



OncoGenex Pharmaceuticals Announces Initiation of a Phase 3 Trial in Men with Metastatic Prostate Cancer

BOTHELL, WA, and VANCOUVER, Jun 21, 2010 (Canada NewsWire via COMTEX News Network) -- OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today the initiation of a Phase 3 registration trial of custirsen sodium (OGX-011/TV-1011), its lead product candidate being developed for the treatment of castrate-resistant prostate cancer (CRPC). This trial, referred to as the Prostate Cancer SATURN Trial, is the first of three Phase 3 trials to be initiated under a global collaboration and license agreement between OncoGenex and Teva Pharmaceutical Industries (NASDAQ: TEVA) to develop and commercialize OGX-011/ TV-1011.

This randomized, controlled, international Phase 3 trial will be conducted in approximately 50 cancer centers and will enroll approximately 300 men with metastatic CRPC who have previously responded to first-line docetaxel therapy, but subsequently have disease progression that involves prostate cancer-related pain despite opioid usage. Patients will be randomized to receive retreatment with docetaxel/prednisone plus OGX-011/ TV-1011 or docetaxel/prednisone plus placebo in a blinded manner. The primary endpoint of the SATURN trial will be to determine whether durable pain palliation for 12 weeks or more is observed in a greater proportion of patients treated with docetaxel/prednisone plus OGX-011/ TV-1011 compared to docetaxel/prednisone plus placebo.

More information on the Prostate Cancer SATURN Trial is available on the Company's website at <http://oncogenex.com/clinicalTrials/index.html>.

The Principal Investigators for the SATURN trial are Dr. Tomasz Beer at the Oregon Health & Science University Knight Cancer Institute for the United States, Dr. Sebastien Hotte at Juravinski Cancer Centre in Hamilton, Ontario for Canada and Professor Karim Fizazi at the University of Paris for Europe. An Investigator meeting was held in May to train and initiate US and Canadian sites. The Company expects to initiate European sites in the third quarter of 2010.

The SATURN trial design is based on the Phase 2 data in patients with metastatic CRPC who were treated with OGX-011/ TV-1011 in combination with docetaxel/prednisone retreatment as second-line chemotherapy.

"Pain is a dominant symptom in patients with progressive prostate cancer and frequently remains a challenge despite treatment with opioid analgesics. Poorly controlled pain has devastating effects on both patients and their family members," stated Dr. Beer. "In the Phase 2 trial, almost half of patients who had pain or were on opioids and were retreated with docetaxel/prednisone with the addition of OGX-011/ TV-1011 had durable pain palliation for 12 weeks or more. This is better than expected based on pain responses seen after initial treatment with docetaxel/prednisone."

A separate Phase 2 trial evaluating OGX-011/ TV-1011 in combination with first-line chemotherapy showed that patients with advanced metastatic prostate cancer who were treated with OGX-011/ TV-1011 plus docetaxel had a median overall survival of 23.8 months compared to 16.9 months for patients treated with docetaxel alone -- a 6.9 month observed survival advantage for the OGX-011/ TV-1011 arm.

OGX-011/ TV-1011 has received Fast Track designation from the U.S. Food and Drug Administration (FDA) and this SATURN trial is being conducted through the Special Protocol Assessment (SPA) process. Earlier this year, the European Medicines Agency indicated that the Committee for Medicinal Products for Human Use was in overall agreement with the company's development plan for OGX-011/ TV-1011 which included this Phase 3 trial.

In 2009, Teva Pharmaceutical Industries Ltd. and OncoGenex Pharmaceuticals, Inc. entered into a global license and collaboration agreement to develop and commercialize OGX-011/TV-1011. In addition to the ongoing SATURN trial assessing durable pain palliation as the primary endpoint for second-line chemotherapy in men with metastatic CRPC, the global Phase 3 clinical program also includes a Phase 3 trial in first-line chemotherapy for metastatic CRPC which assesses survival as the primary endpoint. A Phase 3 trial assessing survival as the primary endpoint in first-line treatment of advanced, unresectable non-small cell lung cancer (NSCLC) is also planned as part of the strategy to develop and commercialize OGX-011/TV-1011.

About Prostate Cancer

The National Cancer Institute reports that in 2009, approximately 192,280 new cases of prostate cancer will be diagnosed in the U.S. As the most frequently diagnosed cancer among men, one in six men will be diagnosed with prostate cancer during their lifetime. It is estimated that in 2009 in the U.S., 27,360 deaths will result due to the disease. The International Agency for Research on Cancer recently published estimates of cancer incidence and mortality in Europe in 2008. They reported 382,300

new cases of prostate cancer and 89,300 deaths related to prostate cancer.

About OncoGenex

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new cancer therapies that address treatment resistance in cancer patients. OncoGenex has a deep oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. OncoGenex and Teva Pharmaceuticals have entered a global collaboration and license agreement to develop and commercialize OncoGenex' lead drug candidate, OGX-011/TV-1011. OGX-011/TV-1011 is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer. The companies plan to begin Phase 3 development of OGX-011/TV-1011 in first-line treatment of advanced, unresectable non-small cell lung cancer in 2011; OGX-427 is in Phase 1 clinical development; SN2310 has completed a Phase 1 clinical trial; and CSP-9222 and OGX-225 are currently in pre-clinical development.

OGX-011/TV-1011, OGX-427 and OGX-225 utilize second-generation antisense technology, licensed from Isis Pharmaceuticals (NASDAQ: ISIS), to target and inhibit production of specific proteins which OncoGenex believes are important in tumor progression and treatment resistance. OncoGenex and Isis partnered in the successful discovery of OGX-011/TV-1011, OGX-427 and OGX-225 and with respect to OGX-011/TV-1011, in its initial development. In 2008, OncoGenex and Isis amended their OGX-011/TV-1011 agreement to provide OncoGenex with sole rights to OGX-011/TV-1011 and sole responsibility for development and related costs and partnering decisions, subject to financial obligations to Isis. OncoGenex is also solely responsible for development and related costs and partnering decisions regarding OGX-427 and OGX-225. Key intellectual property related to OGX-011/TV-1011, OGX-427 and OGX-225 was discovered by the University of British Columbia and the Vancouver Prostate Centre, and were exclusively licensed to OncoGenex.

More information about OncoGenex is available at www.oncogenex.com.

OncoGenex' Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning anticipated clinical and other product development activities, timing of these activities and projected cancer rates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including, among others, the risk that the results of clinical trials may not be sustained in future clinical trials and the factors set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for fiscal year 2009. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

SOURCE: OncoGenex Pharmaceuticals, Inc.

OncoGenex Contact: Scott Cormack, President & CEO, (604) 630-5400, scormack@oncogenex.com; Media and Investor Contact: Jason Spark, Canale Communications, (619) 849-6005, jason@canalecomm.com

Copyright (C) 2010 CNW Group. All rights reserved.

News Provided by COMTEX