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Pharmexa stops one of two phase III trials

Summary: Pharmexa has decided to stop further enrolment for the PrimoVax phase III trial of GV1001 in pancreatic cancer after a preliminary analysis shows no survival benefit.

GV1001 is tested in two large-scale Phase III studies called the PrimoVax trial and the Telovac trial. An important objective of these two trials is to determine the best way to use GV1001 in combination with chemotherapy in patients with non-resectable pancreatic cancer. Today, Pharmexa has decided to stop further enrolment for the PrimoVax trial.

The PrimoVax trial was planned to include 520 patients with non-resectable pancreatic cancer. 77 hospitals in ten European countries as well as Australia and the United States have been enrolling patients for the trial. Approximately 360 patients have been enrolled in the trial to date. The primary endpoint of the trial is survival and secondary endpoints include time to progression and safety.

The patients in the PrimoVax trial were randomly divided into two equally sized groups:

- Half of the patients received the standard treatment with gemcitabine chemotherapy; and
- Half of the patients received GV1001. If/when the condition of these patients deteriorated, treatment with gemcitabine was added.

The preliminary data based on deaths of 174 patients showed that the survival was no better in the GV1001 group in which gemcitabine chemotherapy was added to GV1001 only after progression of disease as defined in the study protocol, compared to the group that received standard gemcitabine chemotherapy immediately. The final conclusions with respect to survival and all secondary endpoints must await the further follow-up of patients and full analyses of the data.

The PrimoVax trial was designed as a continuation of a previous Phase I/II clinical study with GV1001 which showed that treatment with GV1001as monotherapy significantly prolonged patient survival, compared to the effect previously seen with gemcitabine.

Pharmexa's CEO Jakob Schmidt says: "*We are disappointed that the PrimoVax trial fails to demonstrate a survival benefit for these severely ill patients. Our job now will be to collect and analyse all the data this trial has generated to fully understand the results of the PrimoVax trial and to support the ongoing Telovac trial and the other clinical activities with GV1001. It has been an open question from the start whether GV1001 should be administered before chemotherapy, as in the PrimoVax trial, or during or after chemotherapy as in the Telovac trial. We now know that giving it first does not improve overall survival in non-resectable pancreatic cancer patients. The focus going forward will be to show that GV1001 has a role in combination with chemotherapy and we have therefore decided to continue our support of the Telovac trial. The failure of the PrimoVax trial to show a survival benefit of GV1001 in these severely ill patients does not diminish our conviction that targeting the universal tumor antigen telomerase with GV1001 can be a valuable immunotherapeutic adjunct in several cancer indications,*

including pancreatic cancer."

The Telovac phase III trial
The Telovac trial is a prospective, phase III, controlled, multicentre, randomised clinical trial comparing combination gemcitabine and capecitabine therapy with concurrent and sequential chemoimmunotherapy using a telomerase vaccine in locally advanced and metastatic pancreatic cancer. The trial is supported by the National Cancer Research Institute and the Pancreas Cancer Sub-Group of the NCRI and is funded by Cancer Research UK through the Liverpool Cancer Trials Unit. Pharmexa pays for vaccine for the study and a part of the costs related to monitoring and data collection.

In the Telovac study, GV1001 is tested together with a combination of the chemotherapeutic agents gemcitabine (Gemzar®) and capecitabine (Xeloda®). The primary endpoint is survival, and the secondary endpoints include time to progression and safety. The study is planned to include a total of 1,110 patients.

The Telovac trial opened in March 2007 and so far 153 patients have been recruited. Recruitment will accelerate as 39 of 45 UK sites with Local Research Ethical Approval are already open for recruitment and 30 other UK sites are either in the process of obtaining Local Research Ethical Approval or Under Review by Trust R&D Departments.

Chief Investigator Dr. Gary Middleton (Guildford Hospital, Surrey) says: "*In the Telovac trial we anticipate accelerating recruitment as more sites open and because the vaccine seems to be free of any major side effects. We are excited by the early immunomonitoring data in the Telovac trial showing immunostimulation by the vaccine, supporting the choice of scheduling. Combining the vaccine with chemotherapy places the Telovac trial in the vanguard of studies developing the paradigm that immune therapies will be maximally effective when combined with treatments which cause apoptosis such as chemotherapy.*"

Updated financial expectations for 2008
The decision to stop further enrolment in the PrimoVax trial is expected to lead to savings in Pharmexa of DKK 20 million in 2008 and DKK 28 million in 2009. The cost of Pharmexa's ongoing support to the Telovac trial is approximately DKK 7 million per year.

Based on the company's current activities, agreements already entered into and grants already made, revenue, interest income and other operating income in the 2008 financial year will total approximately DKK 35 million. Research and development costs are expected to total DKK 145 million (against 165 million previously expected), while administrative expenses are expected to be approximately DKK 20 million. The net loss, including financial income is expected to be approximately DKK 130 million (against DKK 150 million previously expected).

Hørsholm, May 13, 2008

Jakob Schmidt
Chief Executive Officer

Additional information*:*
Jakob Schmidt, CEO, tel +45 4516 2525
Claude Mikkelsen, Vice President, Corporate Affairs and Communication, tel +45 4516 2525 or +45 4060 2558

For the 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 and chronic diseases, 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, GENimmune, IDM Pharma, Bavarian Nordic and Ichor Medical Systems. With operations in Denmark, Norway and USA, Pharmexa employs approximately 80 employees and is listed on the Copenhagen Stock Exchange under the trading symbol PHARMX.*

GV1001: A Therapeutic Vaccine against Cancer
GV1001 is a peptide vaccine which activates the immune system so that it recognizes and kills cancer cells. GV1001 targets an enzyme called telomerase. Telomerase is rarely found in normal cell types but is over-expressed in most cancer cells. Telomerase activity is considered a key factor in the process whereby cancer cells loose their normal mortality, a common feature for all cancers. GV1001 could therefore theoretically turn out to be a universal cancer vaccine.

GV1001 has achieved orphan drug status for the treatment of pancreatic cancer both in Europe and in the United States. Pharmexa holds all rights to GV1001.