



**Media Contact**  
Jason Spark  
Atkins + Associates  
(858) 527-3491  
jspark@irpr.com

**FOR IMMEDIATE RELEASE**

**OncoGenex Phase I Study of OGX-011 in Prostate Cancer Meets Primary and Secondary Endpoints**

*Complete Data from Phase I Study Published in the Journal of the National Cancer Institute*

**Vancouver, BC Canada – September 7, 2005** – OncoGenex Technologies announced today that data from a completed Phase I study of OGX-011, a cancer drug found to sensitize tumours to standard therapy, is well tolerated and reduces clusterin expression in primary prostate cancers in humans. Clusterin is a protein found in tumour cells that, when over expressed, causes resistance to cell death induced by standard anti-cancer therapies. The study concluded that OGX-011, targeted to clusterin, can be safely given to humans in therapeutic doses that inhibit clusterin expression in cancer tissues resulting in increased cancer cell death. Primary and secondary objectives were achieved with statistical significance of OGX-011 in prostate cancer.

These findings were published in an article titled, “A Phase I Pharmacokinetic and Pharmacodynamic Study of OGX-011, a 2'-Methoxyethyl Antisense Oligonucleotide to Clusterin, in Patients With Localized Prostate Cancer” (Kim N. Chi, et al) in the September 7, 2005 issue of the *Journal of the National Cancer Institute*, available online this week.

“We were initially pleased to have observed such exceptional results from preliminary Phase I data presented at ASCO 2004, and we are now thrilled to have achieved both primary and secondary endpoints of OGX-011 in the final data set,” said Scott Cormack, president and CEO of OncoGenex. “The data presents strong support for moving forward in Phase II studies already underway. We are particularly excited to have confirmation from these findings that increasing doses of OGX-011 is associated with a statistically significant increase in cancer cell death.”

The unique trial design, in which treatment with OGX-011 was followed by radical prostatectomy, enabled Dr. Chi and co-authors from the Prostate Center, Vancouver General Hospital; BC Cancer Agency; and the National Cancer Institute of Canada Clinical Trials Group to draw several important conclusions:

**Primary Endpoint**

- The recommended Phase II dose for OGX-011 based on toxicity and biologic activity on clusterin expression in prostate tumours is 640 mg.

**Secondary Endpoints**

- Increases in peak plasma concentration based on dose were both predictable and statistically significant ( $P < .001$ );  $P$  values of less than .05 were considered statistically significant.
- The concentration of OGX-011 in prostate tissue increased proportionally with dose, expressing statistical significance ( $P < .001$ ).
- OGX-011 decreased clusterin expression in prostate cancer cells by more than 90 percent ( $P = .008$ ).



#### Additional Relevant Observations

- Given the known anti-apoptotic effect of clusterin, the apoptotic index, a measurement of cell death, was used to determine whether suppression of clusterin levels by OGX-011 was associated with apoptosis. The apoptotic indices for cancer cells treated at the lower dose levels of OGX-011 was 7.1 percent but at the 640 mg dose level, the mean apoptotic index was 21.2 percent ( $P < .001$ ).

“The completed Phase I data display the potential of OGX-011 to potentially inhibit clusterin expression in localized prostate cancers,” said Dr. Kim N. Chi, Medical Oncologist at the Vancouver Prostate Center and the BC Cancer Agency, and the lead author of the paper. “With its proven ability to down-regulate clusterin in cancer cells and consequently enhance the effectiveness of standard cancer therapies, OGX-011 has the potential to significantly expand our capabilities to treat cancer.”

The study was supported by a grant from the U.S. Department of Defense Army Medical Research and Materiel Command Prostate Cancer Research Program and by an unrestricted grant from sanofi-aventis Canada. The study was coordinated by the National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG), which is funded by the Canadian Cancer Society.

#### **About OGX-011**

OGX-011 is a targeted therapeutic that sensitizes resistant tumors to conventional cancer therapeutics, such as chemotherapy, hormone ablation therapy and radiation therapy by inhibiting the expression of the clusterin protein. Clusterin is a protein that prevents cancer cell death and undermines the effectiveness of standard cancer therapies. Clusterin is highly expressed protein in many cancers including prostate, lung and breast cancer when threatened by conventional therapeutics. OGX-011 is currently in Phase II clinical studies in prostate cancer and non-small cell lung cancer, and two additional Phase II studies in breast and lung cancer are slated to begin this year. OncoGenex is developing OGX-011 in collaboration with Isis Pharmaceuticals Ltd (NASDAQ:ISIS).

#### **About OncoGenex Technologies**

OncoGenex Technologies Inc. (OncoGenex) is a clinical-stage biotechnology company dedicated to improving survival and quality of life of cancer patients by developing targeted therapeutics for treatment-resistant and metastatic cancer. The company currently has several programs in mid and early stage clinical development for various cancers including prostate cancer, non-small cell lung cancer and breast cancer. OncoGenex' ability to advance drugs quickly and efficiently results from its ability to unite groups with a common interest in treating cancer: universities, hospitals, clinical networks, companies, granting agencies and investors. This efficient business model has enabled OncoGenex to add three products to its development program since 2001. Additional information about OncoGenex is available at [www.oncogenex.ca](http://www.oncogenex.ca).