



## Oncothyreon announces temporary suspension of Stimuvax clinical trials by Merck Serono

SEATTLE, March 23, 2010 /PRNewswire via COMTEX News Network/ -- ONCOTHYREON TO HOLD TELECONFERENCE AT 5:00 PM EDT

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., have temporarily suspended the worldwide clinical development program for Stimuvax(R) (BLP25 liposomal vaccine). The suspension is the result of a suspected unexpected serious adverse reaction in a patient with multiple myeloma participating in an exploratory clinical trial. This decision was taken in alignment with the U.S. Food and Drug Administration's (FDA) clinical hold placed on the Investigational New Drug (IND) application for Stimuvax.

The suspension affects the Phase 3 clinical program for Stimuvax, including the START and INSPIRE trials in non-small cell lung cancer (NSCLC) and the STRIDE trial in breast cancer. Further recruitment of patients into all trials actively recruiting patients and ongoing treatment with Stimuvax in these trials are suspended.

"Patient safety is of paramount importance to Merck Serono and to Oncothyreon," said Robert L. Kirkman, M.D., President and CEO of Oncothyreon. "We understand that Merck Serono is working closely with the FDA, other regulatory agencies and the patient's physicians to evaluate the implications of this adverse reaction and to determine an appropriate course of action."

The exploratory trial in multiple myeloma is designed to investigate the mechanism of action of Stimuvax and the effect of cyclophosphamide on regulatory T cells, which may affect the response to the therapeutic vaccine. The adverse event occurred in a patient receiving a more intensive regimen of low-dose cyclophosphamide than is utilized in the Phase 3 program. The patient developed an encephalitis, or inflammation of the brain. No other events of this kind have been reported in other trials of Stimuvax to date.

### Conference Call Information

Oncothyreon will host a conference call and webcast today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time. To participate in the call by telephone, please dial 877-280-7291 (United States) or 707-287-9361 (International). In addition, the call is being webcast live and can be accessed on the "Events" page of the "News & Events" section of the Company's Web site at [www.oncothyreon.com](http://www.oncothyreon.com). An archive of the webcast will be available after completion of the discussion and will be posted on the Oncothyreon website.

### About Stimuvax

Merck KGaA has an exclusive world-wide license from Oncothyreon for Stimuvax. Merck KGaA is investigating the use of Stimuvax(R) (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 by its affiliate, EMD Serono Inc.

START is a multi-center, randomized, double-blind, placebo-controlled Phase 3 study that will evaluate patients with documented 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 INSPIRE study is a multi-national, 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 III NSCLC and demonstrating either stable disease or objective response following primary chemo-radiotherapy. 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 III study designed to determine if Stimuvax(R) 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](http://www.oncothyreon.com).

#### Forward-Looking Statements

This press release contains statements that are forward-looking, including the Company's expectations regarding the clinical development program for Stimuvax, the possible outcome of discussions with the FDA and other regulatory authorities, and the ability of Merck KGaA to resume clinical trials with Stimuvax. These forward-looking statements involve risks and uncertainties, many of which are beyond the Company'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 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](http://www.sec.gov) and on SEDAR at [www.sedar.com](http://www.sedar.com).

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