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TC BioPharm Initiates Phase I Trial of Allogeneic Gamma Delta T Cell Therapy in Acute Myeloid Leukemia Patients

Study to provide safety data on allogeneic use of GDTs prior to subsequent use of CAR-modified variants

GLASGOW, Scotland--(BUSINESS WIRE)-- TC BioPharm (TCB), a developer of allogeneic CAR-T immuno-oncology products, and leaders in Gamma Delta T (GDT) cell therapies, today announced it has initiated a Phase I clinical study of TCB002, an allogeneic cell therapy consisting of activated and expanded gamma delta T cells. The trial, for treatment of patients suffering from Acute Myeloid Leukemia (AML), is being conducted at the Institute of Hematology and Blood Transfusion (ÚHKT) in Prague, Czech Republic. Patient recruitment commenced January 2019 following regulatory approval late 2018. Dose escalation is in progress, with completion of treatment imminent for the first patient cohort. The clinical trial is registered with identifier NCT03790072.

Developed by TC BioPharm, TCB002 comprises GDT cells sourced from healthy donors, expanded and activated in large numbers before being purified and formulated for infusion into patients. The donors are selected based on criteria designed to ensure that the cells are potent killers of cancer cells, and can be a more effective and consistent treatment compared to the patient's own cells. GDT cells are a subset of lymphocytes which have both innate and adaptive immune properties and represent an emerging therapeutic option for cancer and other diseases. Use of allogeneic GDT cells from healthy donor cell banks paves the way for development of superior drug products through screening and selection of the highest quality starting material, facilitating preparation of consistent batches capable of treating many patients.

The study in Prague is designed to provide safety data on allogeneic use of GDTs prior to subsequent use of CAR-modified variants later in the year. GDTs are an obvious vehicle for allogeneic cell therapies as they do not elicit 'graft versus host' rejection. TCB is developing its proprietary GDT CAR-T (Chimeric Antigen Receptor T Cell) platform in a stepwise manner, evolving the clinical development program from autologous to allogeneic to CAR-modified products.

The first human trial of TCB002 is an ICH GCP compliant, open-label single arm study expected to enroll 9 patients, with three escalating doses of the drug product. Cancer patients in the study are suffering from relapsed or refractory AML and are ineligible or non-consenting to a stem cell transplant. The product is manufactured at TCB's GMP-compliant manufacturing site in the UK using cells sourced from healthy allogeneic donors. The development of this allogeneic product has been supported by a €4m grant from the European Union's Horizon 2020 research and innovation program.

Angela Scott, Chief Operating Officer, TC BioPharm, said:"*Treatment of the first patients with TCB002 represents the culmination of a concerted collective effort from our in-house product development, quality, manufacturing, regulatory and clinical teams, as well as the expert physicians at ÚHKT. We are now focused on successful completion of this trial and the progression of our CAR-T products to treat further patient groups with unmet clinical needs, as part of our strategic plan of delivering allogeneic CAR-T medicines as mainstream cancer therapies.*"

Prof. Petr Cetkovský, Director, ÚHKT, added:"*Collaborating with TC BioPharm on clinical evaluation of Advanced Therapy Medicinal Products allows us to offer experimental options to patients with acute clinical need, and builds upon our position of expertise with pioneers of cellular immuno-oncology products."*

This project has received funding from the European Union's Horizon 2020 Research and Innovation program.

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