



September 27, 2012

OncoGenex Announces Initiation Of A Phase 3 Trial For Custirsen In Advanced Non-Small Cell Lung Cancer

ENSPIRIT is the Third Phase 3 Trial Initiated as Part of a Global Collaboration Between OncoGenex and Teva Pharmaceuticals to Develop and Commercialize Custirsen

BOTHELL, Wash. and VANCOUVER, British Columbia, Sept. 27, 2012 /PRNewswire/ -- OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today the initiation of ENSPIRIT, a Phase 3 trial evaluating custirsen for the treatment of advanced or metastatic non-small cell lung cancer (NSCLC) in patients who have progressed after initial chemotherapy treatment has failed. The trial will investigate if combining custirsen with docetaxel, a standard second-line NSCLC chemotherapy, has the potential to improve survival outcomes compared to docetaxel alone in these patients. Two formal interim analyses are planned for stopping the trial early based on inadequate evidence of clinical benefit or futility. No interim analyses for claiming efficacy are planned.

"Despite breakthroughs in molecular targeting for advanced NSCLC, most patients require chemotherapy and unfortunately, often progress to require second-line treatment," said Cindy Jacobs, Ph.D, MD, Chief Medical Officer and Executive Vice President of OncoGenex Pharmaceuticals. "Given custirsen's enhancement of taxanes pre-clinically as well as with a wide range of anti-cancer agents, even in chemo-resistant models, we are eager to learn if custirsen can improve docetaxel outcomes in patients with progressive NSCLC."

Custirsen is unique in that it augments anti-cancer treatments by blocking the production of clusterin, a protein linked to faster rates of cancer progression and shorter survival duration. A single-arm trial in first-line NSCLC evaluating custirsen in combination with a gemcitabine/platinum-based chemotherapy regimen demonstrated a median overall survival of 14.1 months, decreased serum clusterin levels in 95% of patients evaluated, and an acceptable safety profile. In this trial, lower serum clusterin levels correlated to longer survival outcomes.

"The custirsen development program now has three Phase 3 studies enrolling patients to evaluate the potential benefit of combining custirsen with chemotherapy regimens," said Scott Cormack, CEO and President of OncoGenex Pharmaceuticals. "We are pleased that Teva has initiated this Phase 3 study of custirsen in advanced NSCLC, a difficult disease to treat and where effective and tolerable treatment options are desperately needed."

Custirsen received Fast Track designation from the U.S. Food and Drug Administration (FDA) for treatment of patients with castrate-resistant prostate cancer (CRPC) receiving first-line docetaxel chemotherapy. The Phase 3 SYNERGY study, evaluating a survival benefit in the first-line CRPC setting, continues to accrue patients and is expected to complete enrollment later this year. Additionally, OncoGenex recently announced initiation of patient enrollment in AFFINITY, a second Phase 3 study in patients with CRPC, evaluating a survival benefit in combination with second-line chemotherapy, Jevtana® (cabazitaxel).

For more information on the ENSPIRIT trial, please visit <http://clinicaltrials.gov/ct2/show/NCT01630733>.

ABOUT ENSPIRIT

ENSPIRIT is an international, randomized, open-label study that will enroll approximately 1,100 patients with advanced or metastatic NSCLC who have been previously treated with a first-line platinum-based chemotherapy and have documented disease progression. Patients will be randomized to receive custirsen plus docetaxel or docetaxel alone. The primary objective of the study will be overall survival with additional secondary and exploratory analyses of other efficacy outcomes and biomarker relationships. Two formal interim analyses are planned for stopping the trial early based on inadequate evidence of clinical benefit or futility. No interim analyses for claiming efficacy are planned.

ABOUT CUSTIRSEN

Custirsen is the only compound currently in development designed to inhibit the production of clusterin, a protein commonly over-produced in cancer cells, and one cause of treatment resistance. As part of Phase 1 and Phase 2 clinical trials, custirsen was administered to 294 patients with various types of cancer. Some of the patients experienced a variety of adverse events, the majority of which were associated with other treatments in the protocol and the disease. The majority of adverse events were mild and the most common adverse events associated with custirsen consisted of flu-like symptoms. The most common serious adverse events (SAE) associated with custirsen were febrile neutropenia, fever, pleural effusion, and dyspnea. Each SAE event was observed in approximately 2%-4% of patients.

ABOUT ONCOGENEX

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. OncoGenex has a diverse oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. OncoGenex and Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) have entered a global collaboration and license agreement to develop and commercialize OncoGenex' lead drug candidate, custirsen. Custirsen is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer and in patients with advanced, unresectable non-small cell lung cancer. OGX-427 is in Phase 2 clinical development and OGX-225 is currently in pre-clinical development. More information 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 our anticipated product development activities, such as expected clinical trial initiation and completion and statements regarding the potential benefits and potential development of our product candidates. 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. Such forward-looking statements are subject to risks and uncertainties, including, among others, the risk that final trial results will not demonstrate the same or any potential benefit as observed in preliminary trial results, the risk that subsequent studies may not confirm earlier trial results, the risk of delays in our expected clinical trials, the risk that new developments in the rapidly evolving cancer therapy landscape require changes in our clinical trial plans or limit the potential benefits of our product, the risk that our cash resources are insufficient to fund our planned activities for the time period expected and the other factors described in our risk factors set forth in our filings with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. 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.

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