April 28, 2014

OncoGenex Announces Top-Line Survival Results of Phase 3 SYNERGY Trial Evaluating Custirsen for Metastatic Castrate-Resistant Prostate Cancer

BOTHELL, Wash. and VANCOUVER, British Columbia, April 28, 2014 /PRNewswire/ -- OncoGenex Pharmaceuticals, Inc. **(NASDAQ: OGXI)** today announced results from the Phase 3 SYNERGY trial. Top-line survival results indicate that the addition of custirsen to standard first-line docetaxel/prednisone therapy did not meet the primary endpoint of a statistically significant improvement in overall survival in men with metastatic castrate-resistant prostate cancer (CRPC), compared to docetaxel/prednisone alone (median survival 23.4 months vs 22.2 months, respectively; hazard ratio 0.93 and one-sided p value 0.207). The adverse events observed were similar to custirsen's known adverse event profile.

"The results of SYNERGY are unexpected, particularly given the wealth of scientific evidence supporting the targeting of clusterin to combat treatment resistance in first-line prostate cancer," said Scott Cormack, President and CEO of OncoGenex. "A thorough analysis of the data is underway to understand the potential factors that may have contributed to the results. Importantly, we remain strong in our belief that targeting mechanisms of treatment resistance is a critical path forward in the fight against cancer and we continue to actively pursue this approach through the two ongoing Phase 3 trials of custirsen and the seven Phase 2 trials of apatorsen in four tumor types. We would like to thank the men who participated in the SYNERGY trial and the friends and families who supported them."

OncoGenex will host a conference call and live webcast at 7:30 a.m. ET this morning.

To access the webcast, log on to the Investor Relations page of the OncoGenex website at www.oncogenex.com. Alternatively, you 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 Custirsen

Custirsen is an experimental drug that is designed to block the production of the protein clusterin, which may play a fundamental role in cancer cell survival and treatment resistance. Clusterin is upregulated in tumor cells in response to treatment interventions such as chemotherapy, hormone ablation and radiation therapy and has been found to be overexpressed in a number of cancers, including prostate, lung, breast and bladder. Increased clusterin production has been linked to faster rates of cancer progression, treatment resistance and shorter survival duration. By inhibiting clusterin, custirsen is designed to alter tumor dynamics, slowing tumor growth and resistance to partner treatments, so that the benefits of therapy, including survival, may be extended.

As part of Phase 1 and Phase 2 clinical trials, custirsen was administered to 294 patients with various types of cancer. The majority of adverse events were mild. 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 SYNERGY

The SYNERGY trial enrolled 1,022 men with mCRPC at more than 130 cancer centers throughout North America, Europe, Israel and South Korea. In the investigational arm of the trial, custirsen was administered as a weekly infusion of 640 mg following three loading doses, in combination with docetaxel and prednisone given as standard 3-week cycles. Patients in the active comparator arm received docetaxel and prednisone without custirsen. In both arms, patients were treated until disease progression, unacceptable toxicity, or completion of up to 10 cycles, unless additional cycles were deemed beneficial. Full efficacy and safety data from SYNERGY will be submitted for presentation at an upcoming scientific conference.

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. have entered a global collaboration and licensing agreement to develop and commercialize OncoGenex' lead drug candidate, custirsen. Custirsen utilizes second-generation antisense technology, licensed from Isis Pharmaceuticals (NASDAQ: ISIS), to effectively target and inhibit production of clusterin. OncoGenex and Isis partnered in the successful discovery of custirsen and in its initial 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 concerning the potential benefits 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, including, among others, the risk that our product candidates will not demonstrate the hypothesized or expected benefits, the risk of delays in our expected clinical trials 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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