Press Release

EURE-CART shares its experience with CAR-T cell immunotherapy against acute myeloid leukaemia and multiple myeloma

The central goal of EURE-CART (EURopean Endeavour for Chimeric Antigen Receptor Therapies) is to conduct a multicentre, first-in-man Phase I/IIa clinical trial to demonstrate the safety and the efficacy of CD44v6 CAR-T cell immunotherapy in acute myeloid leukaemia and multiple myeloma. As it turned out, the regulatory requirements for this endeavor were much more challenging than anticipated. The EURE-CART project now publishes a White Paper on CAR-T cell therapy development with respect to regulatory issues and challenges in the harmonisation process from bench to bedside.

Milan, 30 June 2021 Adoptive immunotherapy with T cells genetically modified to express a tumour-reactive chimeric antigen receptor (CAR) is an innovative therapeutic concept, promising to eradicate cancer once for all, without causing chronic disabilities. The ultimate goal of EURE-CART is to bring EU at the forefront CAR-T cell immunotherapy and extending its applicability to incurable tumours that so far have never been approached with it. The core element of the EURE-CART project is a multicentre, first-in-man Phase I/IIa clinical trial to demonstrate the safety and the efficacy of CD44v6 CAR-T cell immunotherapy in acute myeloid leukaemia and multiple myeloma. The clinical trial was planned to be performed in Italy, Germany, Spain and Czech Republic. Hence, the project experienced the process of clinical trial approval in four EU member states.

With the project coming to an end in June 2021, EURE-CART publishes its experience with regulatory approvals for a CAR-T cell clinical trial in a White Paper.

Obstacles on the way to the clinical trial

"When planning the EURE-CART project, we had not anticipated that the regulatory authorities would react so differently on the same clinical trial application", project coordinator Dr. Catia Traversari from AGC Biologics, Milan explains. When planning the EURE-CART project, it was anticipated that the clinical trial application can be done through the Voluntary Harmonization Procedure (VHP) which is widely used to harmonize the approval process into a single assessment procedure for European multinational clinical trials. During the application phase, it turned out that in the EURE-CART case VHP cannot be applied since the CAR-T cells, being classified in Europe as a gene therapy medicinal product, are considered as GMO that are dealt with at national level. Therefore, EURE-CART had to separately apply to four national Competent Authorities who conducted their approval independently from each other. Surprisingly, the assessment of the clinical trial varied significantly between the four EU member states, even though the same body of data was presented to all the Competent Authorities. Thus, the clinical trial was approved and could start in Italy and Czech Republic

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while the German and Spanish Authorities did not approve it, even though a significant amount of additional data and information was presented when requested.

Shared experience to foster future developments

For the EURE-CART project, it was not possible to conduct the clinical trial as originally planned due to the regulatory barriers to obtain the clinical trial approval in all four European Member States participating in the project. The project consortium now shares its experience in a White Paper to foster future developments in the clinical trial harmonisation process for the benefit of upcoming clinical trials with CAR-T cell medicinal products.

EURE-CART Background

EURE-CART (EURopean Endeavour for Chimeric Antigen Receptor Therapies) is a European research project funded by the European Commision under Grant Agreement number 733297. EURE-CART project is awarded a 5,903,146 Euro grant by the European Commission partially covering R&D expenses of the project over a 54-month period, within the Horizon 2020 Research and Innovation Framework Programme, section reserved to the new therapies for chronic diseases (including cancer). To carry out this project and to reach clinical translation, a consortium of ten partners from five different EU countries has been established, including clinical, scientific and industrial groups clearly representing excellences in their fields: AGC Biologics (formerly MolMed SpA; Italy), Ospedale San Raffaele (Italy), Universitätsklinikum Würzburg - (Germany), Ospedale Pediatrico Bambino Gesù (Italy), Fundacio Privada Institut de Recerca de L' Hospital de la Santa Creu i Sant Pau (Spain), Fakultni Nemocnice S Poliklinikou Ostrava Foundation (Czech Republic), Istituto Superiore di Sanità (Italy), Acromion GMBH (Germany), ARTTIC SAS (France), ARTTIC Innovation GmbH (Germany).

For more information, visit www.eure-cart.eu
Project flyer
Project logo

Press Contact:

Verena von Scharfenberg
ARTTIC Innovation GmbH (Germany)
scharfenberg@arttic-innovation.de

Project Contacts:

Franca Moretti
Istituto Superiore di Sanità (Italy)
franca.moretti@iss.it

Maria Cristina Galli
Istituto Superiore di Sanità (Italy)
mariacristina.galli@iss.it

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Partner logos

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