TILT Biotherapeutics Announces First Patient Dosed in Phase I Solid Tumors Trial Assessing Oncolytic Adenovirus TILT-123 in Combination with Checkpoint Inhibitor

Helsinki, Finland – 15 May 2023: TILT Biotherapeutics, a clinical-stage biotechnology company developing cancer immunotherapies, today announced that the first patient has been dosed in a Phase I trial of the company's oncolytic adenovirus TILT-123. The multi-centre open-label, phase I, dose-escalation trial will evaluate igrelimogene litadenorepvec (TILT-123) in combination with avelumab in squamous cell carcinoma of head and neck (SCCHN), and melanoma in patients with advanced solid tumors refractory to, or progressing after, anti-PD(L)1. The study is part of TILT Biotherapeutics' agreement with Merck KGaA, Darmstadt, Germany and Pfizer, Inc. to evaluate this combination in patients with solid tumors refractory to immune checkpoint inhibitors. The European trial is taking place at the Docrates Cancer Center (Helsinki, Finland) and the company expects to open its US site in Q3 2023.

TILT Biotherapeutics' founder and CEO, Akseli Hemminki, a cancer clinician who has personally treated hundreds of cancer patients with oncolytic viruses, said, "We are delighted with the progress of our lead oncolytic virus in combination with avelumab as we believe it has the potential to increase the response rate of immune checkpoint inhibitors to deliver synergistic benefits to patients who have failed to benefit from immune checkpoint inhibitors, or where immunotherapy has become an ineffective treatment option. Our lead asset, TILT-123, has been administered as monotherapy or in combination to about 50 patients in four international TILT sponsored trials with promising initial efficacy responses observed in some of the patients. We believe our innovative armed oncolytic virus that can be administered through intravenous, and intratumoral, routes will deliver better treatment outcomes for cancer patients. We expect to make key interim clinical data announcements at leading scientific conferences during this and next year."

Igrelimogene litadenorepvec (TILT-123) is TILT Biotherapeutics' lead product, a 5/3 chimeric serotype adenovirus armed with two human cytokines that can be delivered intravenously or intratumorally. It treats cancer by working synergistically with immune checkpoint inhibitors, such as avelumab, in solid tumors. The heart of TILT's innovative approach revolves around the use of oncolytic adenoviruses armed with cytokines to boost the patient's systemic immune response to better enable it to find and destroy cancer cells. The company is advancing its pipeline of programs including its lead asset TILT-123, in further clinical trials, including in combination with immune checkpoint inhibitors.

Clinical trial registry link: https://clinicaltrials.gov/ct2/show/NCT05222932

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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 stimulate, or suppress, T cells.

The company's patented TILT® technology can be delivered intravenously and intratumorally both 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. 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 a Phase II trial in ovarian cancer.

The company's pioneering approach has been recognized by industry leaders including Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The company 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.

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.