

Dr Christoph Giese Receives Animal Protection Award from Germany's Federal Ministry of Food, Agriculture and Consumer Protection

Berlin, December 12, 2007 – ProBioGen AG, a leading biotechnology company in vertebrate cell engineering and cell culture, today announced that Dr Christoph Giese, Head of ProBioGen's department Cell and Tissue Services, has been granted the 26th Animal Protection Award by Germany's Federal Ministry of Food, Agriculture and Consumer Protection. The award is endowed with 15,000 Euros and granted for innovative methods aiming at a reduction or replacement of animal tests. This year's prize was jointly awarded to Dr Giese and Dr Ellen Fritsche of the Institute of Environmental Medicine at Heinrich-Heine University in Düsseldorf. By sponsoring this award, the ministry is promoting scientific activities which support the advancement of pharmacological-toxicological methods.

The federal ministry awarded Dr. Giese's pivotal contribution to the development of a novel technology which can be used to reliably assess human immune reactions against a given chemical substance prior to its use in humans. The four-year scientific program was sponsored by the Federal Ministry of Education and Science (BMBF) and led to the development of a bioreactor system which emulates immunological functions of human lymph nodes (*Artificial Lymph Node Technology, ALN*). A European patent was granted recently, further supporting the innovative leadership of the technology. First contracts for the commercial application of the bioreactor system have already been closed by ProBioGen.

„This award confirms our team's innovative strength,“ states Dr Uwe Marx, Chief Scientific Officer at ProBioGen. “By enabling the assessment of immune reactions in a fully human system, we can address an unresolved and serious problem of the biopharmaceutical industry. Not only do we circumvent the limitations associated with the use of animal models, we can also assess the desired and undesired immunogenicity in a human system based on more than just isolated human immune cells. With our artificial lymph node (ALN) technology, we are enabling our customers to run a more efficient drug development process.”

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. Modern biopharmaceuticals show a very high degree of species-specificity which often is not represented in currently used animal models and sometimes leads to unexpected and often unwanted responses in clinical trials. To address this challenge, ProBioGen developed the *Artificial Lymph Node Technology* (human ALN). Models - like the human ALN - which emulate human immune organ function, provide 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.

About ProBioGen AG

ProBioGen is a specialist for vertebrate cell engineering and production. 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 favorable 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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