OncoGenex Announces Data from Borealis-1™ Trial Showing Clinical Benefit with Apatorsen in Metastatic Bladder Cancer

BOTHELL, Wash. and VANCOUVER, British Columbia, June 1, 2015 /CNW/ -- OncoGenex Pharmaceuticals, Inc. (NASDAQ: OXGI) announced that results from an exploratory analysis of the Phase 2 Borealis-1™ trial showed that metastatic bladder cancer patients with poor prognostic features benefited from apatorsen 600mg added to first-line chemotherapy compared to chemotherapy alone. Patients in the trial with a Karnofsky Performance Status (KPS) of 80 percent or less, a common indicator of poor prognosis, experienced a 50 percent reduction in risk of death with the addition of apatorsen therapy (OS HR = 0.50). These results were presented in an oral session at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

"After decades with little progress in the treatment of metastatic bladder cancer, we are finally beginning to see exciting innovation in treatment approaches that may improve outcomes, even in patients with poor prognosis," said Joaquim Bellmunt, MD, PhD, Director, Bladder Cancer Center at the Dana-Farber Cancer Institute, Associate Professor of Medicine at Harvard Medical School, and one of the Primary Investigators of the trial. "This unique approach of combining apatorsen with chemotherapy may lead to a survival benefit in the most vulnerable patients by targeting Hsp27, which is associated with metastasis and treatment resistance."

Borealis-1 was an international, randomized, placebo-controlled trial that evaluated the effect of apatorsen when added to first-line gemcitabine and cisplatin in patients with metastatic bladder cancer. The trial enrolled approximately 180 patients with documented metastatic or locally inoperable transitional cell carcinoma (TCC) of the urinary tract who had not previously received chemotherapy for metastatic disease and were not candidates for potentially curative surgery or radiotherapy. Patients were randomized to receive standard chemotherapy (gemcitabine/cisplatin) in combination with apatorsen at two dose levels (600mg and 1000mg) or gemcitabine/cisplatin plus placebo. The primary endpoint of the trial was overall survival. Secondary endpoints measured disease response as well as safety of each of the two doses of apatorsen.

Exploratory analysis of study results showed that survival outcome was impacted by the following prognostic risk factors: KPS, liver involvement, low hemoglobin and high alkaline phosphatase. Patients who had these poor prognostic features benefited most from 600mg apatorsen therapy. Median overall survival in the poor prognostic group was 11.9 months with 600mg apatorsen + gemcitabine/cisplatin compared to 9 months with gemcitabine/cisplatin alone (OS HR = .77). Importantly, 33 percent of patients in the trial had a KPS less than or equal to 80 percent, which was found to be the single most important risk factor for poor prognosis. These lower KPS, high-risk patients experienced a 50 percent reduction in risk of death (OS HR = 0.50) when 600mg apatorsen was added to chemotherapy.

Overall treatment was well tolerated. Most common Grade ≥3 adverse events (AEs) were neutropenia, anemia, thrombocytopenia and hypertension. Frequency of ≥3 Grade toxicities were: 89 percent (GC), 93 percent (GC+A 600) and 95 percent (GC+A 1000). GC+A 1000 had a higher treatment discontinuation rate due to AEs.

"These results, along with our previous Phase 1 trial in superficial bladder cancer patients who received apatorsen intravesically, demonstrate the potential of this compound across the paradigm of bladder cancer treatment. We are working closely with investigators and plan to engage regulatory agencies to determine next steps," said Scott Cormack, President and CEO of OncoGenex. "The Borealis-1 data underscore the importance of understanding the potential of inhibiting Hsp27 to benefit patients with poor prognosis and those with the most aggressive cancers where patients commonly cycle quickly through all available therapies."

Additionally at ASCO, OncoGenex is presenting data from the Phase 3 SYNERGY trial of its other compound, custirsen, as well as two trials-in-progress posters from the apatorsen ORCA™Ongoing Studies Evaluating Treatment Resistance in Cancer program. The first of these is Borealis-2™, an investigator-sponsored, randomized Phase 2 trial evaluating apatorsen in combination with docetaxel in patients with advanced or metastatic bladder cancer, and who have disease progression following first-line platinum-based chemotherapy. This trial is sponsored by the Hoosier Cancer Research Network and is currently enrolling patients. The second is Cedar™, an investigator-sponsored, randomized, open-label Phase 2 study evaluating apatorsen in previously untreated patients with advanced squamous non-small cell lung cancer (NSCLC). Over the next 12 months, the Company expects a number of significant clinical events from several apatorsen clinical trials within the ORCA™ trial program that are currently evaluating patients in some of the most aggressive tumor types.

OncoGenex will be hosting a webcast on June 10, 2015 at 9:00 AM PT / 12:00 PM ET to discuss the results from the Borealis-1 trial as well as data presented at ASCO from the SYNERGY trial of custirsen in patients with metastatic castrate-resistant
prostate cancer (CRPC). Access to this live event will be available on the Investor Relations section of the OncoGenex website at www.OncoGenex.com. Alternatively, the event may be accessed 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 Apatorsen and ORCA™
Apatorsen (OGX-427) is a once-weekly intravenous (IV) experimental drug that is designed to inhibit production of heat shock protein 27 (Hsp27) to 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, pancreatic and prostate cancers. For more information on apatorsen and ORCA, please visit www.OncoGenex.com or www.orcatrials.com.

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 in patients. 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.

Custirsen has Fast Track designation by the U.S. Food and Drug Administration for NSCLC and metastatic CRPC.

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 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 our product candidates do not demonstrate the hypothesized or expected benefits, 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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