

TrakCel selected for EU CAR-T Cell Therapy Project

€6 million EU project CARAT to optimise CAR-T development

Cardiff, UK, February 11, 2016 – TrakCel Ltd., a leading provider of Clinical supply chain orchestration technology for cell, gene and immunotherapies, today announces its selection as a key partner in CARAT, an EU-funded project to support the development of CAR T cell therapies.

The CARAT (Chimeric Antigen Receptors (CARs) for Advanced Therapies) project aims to integrate innovative cell manufacturing tools and enabling technologies into a single new platform that will facilitate the safe, automated and cost-efficient manufacture of highly effective CAR T-cells.

TrakCel Ltd. joins a consortium of leading biotechnology pioneers including:

- Miltenyi Biotec GmbH
- Institut national de la santé et de la recherche médicale
- Institut (Federal Institute for Vaccines and Biomedicines)
- European Research and Project Office and Universitätsklinikum Freiburg
- Ospedale San Raffaele
- University College London

CARAT will contribute to enabling the development, delivery and commercialisation of CAR T-cell technologies serving patients with so far incurable hematologic malignancies and solid tumours like colon, pancreas or lung cancer.

CARAT will enable clinical investigators and companies to focus on treatments rather than hurdles and thus be instrumental for the implementation of improved and more accessible treatment options that harnesses the strengths of the immune system.

TrakCel will work towards simplifying the management and manufacture CAR-T therapies by examining supply chain challenges in detail to produce exemplar methods of managing CAR-T supply chains. Detailed scrutiny will be applied to different delivery and management models including local and centralised manufacturing strategies. Furthermore, an application programming interface will be developed to provide a seamless exchange of data between TrakCel's technology platform and Miltenyi's cell therapy manufacturing equipment which will simplify needle to needle management, tracking and documenting of cell therapy products.

Dr Matthew Lakelin, TrakCel's Vice President of Scientific Affairs, said: "Participating in this European project will give TrakCel access to some of Europe's leading cell therapy developers and allow the company to integrate with cell therapy processing equipment. "This is a fantastic opportunity for the company to be at the forefront of innovation in technology for cellular therapies."

All available clinical data on CAR T-cell therapy, in particular the efficacy and long-lasting effect suggest this approach will have a clear and profound effect upon quality of life of cancer patients and a high acceptance of the therapy among patients can be expected.

The first milestone will have TrakCel execute a supply chain risk assessment that details the risks and mitigation strategies for an exemplar CAR-T therapy.

- ENDS -

TrakCel

publicrelations@trakcel.com

About TrakCel

TrakCel's cell therapy process management solution improves clinical study efficacy and accelerates product scale-up/scale-out by implementing communications technology to integrate the supply chain from end-to-end. The technology provides interactive instructions to professionals within the cell therapy supply chain and gives stakeholders on-demand visibility of procedural results and chain-of-custody data for immediate traceability, validation and compliance audits. Founded in 2012, TrakCel technology has been adopted by GlaxoSmithKline and other leaders in the cell therapy industry. TrakCel is based in Cardiff, Wales, UK.

TrakCel Ltd.
11 Raleigh Walk
Brigantine Place
Cardiff, UK, CF10 4LN
www.trakcel.com

About CAR T-Cell therapy

Cancer is highlighted by the WHO as one of the leading causes of mortality and morbidity with more than 50,000 people losing their lives to leukaemia every year in Europe.

Chimeric antigen receptors (CARs) are specifically tailored surface receptors that can be introduced into cells of the immune system, especially T-cells, by genetic engineering. They act as recognition molecules like antibodies or T-cell receptors and allow honing of immune responses towards selected targets. T-cells are essential for the human immune system as they scan the human body to eliminate infections and abnormalities. In this respect, CARs are increasingly used for cellular therapy to redirect T-cells specifically towards killing of cancer cells.

Recent success stories of cancer therapies based on CAR T-Cells have raised scientific and public expectations to cure severely ill patients. In latest studies T-cell treatments have proven to be very

TrakCel

successful; for example, in a clinical trial of a highly aggressive form of acute lymphoblastic leukaemia at the University of Pennsylvania, 89% of children and adults showed no evidence of cancer after receiving a CAR T-cell therapy (Grupp et al., 2013). Consequently, the Food and Drug Administration (FDA) designated T-cell treatment in 2014 as a “breakthrough therapy” for relapsed and treatment-resistant acute lymphoblastic leukaemia in adults and children.

However, translation into clinics and broad application of such advanced personalized cell therapy is currently hampered by the technologically complex, costly and error-prone procedure of manufacturing gene-modified T-Cells for each patient individually.