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OncoGenex Announces Results from the Phase 3 AFFINITY Trial of Custirsen in Men with Metastatic Castrate-Resistant Prostate Cancer

Conference Call on Tuesday, August 16, 2016 at 7:30 a.m. EDT

BOTHELL, Wash. and VANCOUVER, British Columbia, Aug. 16, 2016 /PRNewswire/ -- OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGX1) announced today results from the final analysis of AFFINITY, the Phase 3 trial of custirsen in men with metastatic castrate-resistant prostate cancer (CRPC) whose disease has progressed after treatment with docetaxel. The trial did not meet the primary endpoint of demonstrating a statistically significant improvement in overall survival for patients treated with custirsen in combination with cabazitaxel/prednisone compared to cabazitaxel/prednisone alone.

The adverse events were consistent with those observed in previous trials of custirsen in metastatic CRPC. The final data will be submitted as a late-breaking abstract to the European Society for Medical Oncology (ESMO) Annual Congress 2016.

"We are obviously disappointed that custirsen was unable to demonstrate a survival benefit in prostate cancer. We would like to thank the patients who participated in the AFFINITY trial and their caregivers, as well as the investigators and their teams for their commitment to improving cancer care for patients who are in desperate need of new treatment options," said Scott Cormack, President and CEO of OncoGenex.

As a result of these data and previous custirsen findings, OncoGenex plans to initiate discussions with the U.S. Food and Drug Administration (FDA) to evaluate options related to an early analysis of the Phase 3 ENSPIRIT trial investigating custirsen in combination with docetaxel as second-line chemotherapy in patients with non-small cell lung cancer (NSCLC).

"Given that the ENSPIRIT trial has nearly completed enrollment and we believe there are likely a sufficient number of events to determine the effect of custirsen in NSCLC, we are eager to expedite the final data analysis, which would allow us to conserve resources and fully understand the value of the asset as we evaluate our alternatives to maximize shareholder value," said Cormack.

OncoGenex has engaged MTS Health Partners, LP as its advisor to assist with the exploration of strategic alternatives.

Conference Call Details

OncoGenex will host a conference call at 7:30 a.m. Eastern Time today, Tuesday, August 16, 2016, to discuss today's news. A live event will be available on the Investor Relations section of the OncoGenex website at www.OncoGenex.com. Alternatively, visitors may access the live conference call by dialing (877) 606-1416 (U.S. & Canada) or (707) 287-9313 (International). A webcast replay will be available approximately two hours after the call and will be archived on www.OncoGenex.com for 90 days.

About the AFFINITY Trial

The Phase 3 AFFINITY trial was an international, randomized, open-label study designed to evaluate whether custirsen, when combined with cabazitaxel, could improve survival outcomes for patients with metastatic CRPC whose disease has progressed after treatment with docetaxel.

Patients received cabazitaxel in combination with weekly custirsen or cabazitaxel alone, and treatment continued until disease progression, unacceptable toxicity or completion of 10 cycles. The AFFINITY trial enrolled 634 men with metastatic CRPC at 95 sites throughout North America, Europe, Russia and Australia. For more information on the AFFINITY trial, please visit ClinicalTrials.gov (NCT01578655).

About ENSPIRIT Trial

The Phase 3 ENSPIRIT trial is an international, randomized, open-label trial designed to evaluate custirsen for the treatment of advanced or metastatic NSCLC in 700 patients who have progressed after initial chemotherapy treatment. The trial is investigating 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. ENSPIRIT is expected to enroll patients at approximately 50 sites globally. For more information on the ENSPIRIT trial, please visit ClinicalTrials.gov (NCT01630733).

About Custirsen

Custirsen is a highly specific clusterin inhibitor designed to improve survival in patients with advanced cancer by disabling a

fundamental cellular repair mechanism used by tumor cells. Custirsen binds to clusterin mRNA to block the production of clusterin protein and has enhanced the tumor cell destructive effects of multiple anti-cancer therapies across a variety of tumor models. By inhibiting clusterin, custirsen is designed to alter tumor dynamics by slowing tumor growth and inhibiting tumor resistance to partner treatments, so that the benefits of therapy, including survival, may be extended.

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 patients with advanced, unresectable NSCLC. 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 the potential benefits and development of our product candidates, potential modifications to clinical development plans and business strategies. 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 risks and uncertainties include, among others, the risk that our product candidates do not demonstrate the hypothesized or expected benefits, the risk that our proposed modifications to clinical development activities are not agreed on by the FDA or do not result in the intended benefits, the risk that we cannot achieve our business strategies, 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 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.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/oncogenex-announces-results-from-the-phase-3-affinity-trial-of-custirsen-in-men-with-metastatic-castrate-resistant-prostate-cancer-300313767.html>

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