

Press release

Medigene joins Max Delbrück Centre and Charité for first clinical TCR study in Germany

BMBF funded investigator initiated clinical trial targets unmet medical need in multiple myeloma

Martinsried/Munich, 29 June 2016. [Medigene AG](#) (MDG1, Frankfurt, Prime Standard), a clinical stage immuno-oncology company focusing on the development of T-cell immunotherapies for the treatment of cancer, has entered into a cooperation agreement with the Max Delbrück Centre for Molecular Medicine in the Helmholtz Association (MDC), Berlin, and the Charité – Universitätsmedizin Berlin (Charité). The partners will collaborate on a research project entitled “MAGEA1-TCR Gene Therapy of Multiple Myeloma (MAGEA1-TCR)”, which is funded by the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung; BMBF). The planned trial is currently the first study in Germany with patients with relapsed or refractory multiple myeloma that will equip a patient’s own T cells with tumor-specific T-cell receptors.

The clinical investigator-initiated phase I trial (IIT) is entitled “A Phase I study of MAGE-A1-specific TCR-transduced T cells in patients with relapsed/refractory multiple myeloma”. As part of the study, the patient’s own T cells are activated and transduced with tumor antigen MAGE-A1-specific T-cell receptors using viral vectors. Following expansion, these modified cells are then re-administered to patients to destroy the cancer cells. The aim of this trial is to investigate the safety and tolerability of this innovative therapy approach.

Charité is responsible as the clinical partner for conducting the clinical trial and is a beneficiary of the public funding along with the MDC, which is in charge of the analytics and ensuring good manufacturing practices (GMP)¹. Medigene is supporting both the MDC and Charité by handling regulatory affairs matters related to trial approval in addition to advising on the development of the analytics and GMP production. Medigene holds a first right of negotiation for an exclusive license to the study results for the commercial exploitation of the investigated TCR product candidate in multiple myeloma, and is additionally entitled to a undisclosed profit participation in the case of subsequent commercial exploitation by a third party.

Prof. Dr Dolores Schendel, CEO and CSO of Medigene and Project Leader in the collaborative project, comments on the signing of the contract: “We are delighted to be part of this first promising TCR project in Germany. The preparations required for this project will help pave the way for our own product candidates, which are also being developed for the treatment of diseases with a high unmet medical need.”

Prof. Dr Antonio Pezzutto, Medical Director at Charité Campus Benjamin Franklin and Project Lead in the collaborative project, explains: “After signing this contract, we are pleased that the preparations for the clinical trial are in full swing. Our goal is to offer this new, innovative therapy to patients suffering from multiple myeloma with MAGE-A1 expression who do not or no longer respond to traditional chemotherapy.”

Prof. Dr Blankenstein, Head of Molecular Immunology and Gene Therapy at the MDC, Director of the Institute of Immunology at Charité Campus Berlin Buch and Project

¹ Good manufacturing practices (GMP) are guidelines on quality assurance for production processes and environment in the production of medicines and active ingredients.

Coordinator in the collaborative project, adds: “This allocation of funding will now enable us to enter the clinical development phase with our MAGE-A1 T-cell receptor and consequently bring German research in this field up to the highest international level. The MDC is proud to be playing an important role by carrying out the required analytics and ensuring GMP-compliant production of the living cells for this personalized treatment of cancer.”

About TCR technology:

The TCR technology aims at arming the patient’s own T cells with tumor-specific T-cell receptors. The receptor-modified T cells are then able to detect and efficiently kill tumor cells. This immunotherapy approach attempts to overcome the patient's tolerance towards cancer cells and tumor-induced immunosuppression by activating and modifying the patient's T cells outside the body (*ex-vivo*). A large number of specific T cells to fight the tumor is thereby made available to patients within a short period of time.

Medigene’s technology for T-cell receptor-modified T cells is one of the company’s highly innovative and complementary immunotherapy platforms for adoptive T-cell therapy. The TCR therapy is designed to treat patients with high tumor loads. The clinical development of Medigene has now begun preparing its own TCRs, and developing a library of recombinant T-cell receptors. Moreover, a good manufacturing practice (GMP)-compliant process for their combination with patient-derived T cells is currently being established.

Medigene AG is a publicly listed (Frankfurt: MDG1, prime standard) biotechnology company headquartered in Martinsried near Munich, Germany. The company is developing highly innovative complementary treatment platforms to target various types and stages of cancer with candidates in clinical and pre-clinical development. Medigene concentrates on the development of personalized T cell-based immunotherapies.

For more information, please visit www.medigene.com

About Multiple Myeloma

Multiple myeloma (MM) is a cancer of plasma cells, characterized by monoclonal plasma cell proliferation in the bone marrow. According to WHO criteria, it is a B-cell lymphoma associated malignant disease with increased production of complete or incomplete monoclonal immunoglobulins. These proteins are detectable in serum and/or urine. Each year, in Germany, about 3,000 men and 2,700 women are newly diagnosed with multiple myeloma (ICD10 C90). MM is the third most common hematologic malignancy after leukemia and non-Hodgkin's lymphoma, accounting for around 1% of all cancers in Germany.

This press release contains forward-looking statements representing the opinion of Medigene as of the date of this release. The actual results achieved by Medigene may differ significantly from the forward-looking statements made herein. Medigene is not bound to update any of these forward-looking statements. Medigene® is a registered trademark of Medigene AG. This trademark may be owned or licensed in select locations only.

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