TILT Biotherapeutics Presents Clinical Data on TILT-123 in Combination with KEYTRUDA® (pembrolizumab) for Ovarian Cancer at AACR 2024

Results Reveal Mechanism of Action and Correlative Analyses Data

Helsinki, Finland – 10 April 2024: TILT Biotherapeutics (TILT), a clinical-stage biotechnology company developing cancer immunotherapies presented promising preliminary safety and efficacy data from their ongoing Phase I clinical trial (NCT05271318) in platinum resistant or refractory ovarian cancer patients at the American Association for Cancer Research (AACR) Annual Meeting 2024.

TILT-123 in combination with MSD's (a tradename of Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) was safe and demonstrated signs of efficacy in both platinum resistant and refractory ovarian cancer patients. Analysis of biological samples revealed insights into mechanism of action, including an immunological profile potentially predictive of clinical response.

The study results were based on 15 patients who received intratumoral or intraperitoneal doses of TILT-123 therapy in combination with intravenous doses of pembrolizumab in an open label phase I clinical trial using a standard 3+3 dose escalation scheme.

Notably, disease control was seen in 71% of evaluable patients including one long lasting partial response in a patient with mucinous carcinoma. Tumor size reductions and significant immunomodulation were seen in injected and non-injected tumors, indicating the potential for a systemic response.

The results demonstrated that a strong humoral response and increased presence of IgE+ plasma cells significantly correlated with clinical response and overall survival. They also revealed insights into the mechanism of action of the combination therapy.

TILT Biotherapeutics' founder and CEO, Akseli Hemminki, a cancer clinician who has personally treated hundreds of cancer patients with oncolytic viruses, said *"We are excited to see the latest ongoing positive potential to bring a more effective treatment to patients with refractory ovarian cancer that have few other treatment options. Importantly, an immune response and reduction in tumour size was seen from intratumoral injections of the combination therapy as well as those away from the tumour site, which demonstrates the potential for a systemic response."*

TILT-123, an oncolytic adenovirus armed with tumor necrosis factor alpha (TNFα) and interleukin-2 (IL-2), is designed to enhance the efficacy of T-cell therapies, including immune checkpoint blockade or adoptive cell transfer 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 results presented at AACR 2024, along with data from other ongoing trials, underscore the promise of TILT-123 as a novel cancer therapy. Continued clinical evaluation, including ongoing trials (NCT04695327, NCT04217473, NCT06125197, and NCT05222932), will further elucidate the therapeutic potential of TILT-123 across various solid cancer types.

Reference:

Immunological activity of oncolytic adenovirus encoding TNFα and IL-2 (TILT-123) in combination with pembrolizumab in platinum resistant or refractory ovarian cancer patients

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 also known as *Igrelimogene litadenorepvec*, 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.

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 KEYTRUDA® (pembrolizumab) 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, the European Innovation Council, and the U.S. Department of Defense.

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