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PROFILE

TILT Biotherapeutics

Akseli Hemminki

TILT Biotherapeutics Ltd, Helsinki, Finland; Cancer Gene Therapy Group, Department of Oncology, University of Helsinki, Helsinki, Finland; Helsinki University Comprehensive Cancer Center, Helsinki, Finland

1) How and when did your company start, and where are you located?

TILT Biotherapeutics Ltd. was founded in 2013 by Akseli Hemminki (MD, PhD, CEO) based on his team's important patient observations and findings in the lab. The company is based in Helsinki, Finland.

2) How many employees do you have, and how do you find and attract them?

TILT has a team of 7 permanent employees and 2 PhD students. Some of the ways to attract the team include interesting work, autonomy, and employee options. The ability to help patients with cancer is a powerful motivating factor for many individuals.

3) What are the main focus and platform technology(ies) of your company?

Solid tumors, for which TILT is developing treatments constitute over 90% of all cancers. Current treatments of metastatic disease lack curative potential and limited treatment options are available. TILT technology can be used in most types of metastatic solid tumors and thus there are thousands of patient candidates for therapy annually.

The company's patented technology involves utilization of oncolytic viruses for enhancement of tumor T-cell therapy. Initial embodiments of the technology will be used to enable tumor infiltrating lymphocyte (TIL), chimeric antigen receptor (CAR-T) and checkpoint inhibiting antibody therapy of solid tumors.

4) Can you provide a short overview of your product pipeline?

The products of TILT are armed oncolytic adenoviruses modified in various ways, to allow their use for enhancing T-cell therapy. The lead candidate is a preclinical stage TNF α /IL2 armed oncolytic adenovirus (TILT-123). Curative preclinical efficacy results have been published and the virus backbone has been previously demonstrated safe in humans. GMP production is ongoing and the first phase I clinical trial is aimed to start early 2018. The first trial will take place in Europe and address metastatic melanoma in patients receiving TILs and TILT-123. Additional trials in other solid tumor indications are

planned in combination with TILT-123 and a checkpoint modulator or a CAR-T product.

In addition to TILT-123, the company has other patent-protected products in the pipeline, including oncolytic viruses coding for bispecific antibodies.

5) Who is your competition, and what advantage(s) do your products / technology offer?

TILT's competitors include companies like Psioxus, Lokon Pharma, Viralytics, Transgene, and Amgen (T-VEC).

TILT-123 is innovative in many aspects as compared with the competition. It is the only oncolytic virus designed with T-cells in mind, and this design is based on patient observations, not just laboratory data. TILT-123 is armed with the most potent cytokines in the context of adaptive anti-tumor responses, it is genetically modified for improved access to cancer cells and for improved safety. Moreover, adenovirus is the most immunogenic virus type and possible to upscale in manufacturing for industrial production. Importantly, TILT's virus backbone has already been demonstrated safe in human and is able to access distant tumors by vascular route. Therefore, in addition to intratumoral administration, the product can be administered by systemic route.

6) What were the "highlights" in your recent product development?

Recent highlights include publication of curative preclinical efficacy with TILT-123 as well as proof of concept with CAR-T and anti-PD-1 therapy. TILT also successfully completed Scientific Advice with EMA and obtained an Advance Therapy Medicinal Product Classification for TILT-123. The company is now advancing with local regulatory authorities to obtain clinical trial authorizations for its first-in-human clinical trial. A new funding round was closed last year, which allows TILT to complete one Phase I trial. The company has raised almost 10M€.

7) What have been the most critical problems in developing products in your field, and how can your company's technology help overcome these problems?

Adoptive T-cell therapy of humans has yielded promising results in TIL therapy of metastatic melanoma, but it is

associated with severe side effects due to pre-conditioning chemotherapy and post-conditioning IL-2. TILT-123 is the only virus designed specifically for T-cell stimulation with IL2 and TNF α arming. Improved safety with TIL therapy is reached when used together with TILT's product as pre-conditioning chemo and post-conditioning IL-2 can be left out.

With CAR-T excellent results have been obtained in CD19+ leukemia, but not in solid tumors. With mesothelin + CAR-T therapy, better efficacy in solid tumors has been demonstrated in preclinical setting when administered with TILT-123.

Checkpoint inhibitors have been approved and work in many tumor types, but only 10–50% of patients are benefiting. Adenoviruses are the perfect enabler of checkpoint inhibition in cold and excluded tumors, to greatly extend the population of patients benefiting.

8) What is your company's value proposition?

TILT is the world leading company developing oncolytic immunotherapies for enabling T-cell therapy of solid tumors. The patented technology will be available for licensing and can be a valuable asset for the immuno-oncology pipeline of a big pharma. Vision of TILT's founder is to cure solid tumors with TILT technology.

9) What business development strategy do you pursue?

Objective is to establish collaborations with international venture capitalists or other funding organizations to fund additional phase I work. Moreover, TILT aims to fund later development with upfront and milestone payments from potential licensing and/or co-development deal(s) with pharma. Companies having synergic technologies in the immuno-oncology field, notably those with checkpoint inhibitors or CAR-T are interesting potential future partners.

10) How does your company attract partners?

By scientific excellence, IP protection, and efficient early development work. Partners are attracted by communication

and press releases on major development advancements, publications of scientific results in peer-reviewed journals, poster presentations in scientific congresses, and by participation to the main business development events.

11) Who are your most important partners?

TILT's important financial supporters are Tekes, Lifeline Ventures, angel investors, and European Commission. In terms of science, TILT is collaborating with world's leading research groups: University of Helsinki – CGTG, University of Pennsylvania - Carl June's group, and Heidelberg – DKFZ. Process development work is supported by Merck group.

12) How do you balance performing work in-house vs outsourcing?

TILT has enough internal resources to manage all the main functions: preclinical and clinical research, regulatory and GMP production, and business. Out-sourcing of tasks like GLP studies, GMP production, and clinical operations allows the use of external expertise with low fixed costs. Collaboration with Akseli Hemminki's research group at University of Helsinki allows TILT to generate new preclinical data and in return gives the research a translational aspect.

13) What are your product development goals for the next 3 years?

In 3 years from now, TILT's objective is to have generated clinical data of dozens of patients from at least two Phase I trials and to have helped some cancer patients to live longer. Initiation of first-in-man trials with TILT's lead product (TILT-123) is planned for next year. One of the trials will take place in France and Denmark and address metastatic melanoma with TIL-treatment. An additional trial, with anti-PD1 treatment in melanoma is planned in the US. GMP production of the clinical material is currently ongoing. In the future, TILT is also interested in initiating clinical trials in other solid tumor indications and with other T-cell therapies, notably with CAR-T.

For more information visit <http://tiltbio.com/>