DASGIP and the Fraunhofer IZI cooperate in 1.1 Million Euro Stem Cell Project

Juelich/Leipzig, 11th April 2008. DASGIP AG, located in Juelich (Germany) and the Fraunhofer Institute for Cell Therapy and Immunology (IZI) in Leipzig (Germany) cooperate in stem cell research. The German Federal Ministry of Education and Research subsidizes a 1.1 Million € project aiming at the development of alternative drug testing methods without animal testing.

Taking prescription drugs during pregnancy can be harmful to the unborn child. Therefore, identifying the embryotoxic potential of a new drug candidate is an essential part of any preclinical study. These studies are currently conducted in animals according to OECD guidelines. In Europe, 11 Million animals are tested annually. About 50 percent of these tests are performed to explore the bone harming and thus the embryotoxic potential of such drug candidates. Dr. Nicole zur Nieden, leader of the stem cell group at the Fraunhofer Institute, is developing a method to identify the bone harming potential *in vitro*. This shall be enabled by simulating and monitoring the multi-phase differentiation process of pluripotent stem cells in a controlled bioreactor system. By adding compounds with known *in vivo* osteotoxic potential, adverse effects on the differentiation will be identified. Non human embryonic primate stem cells will be compared to human progenitor cells to study varying molecular reactions compared to the established test organisms (mice).

DASGIP, leading manufacturer of parallel bioreactor systems, will contribute its bioreactor system to the project. Through further improvements Dr. Matthias Arnold, CSO DASGIP, and the scientists at the Fraunhofer IZI plan to establish and automate a multi-step cultivation process covering the different phases of differentiating stem cells in drug testing.

The German government subsidizes the research project, acting on behalf of international organizations such as OECD and the EU. Since 1986 the EU commission has stressed its interest in new methods to minimize, replace or optimize animal testing. Recently, the demand to accelerate these processes has been increasing due to the EU Cosmetics and Chemicals Legislation and the desire to avoid complications associated with drug development. To date, only the embryonic stem cell test (EST) could prove as reliable *ex vivo* alternative to animal testing, which builds the basis for the planned improvements. The EU commission will publish its new ideas on how to reduce the need for animal testing and how to promote alternative methods sometime in April.

Not only politicians, but also industry representatives strongly appreciate the development of alternative methods as it can make drug development and approval faster and more cost-effective: In contrast to existing processes the stem cell approach promoted by Fraunhofer IZI is characterized by a high predictability for human effects, by cost-efficiency and by short testing periods. Therefore, Thomas Drescher, President of DASGIP, looks forward to providing the industry with a bioreactor system, which could help replacing up to 50 percent of the animal tests required in bone toxicity test for drugs, chemicals, plant protecting agents and cosmetics.

Further project partners are the ZEBET - Centre for Documentation and Evaluation of Alternatives to Animal Experiments - at the Federal Institute for Risk Assessment (www.bfr.bund.de/cd/1591) and the contract research organization RCC Ltd. (www.rccltd.ch).

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About DASGIP: DASGIP AG develops and manufactures technologically advanced Parallel Bioreactor Systems for the cultivation of microbial and mammalian cells at bench top and pilot scale. Process engineers, scientists and product developers from biotechnological, pharmaceutical and chemical companies as well as research institutions use DASGIP Parallel Bioreactor Systems for their biotechnological processes and benefit from increased productivity, high reproducibility, and ease of scale up, resulting in accelerated product development cycles. DASGIP is located in Juelich (Germany) and Shrewsbury MA (USA).

About the Fraunhofer Institute for Cell Therapy and Immunology IZI: The Fraunhofer-Gesellschaft undertakes applied research of direct utility to private and public enterprise and of wide benefit to society.

The Fraunhofer-Institute for Immunology and Cell Therapy (IZI) founded in April 2005 is member of the Fraunhofer-Life Sciences Alliance. 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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