

TILT Biotherapeutics Announces Positive Update on its Phase 1 Immunotherapy Clinical Trials in Cancer

Helsinki, Finland – 31 March 2022: TILT Biotherapeutics, a clinical-stage biotechnology company developing oncolytic immunotherapy for enabling therapies based on T cells, such as immune checkpoint inhibitors and adoptive cell therapies, announces positive interim progress and safety data from its phase 1 clinical trials in metastatic melanoma (T215 – the ‘TUNINTIL’ trial) and solid tumors (T115 – the ‘TUNIMO’ trial). These two trials, with patients in Denmark, France, and Finland, are of the company’s oncolytic immunotherapy asset TILT-123, designed to stimulate T-cells to better fight cancer.

TILT Biotherapeutics’ CEO, Akseli Hemminki, a biotech entrepreneur and cancer clinician who has personally treated almost 300 patients with ten different oncolytic viruses, said, “We are delighted that our phase 1 trial in solid tumors (T115), which consists of a total of 11 patients being treated to date, is progressing at pace. Our first-in-human melanoma (T215) trial is showing equally positive results, with 10 patients being treated and some now being treated under an extension protocol. I am thankful for the excellent work by the clinical teams. We are showing that the treatment is well tolerated, has prominent biological effects on tumors, and has the potential to increase the efficacy of immunotherapies, and deliver the anti-tumor benefits of armed oncolytic viruses.”

The ‘TUNINTIL’ clinical trial (1) is a phase 1, open-label, dose-escalation study of the company’s oncolytic adenovirus coding for Tumor Necrosis Factor Alpha (TNF alpha) and Interleukin 2 (IL-2), known as TILT-123. A total of about 15 metastatic melanoma patients receive TILT-123 as an initial monotherapy over one month, followed by up to two administrations of tumor infiltrating lymphocytes (TILs) in the second month as well as ongoing consecutive doses of TILT-123, for up to 24 months.

The ‘TUNIMO’ clinical trial (2) is also a phase 1 trial of TILT-123. A total of 15-20 patients with solid tumors receive TILT-123 as a monotherapy over a three-month period, and, as with the TUNINTIL protocol, followed up by a 24-month extension period.

The primary objective of both trials is to evaluate the safety of TILT-123 and to deliver insights about the behavior of TILT-123 in humans, such as systemic tumor transduction following intravenous delivery and virus replication in the tumor, as well as immunological responses.

To date, most frequent adverse events across both trials have been fever, chills, and fatigue, consistent with the administration of an oncolytic adenoviral immunotherapy, with no treatment related serious adverse events.

The heart of TILT’s innovative approach revolves around the use of armed oncolytic adenoviruses, using cytokines and other molecules to boost the patient’s immune

response to better enable it to find and destroy cancer cells. The company is advancing its pipeline of other assets and programs with TILT-123 towards further clinical trials, including in combination with the immune checkpoint inhibitors (3) (4).

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(1) Link to the 'TUNINTIL' clinical trial details:

<https://clinicaltrials.gov/ct2/show/NCT04217473?term=TILT-123&draw=2&rank=1>

(2) Link to the 'TUNIMO' clinical trial details:

<https://clinicaltrials.gov/ct2/show/NCT04695327?term=Tilt+Biotherapeutics&draw=2>

(3) Link to the trial of TILT-123 and Avelumab:

<https://clinicaltrials.gov/ct2/show/NCT05222932?term=TILT-123&draw=2&rank=3>

(4) Link to the trial of TILT-123 and Pembrolizumab:

<https://clinicaltrials.gov/ct2/show/NCT05271318?term=TILT-123&draw=2&rank=1>

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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, which can be delivered locally and systemically, modifies the tumor microenvironment, and eliminates its ability to suppress immune responses to cancer, thereby enhancing T-cell therapies such as checkpoint inhibitors 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. TILT-123 has demonstrated a 100%

response rate in pre-clinical cancer models *in vivo*, and it is currently in Phase 1 clinical trials.

The Company's pioneering approach has been recognized by industry leaders including with the Merck KGaA and Pfizer Alliance, who are collaborating to investigate TILT-123's therapeutic effect in combination with the PD-L1 inhibitor, Avelumab (Bavencio®), in clinical trials. The Company also has a collaboration with MSD investigating TILT-123 with Pembrolizumab (Keytruda®). In 2019, TILT established a partnership with Biotheus, a privately held Chinese company, for the development and commercialization of TILT's proprietary oncolytic virus TILT-123 in Greater China.

Based in Helsinki, Finland, the company was established in 2013 as a spin-out from the University of Helsinki. In addition to licensing revenue, it has funding from Lifeline Ventures, angel investors, Business Finland, and the European Innovation Council (EIC).