ProBioGen
Supporting Biopharmaceutical Visions

PRESS RELEASE

ProBioGen presents new data on its Human Artifical Lymph Node (HuALN) technology

- Integrated model for the comprehensive evaluation of vaccines -

Berlin, November 24, 2009 - ProBioGen AG, a leading biotechnology company in cell engineering and production of biopharmaceuticals, today announced that it has presented new scientific data on its proprietary Human Artificial Lymph Node technology (HuALN) at the recent DECHEMA conference "Organotypic Tissue Culture for Substance Evaluation" held in Potsdam, Germany.

Dr. Christoph Giese, Head of Cell and Tissue Services at ProBioGen, presented new data on the HuALN model, which enables the comprehensive immunological assessment of pharmaceutical, chemical and cosmetic substances. By integrating multiple cell types and mimicking both T cell- and B cell-based human immune responses, ProBioGen´s technology allows for predictive testing of immune functions and immunotoxicity. So far, ProBioGen has closed a number of collaboration partnerships on its proprietary ALN model with biochemical and cosmetics companies looking for reliable alternatives to animal testing – a challenge of increasing importance due to the E.U. ban of animal testing for cosmetic substances for investigations on systemic toxicity, like skin sensitization and allergy, which will be effective end of 2012.

Another major area in need of robust, fast and predictive evaluation methods for novel substances is vaccination - especially since new epidemic influenza viruses like the swine influenza virus (SIV) are on the rise world-wide, requiring prompt, efficient protective measures. The latest data presented in Potsdam result from the successful completion of an application-specific, internal testing program for vaccines. Both commercially available vaccine products (against Hepatitis-A and B virus, HAV and HBV) and vaccine preparations (against Cytomegalovirus, CMV) have been tested for cellular and humoral immune responses using Peripheral Blood Mononuclear Cells (PBMCs) from several healthy human donors, all of which were seronegative ("naïve", "negative") for HAV, HBV, and CMV, respectively.

In summary, the data showed that

- HAV und HBV vaccines induced consistently and remarkable high cytokine immune responses on the level of cytokine releases (e.g., IL-5, IL-6, IL-10),
- repeated dosing by multiple restimulations enhanced the immunogenic effects,
- all artificial lymph node systems assembled from cells of seronegative donors mounted primary immune responses. The HAV und HBV vaccines induced humoral antibody responses in all donors,
- donor-to-donor variation was observed by significant different base levels of cytokine secretion, but all resulted in comparable dynamic secretion profiles.

"The HuALN model can be used to define the immunogenic potential and mode of action of different vaccine products and vaccine candidates," commented Dr. Uwe Marx, Chief Scientific Officer at ProBioGen. "Moreover, we expect an extended panel of cellular read out parameters. Harvested cells can be subcultivated and analysed by functional assays. Our goal is to establish a single, integrated evaluation model for pharmaceutical, chemical and cosmetic companies to predict immune reactions triggered by their substances as early as possible in the development process and to enable a fast and efficient development of new substances."

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About ProBioGen´s Artificial Lymph Node Technology (ALN)

Biopharmaceutical drugs such as antibodies, glycoproteins, cytokines or vaccines may bear the risk of unexpected immunogenicity in the patient (e.g. neutralizing antibody formation, sensitization, allergy or anaphylactic shock). In vitro and in vivo tests using animal species with an often significantly different immune system appear inadequate to assess drug efficacy and drug safety as modern biopharmaceuticals show a very high degree of species-specifity which often is not represented in currently used animal models. This sometimes leads to unexpected and often unwanted responses in clinical trials. To address this challenge, ProBioGen developed the human Artificial Lymph Node Model (human ALN) which emulates human immune organ function, provides insights into the mode of drug action and, in addition, can be used to assess the product related risk profile.

Human leucocytes from healthy adult donors are the basis for the formation of immune competent tissue (a lymph node "organoid") in a 3D matrix-assisted co-culture system. A set of process-related and immune-related parameters can be used for on-line and off-line monitoring of ongoing immune processes within the human ALN. Thus, the immunogenic risk and benefit potential of any given substance can be assessed with high reliability.

In December 2007, ProBioGen has been granted the 26th Animal Protection Award by Germany´s Federal Ministry of Food, Agriculture and Consumer Protection for its pioneering ALN technology.

About ProBioGen AG

ProBioGen is a leading cell specialist. By combining deep molecular understanding of cells with state-of-the-art industry process engineering and production know-how, ProBioGen's technologies enable biopharmaceutical companies to develop products with superior efficiency, safety and a more favourable cost profile. Since its inception in 1994, the company has processed more than 300 cell lines and established a GMP unit based on disposable reactor technology, which supports all currently available manufacturing processes. The company is headquartered in Berlin.

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