To the Copenhagen Stock Exchange
and the press

Release no. 39/2006

Pharmexa-Epimmune and Ichor Medical Systems enter into a collaborative agreement

Summary: Pharmexa-Epimmune and Ichor Medical Systems of San Diego, California have entered into a collaborative agreement and have agreed to licensing terms for Pharmexa's HER-2 DNA AutoVac™.

Pharmexa-Epimmune, a subsidiary of Pharmexa A/S, and Ichor Medical Systems of San Diego, California have entered into a collaborative agreement and have agreed to licensing terms for Pharmexa's HER-2 DNA AutoVac™. This is the second time Pharmexa agrees to grant a non-exclusive license to the HER-2 DNA AutoVac™ vaccine.

HER-2 DNA AutoVac™ is aimed at breast cancer and has previously shown clinical effects in a Phase I/II study in 27 patients. In December 2002, Pharmexa published that active immunotherapy with up to five repeated doses of HER-2 DNA AutoVac™ was safe and well tolerated at all three dose levels examined, and was capable of inducing HER-2 specific cytotoxic T-cells and antibodies in patients with HER-2 positive metastatic breast cancer. Last but not least, even in this small sample size trial, there were several indications that HER-2 DNA AutoVac™ had anti-tumor activity associated to the T-cell responses in these severely diseased metastatic breast cancer patients. Transient but significant tumor regression was observed in two patients, as measured by changes in metastatic lesions in the liver and in a lymph node, respectively. Stable disease was observed in another two patients, in whom the duration of the response was considered of significant duration in one of the cases, a patient with lytic bone metastasis at study entry.

With the aim to finance the further development, Ichor has submitted an SBIR Fast Track Application on Pharmexa's HER-2 DNA AutoVac™ vaccine delivered with Ichor's TriGrid™ Delivery System (TDS) technology. If Ichor receives this SBIR grant, the companies will collaborate on the preclinical and Phase I testing of the vaccine, and Pharmexa will grant Ichor a non-exclusive license to develop the HER-2 DNA AutoVac™ delivered with Ichor's proprietary TDS electroporation technology. The agreement includes future milestone and royalty payments to Pharmexa.

Marc Hertz, CEO of Pharmexa-Epimmune says: "HER-2 DNA AutoVac™ has shown to be effective in stimulating the patients' own immune systems to fight their cancer. However, we and others expect that DNA vaccines can be made even more effective with the right formulation and delivery. Electroporation is one of the most promising delivery technologies for DNA vaccines and Ichor's proprietary approach has key advantages within the field of electroporation to effectively transition the use of DNA vaccines to the clinic."

Robert Bernard, CEO of Ichor says: “Pharmexa’s technology has demonstrated in the clinic that it is safe, capable of bypassing tolerance and inducing anti-HER-2 immune responses. We are confident that the TDS system can enhance these responses in a simple, reproducible and clinically acceptable manner.”

Hørsholm, December 18, 2006

Jakob Schmidt
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Note to editors: *Pharmexa A/S is a leading company in the field of active immunotherapy and vaccines for the treatment of cancer, serious chronic and infectious diseases. Pharmexa’s proprietary technology platforms are broadly applicable, allowing the company to address critical targets in cancer, rheumatoid arthritis, bone degeneration and Alzheimer’s disease, as well as serious infectious diseases such as HIV, influenza, hepatitis and malaria. Its leading programs are GV1001, a peptide vaccine that has entered phase III trials in pancreatic cancer and phase II trials in liver cancer, and HIV and hepatitis vaccines in phase I/II. Collaborative agreements include H. Lundbeck, Innogenetics, IDM Pharma, ImmunoVaccine Technologies and Bavarian Nordic. With operations in Denmark, Norway and USA, Pharmexa employs approximately 100 people and is listed on the Copenhagen Stock Exchange under the trading symbol PHARMX.*

Ichor Medical Systems, Inc. is a private company developing products based on the in vivo application of TDS electroporation. Ichor’s proprietary TriGrid™ Delivery System uses electrical fields to dramatically increase DNA drug delivery efficiency, and combines electroporation technologies to enhance intramuscular DNA drug delivery in a controlled and consistent fashion. This approach enables the safe, effective and reproducible delivery of virtually any DNA vaccine or therapeutic protein. The company’s initial development efforts are focused on the integration of the TriGrid™ Delivery System with existing DNA drug candidates for which initial safety and efficacy have been characterized, thereby leveraging the substantial investments made by others in the DNA drug sector. Early candidates target cancer, autoimmune diseases and infectious diseases.