



Oncothyreon announces that Merck Serono is resuming the Stimuvax clinical program in lung cancer

SEATTLE, WA, June 17, 2010 /PRNewswire via COMTEX News Network/ -- Oncothyreon Inc. (Nasdaq: ONTY) today announced that Merck Serono, a division of Merck KGaA of Darmstadt, Germany, and its U.S. affiliate, EMD Serono, Inc., are resuming the worldwide clinical development program for Stimuvax(R) (BLP25 liposomal vaccine) in non-small cell lung cancer (NSCLC), including the Phase 3 START and INSPIRE trials. The treatment and enrollment in these studies will restart after approval by the local regulatory authorities and ethics committees. The announcement follows a decision by the U.S. Food and Drug Administration (FDA) to partially lift the clinical hold it placed on the Investigational New Drug (IND) application for BLP25 liposome vaccine in March 2010 and allow the START trial to be resumed.

"Merck Serono worked constructively with the FDA and other health authorities to address the questions raised on the safety of BLP25 liposome vaccine in patients with NSCLC and, as a result, we can now resume our NSCLC clinical program," commented Dr. Bernhard Kirschbaum, Head of Global Research and Development of the Merck Serono division, Merck KGaA. "We have meanwhile received a number of regulatory approvals to restart in other countries and await approval in the remaining countries."

The Phase 3 STRIDE trial in advanced breast cancer remains on clinical hold by the FDA. Merck Serono announced that it will continue to work closely with the health authorities, including the FDA, to decide the next steps for this trial.

"Merck Serono remains highly committed to the development of BLP25 liposome vaccine and the well-being of the patients," said Dr. Wolfgang Wein, Executive Vice President, Oncology, Merck Serono. "We believe this therapeutic cancer vaccine has the potential to be a valuable addition to the future range of therapies for oncologists and their patients."

"The resumption of the BLP25 liposome vaccine clinical program is very good news for the oncology community and NSCLC patients. If the START and INSPIRE Phase III trials are successful, BLP25 liposome vaccine could play an important role in the treatment of these currently underserved patients," said Dr. Frances Shepherd, Director of the Medical Oncology Princess Margaret Hospital in Toronto, Ontario, Canada, and Coordinating Investigator of the START trial.

Merck Serono temporarily suspended its global clinical program for BLP25 liposome vaccine in all recruiting studies worldwide following the clinical hold put in place by the FDA in March 2010. The clinical hold followed a suspected unexpected serious adverse reaction of encephalitis, observed in a patient enrolled in an exploratory Phase 2 trial of BLP25 liposome vaccine in patients with multiple myeloma. To ensure the safety of the study subjects, the protocols in the NSCLC trials are being amended to add specific safety measures.

About Stimuvax

Merck KGaA has an exclusive world-wide license from Oncothyreon for Stimuvax. Merck KGaA is investigating the use of Stimuvax (BLP25 liposome vaccine) in the treatment of NSCLC. The vaccine was granted fast-track status in September 2004 by the FDA. Stimuvax is being developed in Europe by Merck KGaA and in the United States and Canada by its affiliate, EMD Serono Inc.

START is a multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical study designed to evaluate the efficacy, safety and tolerability of Stimuvax in subjects suffering from unresectable stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemo-radiotherapy. The study will involve more than 1,300 patients in approximately 30 countries. The primary endpoint of the trial is overall survival.

The INSPIRE study is a multi-center, Phase 3, double-blind, placebo-controlled, randomized clinical trial designed to evaluate the efficacy, safety and tolerability of Stimuvax in subjects suffering from unresectable, stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemo-radiotherapy. The design of the INSPIRE study is almost identical to the START study. The study will enroll approximately 420 unresectable, stage III NSCLC patients across China, Hong Kong, Korea, Singapore and Taiwan.

STRIDE is a randomized, double-blind, controlled, multi-center Phase 3 study designed to determine if Stimuvax can extend progression free survival in patients treated with hormonal therapy who have inoperable, locally advanced, recurrent or metastatic breast cancer. Overall survival, quality of life, tumor response and safety will also be assessed in this study.

About Oncothyreon

Oncothyreon is a biotechnology company specializing in the development of innovative therapeutic products for the treatment of cancer. Oncothyreon's goal is to develop and commercialize novel synthetic vaccines and targeted small molecules that have the potential to improve the lives and outcomes of cancer patients. For more information, visit www.oncothyreon.com.

Forward-Looking Statements

This press release contains statements that are forward-looking, including the Oncothyreon's expectations regarding the clinical development program for Stimuvax, the possible outcome of further discussions with the FDA and other regulatory authorities, and the ability of Merck KGaA to timely resume clinical trials with Stimuvax. These forward-looking statements involve risks and uncertainties, many of which are beyond Oncothyreon's control. These risks, uncertainties and other factors could cause actual results to differ materially from those projected in forward-looking statements. Specifically, there is no assurance that the serious adverse event discussed above was not caused by Stimuvax, that there are not or will not be more such serious adverse events or that Merck Serono will be able to gain sufficient information to fully understand the risks associated with the product. Further, the occurrence of this serious adverse event, or other such serious adverse events, could result in a prolonged delay, including the need to enroll more patients or collect more data, or the termination of the clinical development program for Stimuvax, the FDA or other regulatory agencies may not allow the resumption of clinical trials for Stimuvax in non-NSCLC indications, including the STRIDE trial, in a timely fashion, if at all, Merck KGaA could terminate its license agreement with Oncothyreon, and the integrity of the ongoing trials for Stimuvax could be compromised. Any of the foregoing risks could materially and adversely affect the Company's business, results of operations and the trading price of its common stock. For a detailed description of risks and uncertainties faced by the Company, you are encouraged to review the official corporate documents filed with the securities regulators in the United States on U.S. EDGAR and in Canada on SEDAR. The Company does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

Additional Information

Additional information relating to Oncothyreon can be found on U.S. EDGAR at www.sec.gov and on SEDAR at www.sedar.com.

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