has two collaborations with MSD, a tradename of Merck & Co., Inc., investigating TILT-123 in combination with pembrolizumab (KEYTRUDA®) in ovarian cancer (NCT05271318) and in refractory non-small cell lung cancer (NCT06125197). The company is also collaborating with Merck KGaA, Darmstadt, Germany, and investigating TILT-123 in combination with avelumab.

Based in Helsinki, Finland, and with an office in Boston, the company was established over a decade ago as a spin-out from the University of Helsinki. It has funding from Lifeline Ventures, Finnish Industry Investment (TESI), angel investors, Business Finland, and the European Innovation Council.

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