



Oncothyreon announces initiation of Phase 3 trial of Stimuvax in breast cancer

SEATTLE, Jun 22, 2009 (Canada NewsWire via COMTEX News Network) -- Oncothyreon Inc. (Nasdaq: ONTY) (TSX:ONY) (the "Company") today announced that Merck KGaA of Darmstadt, Germany, has initiated a global Phase 3 trial of Stimuvax(R) (BLP25 liposome vaccine, L-BLP25) in patients with hormone receptor-positive, locally advanced, recurrent or metastatic breast cancer. Stimuvax is an investigational therapeutic cancer vaccine being developed by Merck KGaA under a license agreement with Oncothyreon.

The Phase 3 trial, named STRIDE (STimulating immune Response In aDvanced brEast cancer), is anticipated to enroll more than 900 patients at approximately 180 sites in over 30 countries - including North America, Europe, Asia and Australia. Patients with estrogen receptor-positive and/or progesterone receptor-positive, non-resectable locally advanced, recurrent or metastatic breast cancer receiving hormonal therapy will be randomized to receive either Stimuvax or a placebo in a 2:1 ratio. The primary endpoint of STRIDE is progression-free survival. Overall survival, quality of life, tumor response and safety will also be assessed in this study.

"Advanced-stage breast cancer remains a devastating and challenging disease and we urgently need new treatment options," said Dr. Larry Shulman, Chief Medical Officer and Senior Vice President for Medical Affairs, Dana-Farber Cancer Institute, Boston, Massachusetts, and Principal Investigator of STRIDE. "If the results from the Phase 3 STRIDE study prove positive, this could make a difference for patients with hormone receptor positive metastatic breast cancer."

"The initiation of the STRIDE study is an enormous step forward in clinical breast cancer research and represents our continued commitment to developing Stimuvax within a robust clinical trial program across several cancer types. We are very excited that Stimuvax will now be tested in two different cancer types in Phase III," said Dr. Oliver Kisker, Senior Vice-President, Global Clinical Development Unit Oncology, Merck KGaA.

"We are very pleased by the robust development program our partner, Merck KGaA, is conducting for Stimuvax," said Robert L. Kirkman, M.D., President and Chief Executive Officer of Oncothyreon. "The addition of the Phase 3 STRIDE trial in breast cancer to the Phase 3 START trial in non-small cell lung cancer (NSCLC) is evidence of their strong commitment to this innovative product candidate."

About Stimuvax

Stimuvax is an investigational therapeutic cancer vaccine designed to induce an immune response to cancer cells that express MUC1, a glycoprotein antigen widely expressed on common cancers. MUC1 is over-expressed on many cancers such as lung cancer, breast cancer, prostate cancer and colorectal cancer. Stimuvax is thought to work by stimulating the body's immune system to identify and destroy cancer cells expressing MUC1.

In addition to STRIDE, Merck KGaA currently is conducting a global Phase 3 trial of Stimuvax known as START (Stimulating Targeted Antigenic Responses To NSCLC). START is a randomized, double-blind, placebo-controlled study that will evaluate patients with documented unresectable stage III NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemo-radiotherapy. START is expected to enroll more than 1,300 patients in over 30 countries. For more information on the START trial log on to www.nsclstudy.com or www.clinicaltrials.gov.

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

In order to provide Oncothyreon's investors with an understanding of its current intentions and future prospects, this release contains statements that are forward looking, including statements related to future clinical development plans for Stimuvax. These forward-looking statements represent Oncothyreon's intentions, plans, expectations and beliefs and are based on its management's experience and assessment of historical and future trends and the application of key assumptions relating to future events and circumstances.

Forward-looking statements involve risks and uncertainties, including risks and uncertainties related to Oncothyreon's business and the general economic environment. Many of these risks and uncertainties are beyond Oncothyreon's control. These risks, uncertainties and other factors could cause our actual results to differ materially from those projected in forward-looking statements. Risks, uncertainties, and assumptions include those predicting the timing, duration and results of clinical trials, the timing and results of regulatory reviews, the safety and efficacy of Stimuvax, the indications for which Stimuvax might be developed, and Merck Serono's development plans for Stimuvax. There can be no guarantee that the results of preclinical studies or clinical trials will be predictive of either safety or efficacy in future clinical trials. These and other risks and uncertainties are described in the reports and other documents filed by Oncothyreon Inc. with the SEC and/or Canadian regulatory authorities.

Although Oncothyreon believes that any forward-looking statements contained herein are reasonable, it can give no assurance that its expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For a detailed description of the risks and uncertainties associated with Oncothyreon, 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. Oncothyreon is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.

SOURCE: Oncothyreon Inc.

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