

TILT Biotherapeutics announces two patients pass primary safety endpoint in European cancer immunotherapy trial

Helsinki, Finland - 28 September: TILT Biotherapeutics, a clinical-stage biotechnology company developing cancer immunotherapeutics, announces it has dosed two patients in a phase 1 clinical trial of its dual cytokine armed oncolytic adenovirus, TILT-123, in Denmark's Herlev hospital in Copenhagen. Of the two patients dosed, both have now passed the trial's 36-day primary safety endpoint having received three administrations of TILT-123 at the lowest dose.

TILT-123's [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. In this 'TUNINTIL' trial, up to 15 patients with metastatic melanoma will receive three injections of TILT-123 as an initial monotherapy over one month, followed by multiple administrations of TILT-123 plus up to two administrations of tumor infiltrating lymphocytes.

TILT-123 has been engineered to encode two human immunostimulatory cytokines, Tumor Necrosis Factor (hTNF α) and human interleukin 2, in order to direct a powerful T cell response to selectively destroy cancer cells.

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 putting our recent financing of EUR 6m to good use by progressing our innovative cancer immunotherapies into the clinic. The heart of our approach revolves around the use of armed oncolytic adenoviruses, using cytokines to boost the patient's immune response, better enabling it to find and destroy cancer cells. We are delighted to be working with Denmark's prestigious National Center for Cancer Immune Therapy to initiate our first-in-human phase one trial of TILT-123 and look forward to starting additional sites in Finland and France for the TUNINTIL trial. This should act as a springboard to more European trials, and our first US trials, in other solid tumors."

Principal Investigator Inge Marie Svane, from Denmark's National Center for Cancer Immune Therapy at Herlev Hospital, Copenhagen University, said, "The Nordics have some of the world's most efficient & innovative healthcare system, and we are excited to work with Finland's TILT Biotherapeutics to trial its next generation viruses to boost the body's ability to fight a range of cancers. Our TUNINTIL trial is for metastatic melanoma, which is difficult to treat, and our hope is the trial will help expand the range of therapeutic options available to clinicians and patients, in this and other cancers."

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 and virus replication in the tumor, as well as immunological responses. Overall, the trial has the potential to increase the efficacy of adoptive T-cell therapy, remove the need for toxic pre- and post-conditioning regimens, and deliver the combined anti-tumor benefits of armed oncolytic viruses

and T-cell therapy. The trial will examine both intra-venous and intra-tumoral delivery of TILT-123 and is due to complete in 2021.

-Ends-

Notes to editors:

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

<https://clinicaltrials.gov/ct2/show/NCT04217473?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, best-in-class 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 in combination with tumor infiltrating lymphocytes (TIL) therapy in Europe.

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). For more information, please visit www.tiltbio.com.