



## **Oncothyreon announces clinical data from three product candidates presented at American Society of Clinical Oncology (ASCO) Annual Meeting**

SEATTLE, WA, May 30, 2009 (Canada NewsWire via COMTEX News Network) -- Oncothyreon Inc. (Nasdaq: ONTY) (TSX:ONY) (the "Company") today announced that data from clinical trials for three of the Company's product candidates were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on May 30, 2009 in Orlando, Florida. The presentations included long-term safety data from the Phase 2b trial of Stimuvax(R) in patients with stage IIIB/IV non-small cell lung cancer, preliminary results from the Phase 1 trial of the phosphoinositide-3-kinase (PI-3 kinase) inhibitor PX-866 in patients with advanced malignancy, and final results from two Phase 1b trials of the thioredoxin inhibitor PX-12 in advanced cancer patients.

### Stimuvax

Data concerning the long-term safety of Stimuvax (BLP25 liposomal vaccine) were presented by Dr. Charles Butts, Cross Cancer Institute, Edmonton, Alberta. Sixteen patients who received Stimuvax for between 2 and 8.2 years as part of the Phase 2b trial in patients with stage IIIB/IV non-small cell lung cancer (NSCLC) were studied. Ten of these patients have been treated for more than five years, and eight continue to receive therapy with Stimuvax. Prolonged treatment with Stimuvax was well-tolerated in this trial. The most common treatment-related adverse events were injection site reactions, which tended to diminish after the first year of treatment. There was no evidence of autoimmune reactions with prolonged use.

"We are very pleased that this group of long-term survivors with advanced NSCLC has been able to continue to receive Stimuvax with apparent safety for up to eight years," said Robert L. Kirkman, M.D., President and Chief Executive Officer of Oncothyreon. "These patients were treated as part of the randomized Phase 2b trial conducted by Oncothyreon, in which the subset of patients with Stage IIIB locoregional disease who received Stimuvax had a median survival of 30.6 months compared with 13.3 months for similar patients who did not receive the vaccine, a difference of 17.3 months. Long-term follow-up of these patients was conducted by Merck KGaA of Darmstadt, Germany, which assumed responsibility for the clinical development of Stimuvax in 2007."

Merck KGaA 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.

### PX-866

Preliminary results of Oncothyreon's ongoing Phase 1 trial of PX-866, an inhibitor of PI-3 kinase, were presented by Dr. Antonio Jimenez, University of Colorado Cancer Center, Aurora, Colorado. Twenty-six patients have been treated in this trial at once daily doses ranging from 0.5 mg to 10 mg. The maximally tolerated dose has not yet been identified. The most common treatment-related adverse events at the doses tested include low-grade nausea, vomiting and diarrhea. Of 24 evaluable patients, six patients with previously progressive disease have had stable disease as their best response. Three of these patients remain on therapy. Pharmacodynamic monitoring has demonstrated inhibition of PI-3 kinase activity at doses as low as 1 mg per patient.

"We are excited to have seen stabilization of disease in previously progressing patients, as well as clearcut inhibition of PI-3 kinase activity, even in the early cohorts in this dose escalation trial," said Dr. Kirkman. "We believe these findings may reflect the fact that PX-866 is an irreversible inhibitor of PI-3 kinase, which distinguishes it from other PI-3 kinase inhibitors currently in clinical development."

### PX-12

Final results from two Phase 1b trials of PX-12, an inhibitor of thioredoxin, were presented by Dr. R.K. Ramanathan, Scottsdale Clinical Research Center, Scottsdale, Arizona. These trials in 32 patients were designed to assess the tolerability and pharmacodynamic activity of both 24-hour and 72-hour infusions of PX-12. In both trials, doses up to 400 mg/m<sup>2</sup>/day were well-tolerated. PX-12 was shown to lower levels of circulating thioredoxin in patients whose starting levels were at least three-fold greater than normal. Three patients achieved stable disease.

### 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. 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. The Phase 3 trial is expected to enroll more than 1,300 patients in over 30 countries. For more information on the START trial, or to find a participating center and eligibility criteria, log on to [www.nslcstudy.com](http://www.nslcstudy.com) or [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### About PX-866

PX-866 is an inhibitor of the PI-3-kinase/PTEN/AKT pathway, an important survival signaling pathway that is activated in many types of human cancer. Aberrant activation and regulation of PI-3 kinase is implicated in a large proportion of human cancers including breast, glioma, colon, ovarian, prostate and melanoma, where it leads to increased proliferation and inhibition of apoptosis (programmed cell death). PX-866 has been shown to induce prolonged inhibition of tumor PI-3 kinase signaling following both oral and intravenous administration. The compound has been shown to have anti-tumor activity both as a single agent and in combination with other agents in a number of human tumor models. Oncothyreon initiated a Phase 1 trial of PX-866 in patients with advanced metastatic cancer in June 2008.

#### About PX-12

PX-12 is a small molecule irreversible inhibitor of the redox protein thioredoxin. Thioredoxin is involved in the first unique step in DNA synthesis. Thioredoxin also provides control over a number of transcription factors affecting cell proliferation and death through the mechanism of redox regulation.

An initial Phase 1 trial involving 38 patients with advanced metastatic cancer showed that PX-12 was well tolerated and produced a decrease in plasma concentrations of thioredoxin that was significantly correlated with increased patient survival. Fifteen of the 38 patients achieved stable disease of up to 322 days. A randomized Phase 2 trial comparing two dose levels of PX-12 in up to 80 patients at three sites with advanced pancreatic cancer who have progressed on gemcitabine or a gemcitabine-containing regimen was initiated in January 2007. Enrollment in this trial was terminated in early 2009. The Company intends to seek a partner for further development of this drug candidate.

#### 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

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 preclinical and clinical development plans for our product candidates. 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 our product candidates, and the indications for which our product candidates might be developed. 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.

Investor and Media Relations Contact: Julie Rathbun, Rathbun Communications, (206)  
769-9219, [ir@oncothyreon.com](mailto:ir@oncothyreon.com)

Copyright (C) 2009 CNW Group. All rights reserved.

News Provided by COMTEX