

PRESS INFORMATION

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Manufacturing immunotherapeutics for the treatment of brain tumors – preliminary study results published

Between 2011 and 2017, the Fraunhofer Institute for Cell Therapy and Immunology assisted American biotech company Northwest Biotherapeutics, Inc. in the conduct of a phase three clinical trial investigating the efficacy of the new DCVax®-L cell therapy in the treatment of glioblastomas. Fraunhofer IZI was responsible for preparing the investigational medicinal products for the European part of the trial. On May 29, 2018, the company published initial clinical findings in the *Journal of Translational Medicine*.



Working in a cleanroom environment at Fraunhofer IZI © Fraunhofer IZI

Before it could get up and running, in 2012 the Main Department of GMP Cell and Gene Therapy first had to transfer the GMP process for the DCVax®-L immunotherapeutic, which is based on autologous dendritic cells, and obtain the manufacturing authorization specifically required for this process pursuant to Section 13 of the German Drug Act (Arzneimittelgesetz, AMG). From this point on, the investigational medicinal products were manufactured in the clean rooms of Fraunhofer IZI in Leipzig for the European part of the trial, which covers study centers in Germany and

the UK. The published results give reason to assume that the therapy is having a positive impact on patient survival rates, with the median overall survival time of the 331 patients examined increasing from an expected 15-17 months to an average of 23.1 months, and with 100 of the 331 patients showing median survival of 40.5 months. The personalized therapy also showed a good tolerability profile.

“The data is to be viewed as preliminary for the time being,” explains Linda Powers, CEO of the company behind the drug, Northwest Biotherapeutics, Inc. “The study is still ongoing and all of the data remain blinded at present. The results may still change for the better or worse by the end of the study and following the final analysis. In view of the little progress made in treating glioblastomas over the past few years, these results are, however, encouraging.”

Editor

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The autologous immunotherapy DCVax®-L is based on dendritic cells. These cells play a central role in regulating the immune system. As tumor tissue evolves from the body's own cells, it is often not recognized as foreign by the immune system and therefore not attacked. Through the DCVax® procedure, the dendritic cells are "educated" to recognize certain tumor antigens (biomarkers) which may only exist on the tumor cells. The modified cells subsequently stimulate T cells and additional mechanisms within the immune system to fight the respective tumor cells.

The original publication can be retrieved by following the link below.

Publication: <https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-018-1507-6>

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The Fraunhofer Institute for Cell Therapy and Immunology IZI investigates and develops solutions to specific problems at the interfaces of medicine, life sciences and engineering. One of the institute's main tasks is to conduct contract research for companies, hospitals, diagnostic laboratories and research institutes operating in the field of biotechnology, pharmaceuticals and medical engineering. The Fraunhofer IZI develops, optimizes and validates methods, materials and products for the business units Cell and Gene Therapy, Drugs, Diagnostics and Biosystems Technology. Its areas of competence lie in cell biology, immunology, drug biochemistry, biomarker, bioanalytics and bioproduction as well as process development and automation. In these areas, research specifically focusses on the indications oncology, neuropathology, autoimmune and inflammatory diseases as well as infectious diseases and regenerative medicine.

The **Fraunhofer-Gesellschaft** is the leading organization for applied research in Europe. Its research activities are conducted by 72 institutes and research units at locations throughout Germany. The Fraunhofer-Gesellschaft employs a staff of more than 25,000, who work with an annual research budget totaling 2.3 billion euros. Of this sum, almost 2 billion euros is generated through contract research. More than 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed research projects. International collaborations with excellent research partners and innovative companies around the world ensure direct access to regions of the greatest importance to present and future scientific progress and economic development.

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