TILT Biotherapeutics advances cancer immunotherapy clinical trial achieving primary end point in the first cohort

Second dose escalation site approved in Nantes, France

Helsinki, Finland – 15 March 2021: TILT Biotherapeutics, a clinical-stage biotechnology company developing cancer immunotherapeutics, announces that it has achieved the primary endpoint of safety in its phase I trial with the first dose of its dual cytokine armed oncolytic adenovirus, TILT-123, at Herlev hospital in Denmark. No serious adverse events (SAEs) were observed in the trial for TILT-123 as a monotherapy or in combination with tumour infiltrating lymphocytes (TILs). The company has received regulatory approval to open a second clinical trial site at CHU Nantes, France, with 15 patients in total to be enrolled across the two sites. The clinical trial will now proceed to the second (of five) dose levels and expects interim data by the end of this year.

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. 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.

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 our first-in-human phase 1 trial in metastatic melanoma has successfully met its primary clinical endpoint of safety at the initial dose and is now progressing steadily to the next dose level. I am grateful for the excellent work by the team at Denmark's prestigious National Center for Cancer Immune Therapy and look forward to continuing this and also working with the team in Nantes. Overall, the trial has the potential to increase the efficacy of adoptive T-cell therapy, remove the need for pre- and post-conditioning regimens, and deliver the combined anti-tumor benefits of armed oncolytic viruses and T-cell therapy."

The company has received approval in Denmark to extend this trial for up to two years to demonstrate long term survival benefit. As part of this, the company will be analyzing secondary end points for TILT-123 including response rate, overall survival, progression free survival, and immune response against the tumor, its persistence and shedding.

The heart of TILT's approach revolves around the use of armed oncolytic adenoviruses, using cytokines to boost the patient's immune response to better enable it to find and destroy cancer cells. The TUNINTIL trial's primary objective is to evaluate the safety of TILT-123 and is designed to also 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.

-Ends-

(1) Link to the ‘TUNINTIL’ clinical trial details: https://clinicaltrials.gov/ct2/show/NCT04217473?term=TILT-123&draw=2&rank=1

Media contacts

TILT Biotherapeutics

CBO Aino Kalervo

aino@tiltbio.com

Scius Communications

Katja Stout

+447789435990

katja@sciuscommunications.com

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 recognised by industry leaders including Germany’s Merck KGaA and the USA’s Pfizer, who are collaborating to investigate TILT-123’s therapeutic effect in combination with the PD-L1 inhibitor, Avelumab (Bavencio®), in clinical trials. In 2019, TILT established an additional partnership with Biotheus, a privately held Chinese company based in Zhuhai, Guangdong, China, 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. It has funding from Lifeline Ventures, angel investors, Business Finland, and the European Innovation Council (EIC).