T2EVOLVE: breakthrough alliance boosting Europe to the forefront of cancer immunotherapy

T2EVOLVE is a breakthrough alliance of academic and industry leaders in cancer immunotherapy which started in January 2021, under the European Union's Innovative Medicines Initiative (IMI). The key objective of T2EVOLVE is to accelerate development and to increase access of cancer patients to immunotherapy with reprogrammed immune cells. Reprogramming is accomplished by genetic engineering with a T cell receptor (TCR) or synthetic chimeric antigen receptor (CAR).

Engineered T cell therapy is a revolutionary cancer treatment where a patient's immune cells are reprogrammed to seek and destroy cancer cells. This transformative treatment has the potential to cure cancer with a single shot. This therapy is approved and available in the EU for the treatment of leukemia and has the potential to become a blockbuster therapy for other types of cancer, as well as infectious diseases and autoimmune diseases in the future.

For every type of cancer, engineered T cell treatment has to be adapted in the research lab and go through clinical development. The innovation pipeline of European researchers is fully loaded with novel engineered T cell products; however, their translation into clinical trials and entry into the EU market is slow and at present, Europe is lagging behind the USA and China.

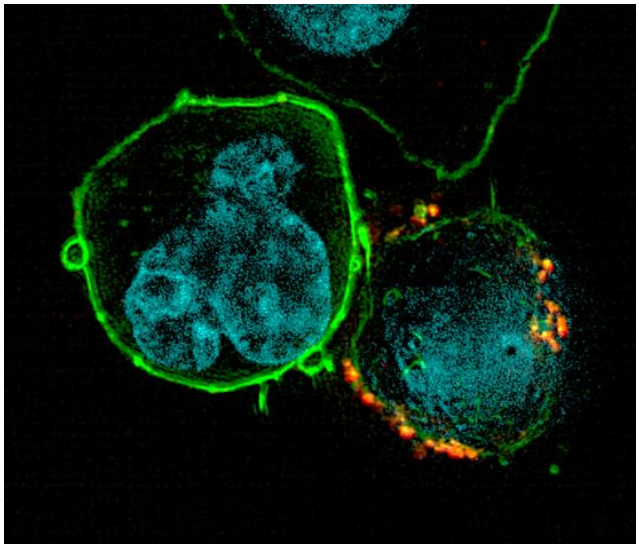

Figure 1: A tumor cell (left: cell nucleus stained blue, cell surface stained green) is tackled by a reprogrammed immune cell (right: synthetic chimeric antigen receptor -CAR- stained yellow). © Universitätsklinikum Würzburg.

T2EVOLVE focuses on standardization, accessibility, education of patients and health care providers

What is holding Europe back from taking the lead in the global clinical development of such innovative therapies and their integration into the healthcare system? There is a lack of innovative and standardized models to predict safety and efficacy during pre-clinical development to accelerate the identification of lead candidates; a lack of strategies for optimal patient conditioning; and a lack of customized manufacturing, release and monitoring schemes for CAR T-cells.

The T2EVOLVE consortium aims to achieve its ambitious goal by working on and improving the state of the art of the following key aspects:

1. Optimization of pre-clinical models **-> for the best safety and efficacy prediction**.
2. Definition of gold standard analytical methods pre- and post-engineered T-cell infusion -> **for the finest patient monitoring**.
3. Selection of optimal lymphodepletion regimens -> **to grant optimal reception of the therapy**.
4. Production of GMP guidance and establishment of standard product profiles -> **to minimize unpredictable variables**.
5. Integration of patient stakeholders into the R&D life cycle of engineered T cell therapy and improve patient experience through the joint creation of innovative communication, education, and training tools **-> to involve and guide patients all over their clinical journey.**
6. Patient access expansion **-> to grant most excellent cancer therapies to all European patients.**

The strategic objective of T2EVOLVE is to accelerate the process of developing CAR T-cell therapy in the EU, to grant EU patients access to the most ground-breaking and best available medical care, while providing guidance on the implementation of this novel treatment into the EU healthcare system in a sustainable way, and to help alleviate the financial burden of health care on the economy and society. Moreover, patient involvement will ensure that the perspectives of cancer patients are at the center, in the research setting as well as along the cancer care continuum.

T2EVOLVE: Public-private partnership to make rapid progress and a lasting impact

All members of the T2EVOLVE consortium are innovators and pioneers in the field of immunotherapy, highly committed to bridge the existing gaps between research and clinical application in Europe and make the EU lead the promising engineered T-cell therapy movement.

The T2EVOLVE consortium is being coordinated by the Universitätsklinikum Würzburg, Germany and Servier, France. The interdisciplinary T2EVOLVE consortium is made up of 27 European partners from 9 different nations. Partners include university and non-university research facilities, pharmaceutical and biotechnology companies, as well as regulatory authorities and patients and professional associations. A core feature of this approach will be to involve patient stakeholders as contributing members of the team across all levels of the R&D process.

Universitätsklinikum Würzburg (UKW) is the lead and coordinating institution for T2EVOLVE and will contribute its expertise in CAR T-cell engineering for cancer immunotherapy. The project work at UKW will be led by Prof. Michael Hudecek as the project coordinator and Prof. Hermann Einsele (both Medizinische Klinik und Poliklinik II).

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Further information on the project will be available from February 2021 on the website www.t2evolve.eu and on the project's LinkedIn profile 'T2EVOLVE'.

The T2EVOLVE project will have its first public appearance at the 3rd EHA & EBMT European CAR-T Cell Meeting (Virtual, Feb 4-6th 2021) with a workshop on Feb 5th @ 7PM CET entitled 'How to rapidly move new CAR-Ts forward from bench to bedside? Key questions and answers!'

T2EVOLVE consortium:
Coordinator: Prof. Michael Hudecek, MD, Universitätsklinikum Würzburg, Germany
Leader: Dr. Hélène Negre, PhD, Servier, France
Projekt Partners:
Academisch Medisch Centrum Amsterdam, Netherlands
Astellas, Netherlands
Bayer, Germany
BioSci Consulting, Belgium
Celgene-BMS, Switzerland
Clinica Universidad de Navarra, Spain
European Hematology Association (EHA), Netherlands
Erasmus School of Health Policy & Management, Netherlands
European Cancer Patient Coalition, Italy
Fraunhofer Institut für Zelltherapie und Immunologie, Germany
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