Valo Therapeutics Announces First Patient Dosed with PeptiCRAd-1 - Innovative Immuno-oncology

Germany based trial of 15 patients with melanoma, triple negative breast cancer or non-small cell lung cancer

Helsinki, Finland, 23 May 2023: Valo Therapeutics Oy (ValoTx), the developer of novel, adaptable immunotherapies for cancer, announces that the first patient has been treated in its Phase I trial of PeptiCRAd-1 (Peptide-coated Conditionally Replicating Adenovirus) in three tumor types.

PeptiCRAd-1 is an innovative approach never before used combining two clinically proven cancer immunotherapy approaches: oncolytic adenoviruses and tumor-specific peptides for the generation of strong systemic cytotoxic T-cell responses against multiple tumor antigens. This is achieved by coating the company's proprietary oncolytic adenovirus with immunogenic tumor-specific peptides thereby directing the immune system to specifically target and kill cancer cells. No other oncolytic virus therapy delivers tumor targets in this simple but effective and adaptable way.

The first patient has been administered with PeptiCRAd-1 successfully, without any initial safety concerns and the Safety Data Committee has concluded that the study can continue enrolment. Following this green light, further patients are now being recruited at the Krankenhaus Nordwest in Frankfurt, and at the National Center for Tumor diseases (NCT) in Heidelberg.

PeptiCRAd-1 combines the power of a tumor-specific adenovirus (expressing immune-stimulatory molecules CD40L and OX40L) with immunogenic tumor peptides derived from NY-ESO-1 and MAGE-A3 proteins thereby generating tumor-specific, cytotoxic T-cells that will attack and kill cancer cells.

The trial is designed to evaluate the safety, immune activity, and tumor response of PeptiCRAd-1 alone and then in combination with the immune checkpoint inhibitor (CPI), pembrolizumab in 15 patients with either melanoma, triple-negative breast cancer or non-small cell lung cancer. The trial will explore local and systemic immune activation, and immune responses against the tumor-specific NY-ESO-1 and MAGE-A3 peptides, as well as clinical responses. It includes intensive immuno-monitoring of tumor and blood samples from patients to confirm the mechanism of action of PeptiCRAd-1 and to identify biomarker-related outcomes, among other signals of clinical benefit.

Paul Higham, CEO of ValoTx, commented, "I'm delighted we have commenced clinical development with the first patient treated in our Phase I trial of PeptiCRAd-1. Our thanks go to Prof. Dr med. Elke Jäger and her team at the hospital Krankenhaus Nordwest in Frankfurt and Prof. Guy Ungerechts and his team at the National Center for Tumor diseases (NCT) in Heidelberg, for all their excellent preparatory work to reach this major milestone. Based on strong *in vivo* data generated by our research team, we expect to see both a potent tumor-directed immune response and changes in the tumor microenvironment that will facilitate tumor control. This first PeptiCRAd program uses well-known, tumor-specific targets (NY-ESO-1 and MAGE-A3) that are highly prevalent on the three tumor types to be included. In the future, the inherent adaptability and flexibility of our platform will allow us to deliver advanced individualized or 'patient-specific' cancer treatments."

The Coordinating Investigator for the trial, Prof. Dr med. Elke Jäger, from the hospital Krankenhaus Nordwest in Frankfurt am Main's Department of Oncology and Hematology, one of Germany's top

oncology treatment centers with a wealth of immuno-oncology experience, said; “We are very excited to be involved in this study. This is a truly innovative immuno-therapy approach which has shown great promise in the pre-clinical setting. We hope to be able to translate this to positive clinical outcomes for patients.”

-FOR PATIENTS-

If you are a patient interested to participate in the study, please go to the “FOR PATIENTS” section on valotx.com for more information!

Clinical trial registry: https://www.clinicaltrials.gov/ct2/show/NCT05492682

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About ValoTx

Valo Therapeutics Oy (Helsinki) is an immunotherapy company developing antigen-coated oncolytic viruses as therapeutic vaccines against cancer. The ValoTx lead platform, PeptiCRAd (Peptide-coated Conditionally Replicating Adenovirus), was developed out of the laboratory of Professor Vincenzo Cerullo at the University of Helsinki. It turns oncolytic adenoviruses into powerful activators of systemic anti-tumor cytotoxic T-cell immunity without the need to generate and manufacture multiple genetically modified viruses. PeptiCRAd-1 is the company’s lead product made up of its virus VALO-D102 coated with MAGE-A3 and NY-ESO-1 peptides. The company is also developing other neoantigen strategies.

Watch our film explaining the PeptiCRAd technology. For more information see our website and follow us on LinkedIn.

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