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PRESS RELEASE

NanoGen – new technology for cell and gene therapy

Fraunhofer IPK and Charité – Universitätsmedizin Berlin are jointly researching a new approach for the effective, safe and cost-efficient treatment of autoimmune patients.

One in ten adults in Germany suffers from an autoimmune disease. When our immune system is intact, it protects us from viruses and bacteria. In the case of an autoimmune disease, this protective mechanism is turned against our own body. Because the immune system can no longer distinguish between »foreign« and »self«, it attacks the body's own healthy tissues. If left untreated, the chronic inflammatory processes can lead to organ failure or even death. Current therapies generally rely on drugs that suppress the immune system. However, immunosuppressants often only have limited success and are stressful for patients due to side effects.

An alternative is the so-called CAR-T cell therapy, in which the patient's immune cells are specifically genetically modified using various techniques, such as viral vectors or electroporation, to make them more effective. »The production of such cell and gene therapeutics requires a high level of scientific, technological and regulatory expertise and is also time-consuming,« explains project leader Prof. Petra Reinke of the Institute of Medical Immunology (IMI) and founding director of the Berlin Center for Advanced Therapies (BeCAT) at Charité. In order to optimize the production of such cell and gene therapeutics in terms of their effectiveness and reproducibility and thus also make them more cost-effective, the two research institutes IMI and BeCAT at Charité and the Fraunhofer Institute for Production Systems and Design Technology IPK are developing a novel process for transporting nucleic acid-based active substances into human cells in the project »NanoGen – Innovative Lipid Nanoparticles for Cell and Gene Therapy (CGT)«. To this end, the active ingredients will be encapsulated in lipid nanoparticles (LNP) to improve the transport process into the cells. This would enable greater efficiency, stability and scalability in the production of cell and gene therapies. The project is being funded by the German Federal Ministry of Education and Research (BMBF) with 1.4 million euros until the end of 2026.

The lipid nanoparticles are produced using the FDmiX technology developed by Fraunhofer IPK and FDX Fluid Dynamix GmbH, which has already been successfully employed for the production of mRNA-based vaccines and drugs. The Fraunhofer team's task now is to adapt this technology to the field of cell and gene therapy and to tailor the lipids to the specific requirements of human T cells and various nucleic acid-based cargoes. »The lipid combinations we have used so far are designed for systemic applications such as vaccines,

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i.e. applications that are applied throughout the body,« explains Dr. Christoph Hein, head of the Ultra- and High-Precision Technology business unit at Fraunhofer IPK. »In this project, we want to use our GMP-compliant mixing technology to produce very homogeneous LNPs with special lipid formulations that are particularly effective on T cells.« In order to improve the transfection of immune cells, the team is investigating the influence of particle size and composition on the properties of the lipid nanoparticles.

Fraunhofer IPK's LNP technology is combined in the project with the approach developed at Charité's BeCAT for the molecular multiplex editing of immune cells. »The aim of the research team at Charité is to develop a complex, multiplex-edited T-cell product for the treatment of autoimmune diseases and also to improve the safety and efficacy of allogeneic T-cell products,« says Petra Reinke. As a result of the project, Fraunhofer IPK and Charité aim to establish a manufacturing process that will contribute to the availability of an effective, safe, scalable and more cost-effective cell and gene therapy for the treatment of autoimmune patients and can serve as a model for a broader application in this field.

About NanoGen
The project is funded as part of the National Strategy for Gene- and Cell-Based Therapies. The strategy was commissioned by the German Federal Ministry of Education and Research (BMBF) and is moderated by the Berlin Institute of Health at Charité (BIH). Support is provided according to the SPARK method, in which SPARK-BIH offers not only financial support but also comprehensive, project-specific consulting and training through a broad, interdisciplinary network of mentors in order to optimize and accelerate product development.

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