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OncoGenex Announces Update on Phase 2 Spruce Trial in Previously Untreated Metastatic Non-Small Cell Lung Cancer

BOTHELL, Wash. and VANCOUVER, British Columbia, Jan. 20, 2016 /CNW/ -- OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGX1) announced today that data from the Phase 2 Spruce™ trial evaluating the combination of apatorsen with carboplatin and pemetrexed in patients with untreated metastatic non-small cell lung cancer (NSCLC) did not reach the statistical significance required to demonstrate a progression-free survival (PFS) benefit. A potential PFS benefit was observed in patients with high baseline serum Hsp27 status when treated with apatorsen. The study is ongoing and overall survival results are expected in the second half of 2016.

Treatment and maintenance therapy with apatorsen was well tolerated. Adverse events were comparable between the arms and as expected for the study chemotherapy treatment.

"We look forward to following the Spruce study through overall survival this year to determine if apatorsen can provide a treatment benefit for this population of lung cancer patients," said principal investigator David Spigel, director, lung cancer research program and chief scientific officer for Sarah Cannon Research Institute. "Despite recent advances including exciting immunotherapies, patients with lung cancer still have a significant need for new treatment options that extend survival. Chemotherapy remains a standard of care and an important option for people with advanced disease."

Spruce is a placebo-controlled, double-blind, randomized trial sponsored and conducted by Sarah Cannon Research Institute. Approximately 155 patients with non-squamous NSCLC received either apatorsen plus carboplatin and pemetrexed therapy or placebo plus carboplatin and pemetrexed therapy in the Spruce trial. In addition to PFS and OS, other analyses are being conducted to evaluate tumor response rates, safety, tolerability, and the effect of therapy on Hsp27 levels. Detailed results will be presented at an upcoming medical meeting.

"PFS can provide an early signal of activity in lung cancer trials, yet overall survival continues to be the benchmark for determining both clinical and regulatory significance," said Scott Cormack, President and CEO of OncoGenex. "Overall survival results from Spruce expected later this year will inform the future development of apatorsen in lung cancer. We plan to continue to evaluate a potential correlation between Hsp27 and survival benefit in this and other apatorsen trials."

Lung cancer is the most common cancer worldwide, with approximately 1.8 million new cases per year. It is the leading cause of cancer death among both men and women in the U.S., with approximately 160,000 Americans expected to die from the disease in 2016. Non-squamous histology NSCLC includes adenocarcinoma and large cell carcinoma and accounts for more than half of all diagnoses.

About Apatorsen and ORCA™

Apatorsen (OGX-427) is designed to inhibit production of heat shock protein 27 (Hsp27), disable cancer cells' defenses and overcome treatment resistance. Hsp27 is an intracellular protein that protects cancer cells by helping them survive, leading to resistance and more aggressive cancer phenotypes. Both the potential single-agent activity and synergistic activity of apatorsen with cancer treatments may increase the overall benefit of existing therapies and augment the durability of treatment outcomes, which could lead to increased patient survival.

The ORCA™ (Ongoing Studies Evaluating Treatment Resistance in Cancer) program encompasses clinical trials of apatorsen. Phase 2 clinical trials are underway in bladder, lung and prostate cancers. For more information on apatorsen and ORCA, please visit www.OncoGenex.com.

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. 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. Apatorsen is in Phase 2 clinical development and OGX-225 is currently in pre-clinical development. More information is available at www.OncoGenex.com and at the company's Twitter account: https://twitter.com/OncoGenex_IR.

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 regarding timing for clinical trial milestones 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 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 we are unable to raise on acceptable terms the capital needed to complete our clinical trials, the risk that our product candidates do not demonstrate the hypothesized or expected benefits 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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