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PRESS RELEASE

Leipzig, May 23, 2011

INNOVATIVE THERAPY METHOD FOR THE TREATMENT OF BRAIN TUMORS

The Fraunhofer Institute for Cell Therapy and Immunology IZI and the American company Northwest Biotherapeutics Inc. are cooperating in the development of production processes and establishment of an innovative therapy method for the treatment of glioblastomas (brain tumors) in Europe.

Northwest Biotherapeutics has developed an autologous (the body's own) "DCVax®" immunotherapy for various types of cancer. In the USA, the company is already conducting clinical trials for the treatment of glioblastomas and other types of cancer. Such immunotherapies for cancer are beginning to succeed after many decades of research and development. DCVax® is one of the leading technologies at the forefront of this new approach to cancer treatment.

In order to make this DCVax® therapy also available to patients in Europe, the company has now entered cooperation with the Fraunhofer IZI. The initial phase of this cooperation comprises adapting the production processes to European regulations and standards, implementing them in the Fraunhofer IZI's facilities and comprehensive quality management system and obtaining the required official authorizations. Later on, the clinical trial products are supposed to be provided by the Fraunhofer IZI.

The current methods for the treatment of glioblastomas are limited and do not yield the desired success: Patients typically only live for about 14 months after diagnosis. Treatment options are restricted to surgical intervention, irradiation and chemotherapy, which are all associated with considerable risks and side effects. The autologous immunotherapy DCVax® Brain is now expected to provide treatment with improved therapeutic success (potentially adding years of survival) and attenuated side effects.

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The autologous immunotherapy DCVax® Brain is based on dendritic cells, which play a key role in the regulation of the immune system. As tumor tissues develop from the body's own cells, the immune system often does not recognize them as foreign tissues and therefore does not attack them. In the DCVax® method, the dendritic cells are primed to specific antigens (biomarkers) that exist on the tumor cells. Consequently, the modified cells stimulate the T cells, the B cells and antibodies, and other agents of the immune system to combat the corresponding tumor cells.

The initial step is the isolation of immune cells (monocytes) from the patient's blood, followed by their cultivation and maturation into dendritic cells in the laboratory. In this process, the cells are co-incubated with fragments of the patient's tumor and primed to the corresponding specific tumor antigens. Several injections of the DCVax® dendritic cells thus generated will stimulate the patient's immune system to combat all tumor cells that bear the corresponding tumor antigens on their surface. This technology offers an important new approach to treating cancer, and is expected to be applicable to all cancers.

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Picture: Manufacturing cell products at the Fraunhofe IZI's clean room facilitiy

We will be happy to send you this and further footage in high resolution upon request.

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The Fraunhofer-Gesellschaft undertakes applied research of direct utility to private and public enterprise and of wide benefit to society. At present, the Fraunhofer-Gesellschaft maintains more than 80 research units in Germany, including 60 Fraunhofer Institutes. The majority of the more than 18,000 staff are qualified scientists and engineers, who work with an annual research budget of €1.66 billion. Of this sum, more than €1.40 billion is generated through contract research.

The Fraunhofer Institute for Cell Therapy and Immunology IZI is member of the Fraunhofer Group for Life Sciences. Its objective being to find solutions to specific problems at the interfaces between medicine, life sciences and engineering for partners active in medicine-related industries and businesses. The Institute's core competencies are to be found in regenerative medicine, or more precisely in cell-therapeutic methods of regenerating non-functioning tissue and organs through to the biological substitution with tissue cultivated in vitro (tissue engineering). In order for the living organism to accept the tissues without any difficulty, it is necessary to study cellular and immunological defense and control mechanisms and take these into account during process and product development. These core competencies entail a multiplicity of tasks to be solved by new products and processes. The Institute works especially closely with hospital institutions, performing quality tests and clinical studies on their behalf. Additionally it also provides assistance in obtaining manufacturing licenses and certifications.

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