

*To the Copenhagen Stock Exchange
and the Press*

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Pharmexa starts pivotal phase III trial in the United States

Summary: The FDA has approved Pharmexas IND to start the PrimoVax trial in the United States. Pharmexa expects the first American pancreas cancer patient to be treated with GV1001 in a few weeks.

PrimoVax is a pivotal phase III trial testing the peptide vaccine GV1001 in patients with non-resectable pancreatic cancer. According to the plan the trial will enrol a total of 520 patients with pancreatic cancer. The trial started in the fall of 2006 in Europe and Australia and has so far enrolled approximately 100 patients from 60 centres. In Denmark, the trial is running at the university hospitals in Herlev, Odense and Århus. With the approval from FDA Pharmexa expects to open an additional 20 centres in the United States before the end of 2007. The first US centre is expected to be opened in California in a few weeks.

Pharmexa's CEO, Jakob Schmidt says: "We regard FDA's acceptance of the IND as a stamp of approval. If GV1001 performs as well in phase III as in previous clinical trials, I expect that we will be able to apply for registration of the product both in the United States and Europe in 2009. That is why we consider the PrimoVax trial pivotal."

GV1001 already has Orphan Drug status in pancreatic cancer both in the United States and Europe.

Brief description of the trial

In the PrimoVax trial, GV1001 will be tested side by side with the current standard treatment gemcitabine (Gemzar®), a chemotherapeutic agent approved for the treatment of pancreatic cancer. The patients in the PrimoVax study will be randomly divided into two equal-sized groups:

- 260 patients receiving the standard treatment with gemcitabine chemotherapy; and
- 260 patients receiving GV1001. If/when the condition of these patients deteriorates, treatment with gemcitabine will be added.

The PrimoVax trial is in continuation of a previous Phase I/II clinical study with GV1001 which showed that treatment with GV1001 as monotherapy prolonged patient survival compared to the effect previously seen with gemcitabine. The primary endpoint in the PrimoVax trial is survival, and the secondary endpoints include time to progression and safety. Results are expected in 2009.

GV1001 represents a new treatment modality in cancer

GV1001 is under development by Pharmexa, a Danish biotech company which is among the leading in the world in the field of active immunotherapy. The vaccine has so far been tested in more than 120 patients in a number of cancer forms. In these tests it has shown to be without significant side effects and to be able to stimulate the patient's immune system.

Besides pancreatic cancer, the vaccine is currently in Phase II trials in liver cancer and lung cancer.

GV1001 is a peptide vaccine that activates the immune system so that it recognises and kills cancer cells. GV1001 targets an enzyme called telomerase which is seldom found in normal cell types but overexpressed in most cancer cells. Telomerase activity is considered a key factor in the process whereby cancer cells lose their normal mortality, a common feature for all cancers. GV1001 could therefore theoretically turn out to be a universal cancer vaccine, which is reflected by Pharmexa's broad development programme for GV1001.

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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, 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 105 people and is listed on the Copenhagen Stock Exchange under the trading symbol PHARMX.