



## OncoGenex Pharmaceuticals Announces OGX-427 Treatment Demonstrates Safety, Evidence of Declines in Circulating Tumor Cells and Reductions in Tumor Markers in a Phase 1 Cancer Trial

BOTHELL, WA, and VANCOUVER, May 30, 2009 (Canada NewsWire via COMTEX News Network) -- OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced preliminary results of a Phase 1 trial presented during an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. Preliminary results as of April 2009 showed that OGX-427 was well tolerated as a monotherapy. In addition, OGX-427 demonstrated declines in circulating tumor cells at all doses evaluated as well as evidence of reduction in tumor markers. Reductions in circulating tumor cells and tumor markers both suggest single-agent activity warranting further clinical investigation.

The Phase 1 trial has evaluated 41 patients with a variety of cancers to date; enrollment is ongoing. The first phase of the study evaluated increasing doses of OGX-427 as a single agent up to 1000 mg. A maximum tolerated dose was not identified up to and including the 1000-mg dose of OGX-427 monotherapy. Subsequently, as defined by the protocol, an 800-mg dose of OGX-427 in combination with docetaxel was evaluated, to be followed by a 1000-mg dose of OGX-427 plus docetaxel. OGX-427 is administered as three loading doses within the first 9 days and then continued weekly, with three weeks defined as a treatment cycle, until disease progression or toxicity. In those groups receiving OGX-427 in combination with docetaxel, 75mg/M (2) docetaxel was administered on Day 1 of every 3-week cycle starting after completion of the OGX-427 loading doses.

### Safety Results

Patients enrolled had a diagnosis of breast, ovarian, prostate or non-small cell lung cancer and most had failed multiple prior chemotherapy treatments. A median of 2 cycles (range of 1-8 cycles) was administered with the following safety results for OGX-427 as monotherapy:

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- Criteria for a maximum tolerated dose were not met at the highest dose evaluated as monotherapy (1000 mg).
- No evidence of altered cardiac activity was observed.
- Majority of adverse events were mild and mainly occurred during the loading doses. Adverse events consisted of chills, itching and fatigue in over a third of patients.
- There was a trend for increasing incidence of some mild adverse events with escalating OGX-427 doses. For example, 33% of patients at the 200-mg dose compared to 67% of patients at the 1000-mg dose had mild adverse events during the loading doses.
- The half-life of OGX-427 in the blood remained constant, although there appeared to be an increase in maximum blood levels and a corresponding decrease in blood clearance of OGX-427 as doses were escalated.

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The combination of 800 mg OGX-427 with docetaxel was also well tolerated and escalation to 1000 mg OGX-427 with docetaxel will be evaluated next.

### Circulating Tumor Cell and Tumor Marker Results

Circulating tumor cells (CTCs), an emerging metric to assess treatment effect, was evaluated at baseline before treatment and during treatment. Both total and Hsp27-positive CTCs were evaluated. Declines of 50% or greater in both total and Hsp27-positive CTCs were observed in over half of the patients in each cohort and in each cancer category. Declines in Hsp27 CTCs to 5 or less cells occurred in 27% of patients who had greater than 5 CTCs at baseline.

Reduction in tumor markers defined as declines of PSA levels in prostate cancer or CA-125 levels in ovarian cancer were also observed. A reduction in PSA level was observed in 7 of 20 patients (35%) with prostate cancer and a reduction in CA-125 levels was observed in 3 of 5 patients (60%) with ovarian cancer.

"CTCs are emerging as an exciting surrogate of anti-cancer activity. The frequent decreases in total and Hsp-27 positive CTC counts, coupled with decreases in serum PSA and CA-125 levels in patients with prostate and ovarian cancer, markers that strongly suggest single agent anti-cancer activity for OGX-427," said Dr. Sebastien Hotte, Principal Investigator and a medical oncologist at Juravinski Cancer Centre, Hamilton, Ontario.

"We are very satisfied with the safety profile of OGX-427 to date in this trial and the early, strong indicators of anti-tumor and biological activity," said Scott Cormack, president and CEO of OncoGenex Pharmaceuticals.

#### About OGX-427

OGX-427 is designed to reduce production of Hsp27, a protein that is over-produced in response to many cancer treatments including hormone ablation therapy, chemotherapy and radiation therapy. Hsp27 production has been shown to inhibit cell death in tumor cells through a variety of mechanisms. OGX-427 is being evaluated in a Phase 1 clinical trial for the treatment of solid tumors including prostate, non-small cell lung, breast, ovarian, and bladder cancers. Like OGX-011, this product candidate has potential as a treatment in a broad number of cancers.

#### About OncoGenex

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address unmet needs in the treatment of cancer. 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. OGX-011, the lead candidate currently completing five Phase 2 clinical studies in prostate, lung and breast cancers, is designed to inhibit the production of a specific protein associated with treatment resistance; OGX-427 is in Phase 1 clinical development; SN2310 has completed the Phase 1 clinical trial; and CSP-9222 and OGX-225 are currently in pre-clinical development.

OGX-011, OGX-427 and OGX-225 utilize second-generation antisense technology, licensed from Isis Pharmaceuticals (NASDAQ: ISIS), to effectively target and inhibit production of specific proteins in tumor cells. OncoGenex and Isis partnered in the successful discovery of OGX-011, OGX-427 and OGX-225 and with respect to OGX-011, in its initial development. In 2008, OncoGenex and Isis amended their OGX-011 agreement to provide OncoGenex with sole rights to OGX-011 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, OGX-427 and OGX-225 were 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](http://www.oncogenex.com).

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 statements concerning the potential survival benefit of OGX-011, anticipated clinical development activities, timing of these activities, the ability of future trials to demonstrate clinical benefit and the potential for regulatory approvals. 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.

The potential risks and uncertainties associated with forward-looking statements include, among others, the possibility that any benefit in patient survival will not be maintained or will become less substantial as patient survival follow up continues, risks that clinical trials will not be successful or confirm earlier clinical trial results, including the risk that the survival benefit will not be confirmed by a Phase 3 clinical trial, risks associated with obtaining funding from third parties or completing a financing necessary to support the costs and expenses of a Phase 3 clinical trial, the timing and costs of clinical trials and regulatory approvals will be different than management currently anticipates, risks relating to the development, safety and efficacy of therapeutic drugs and potential applications for these products and the risk 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 2008. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof.

SOURCE: OncoGenex Pharmaceuticals, Inc.

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