



Oncothyreon announces presentation of Phase 1 data for PX-866 and PX-478 at American Society of Clinical Oncology Annual Meeting

SEATTLE, WA, June 7, 2010 /PRNewswire via COMTEX News Network/ -- DESCRIBES PHASE 2 DEVELOPMENT PLANS FOR PX-866

Oncothyreon Inc. (Nasdaq: ONTY) (the "Company") announced that results from Phase 1 clinical trials of the Company's small molecule product candidates PX-866, an irreversible inhibitor of PI-3 kinase, and PX-478, an inhibitor of HIF-1 alpha, were presented today at the American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, IL. In conjunction with the presentations, the Company announced projected Phase 2 development plans for PX-866.

PX-866 Phase 1 Trial Data

The Phase 1 trial of PX-866 is an open-label, dose escalation study in patients with advanced metastatic cancer of both an intermittent and a continuous dosing schedule, including an expansion cohort at the maximum tolerated dose for each schedule. In the intermittent dosing arm of the trial, which is now completed, 51 patients were treated with escalating doses of PX-866 ranging from 0.5 mg to 16 mg, once daily on days 1-5 and 8-12 of a 28 day cycle. In the continuous dosing arm, which is ongoing, 9 patients included in today's presentation have received a daily oral dose of 8 mg or 10 mg of PX-866. An additional 10 patients have been enrolled in the continuous dosing expansion cohort recently and were not included in the presentation. Endpoints of the trial include safety and tolerability, pharmacokinetics, pharmacodynamics and anti-tumor activity.

PX-866 was well-tolerated in both arms of this trial. The most common adverse events were mild to moderate in severity, and included diarrhea, nausea, vomiting, fatigue and reversible elevation of liver enzymes. There was no significant increase in adverse events noted in patients receiving more than two cycles of treatment in either arm of the trial. The maximum tolerated dose of PX-866 was 12 mg in the intermittent schedule and 8 mg in the continuous schedule. Pharmacokinetic analysis confirmed that PX-866 is rapidly metabolized to a more potent derivative, consistent with preclinical data.

In the continuous dosing arm, 6 of 8 patients evaluable to date (or 75 percent) had stable disease as the best response, 3 of whom are continuing to receive treatment with PX-866. In the intermittent dosing arm, 7 out of 45 evaluable patients (or 16 percent) experienced stable disease. Patients enrolled in the trial had a median number of four prior therapies.

"It is encouraging that PX-866 demonstrated disease stabilization in these heavily pre-treated patients, especially with the continuous dosing schedule," said Dr. Antonio Jimenez, lead investigator of the study from the University of Colorado Cancer Center, Aurora, Colorado, who presented the data at ASCO. "We are looking forward to participating in future trials with this novel agent."

PX-866 Phase 2 Development Program

Oncothyreon also announced today that it plans to initiate a Phase 1/2 trial of PX-866 in combination with docetaxel in the third quarter of 2010. The Phase 1 portion of the trial will be a dose escalation of PX-866 in combination with the standard dose of docetaxel in patients with advanced cancer normally treated with docetaxel. Once the recommended dose of PX-866 in combination with docetaxel is established, the Phase 2 portion will consist of up to three arms examining PX-866 in combination with docetaxel in second or third line non-small cell lung cancer patients, in second or third line squamous cell carcinoma of the head and neck patients, and a third indication to be determined.

"Based on the disease stabilization and tolerability seen to date with PX-866, we are excited to move this program into a broad Phase 2 development program," said Robert L. Kirkman, M.D., President and CEO of Oncothyreon. "In addition to the planned trial in combination with docetaxel, which includes up to three indications, we currently plan to initiate a second Phase 2 trial in combination with another targeted agent late this year. We also currently expect that the National Cancer Institute of Canada Clinical Trials Group will conduct two Phase 2 trials of PX-866, one in patients with castration-resistant prostate cancer and the second in patients with relapsed glioblastoma."

PX-478 Phase 1 Trial Data

PX-478 is an inhibitor of HIF-1 alpha derived from melphalan. The Phase 1 trial of PX-478 was an open-label, dose escalation

trial in 41 patients with advanced cancer to examine safety and tolerability, pharmacokinetics and pharmacodynamics and anti-tumor activity. PX-478 was administered orally on days 1-5 of a 21 day cycle at doses ranging from 1 mg/m² to 88.2 mg/m². Adverse events occurring in more than 10 percent of patients were nausea, fatigue, diarrhea and vomiting. One patient experienced prolonged Grade 3 thrombocytopenia at the highest dose level. Thirteen of 37 evaluable patients (or 35 percent) had stable disease. Pharmacodynamic studies revealed dose-proportional inhibition of HIF-1 alpha levels. Pharmacokinetic studies demonstrated low levels of PX-478 with evidence for conversion to melphalan and other metabolites.

"The relatively high proportion of patients achieving stable disease and the dose-proportional inhibition of HIF-1 alpha are encouraging," said Dr. Kirkman. "However, the rapid conversion of PX-478 to melphalan complicates the development of this compound. As preclinical studies have demonstrated that melphalan does not inhibit HIF-1 alpha, our data suggest that one or more active metabolites may contribute to the pharmacological effects of PX-478."

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 xenograft models of human tumors.

About PX-478

PX-478 is a novel small molecule compound that inhibits the activity of hypoxia inducible factor (HIF)-1 alpha, a component of the transcription factor HIF-1 that controls the expression of a number of genes important for growth and survival of cancer cells. Genes regulated by HIF-1 contribute to diverse functions including new blood vessel growth (angiogenesis), use of glucose for energy, and protection against apoptosis (programmed cell death). Preclinical data have demonstrated that PX-478 can induce apoptosis in experimental tumor models, as well as the down-regulation of factors that control angiogenesis, such as vascular endothelial growth factor (VEGF). PX-478 is effective when delivered orally in animal models, and has shown marked tumor regressions and growth inhibition in model systems across a range of cancers, including lung, ovarian, renal, prostatic, colon, pancreatic, and breast cancer.

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 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.

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