



OncoGenex Receives Confirmation from FDA on the Design of a Second Phase 3 Trial Evaluating OGX-011 for the Treatment of Advanced Prostate Cancer

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FDA confirms durable pain palliation as an acceptable primary endpoint for a regulatory submission in support of market approval

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OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today that the company has reached an agreement with the U.S. Food and Drug Administration (FDA) on the design of a second Phase 3 registration trial of OGX-011, its lead product candidate targeting castrate resistant prostate cancer (CRPC), via the Special Protocol Assessment (SPA) process. The FDA has agreed that the design and planned analysis of our Phase 3 trial featuring durable pain palliation as the primary endpoint adequately addresses the objectives necessary to support a regulatory submission.

"We have now received confirmations on two separate Phase 3 trial designs from the FDA via the SPA process, each in second-line treatment of advanced prostate cancer," said Scott Cormack, President and CEO of OncoGenex Pharmaceuticals. "One trial design evaluates overall survival benefit while the second trial design evaluates reduction in pain as the primary endpoint. Having evaluated both of these endpoints in our Phase 2 trials, we are well positioned to re-evaluate each of these endpoints in larger Phase 3 registration trials."

"The FDA's acknowledgement of pain in addition to survival as key endpoints for market approval supports the basis of our OGX-011 development program for advanced prostate cancer," added Cormack. "Although we observed a positive effect on PSA in our Phase 2 trials of OGX-011, we recognize that PSA response has not been shown to correlate to a clinical benefit and therefore is not an acceptable endpoint for FDA approval. Our focus remains on survival and pain palliation, both endpoints that FDA has confirmed are appropriate for marketing approval, and both endpoints for which we have had success in our Phase 2 clinical trials. Based on the recent survival benefit of combining OGX-011 with first-line docetaxel chemotherapy, we have initiated discussions with FDA for evaluating the overall survival benefit in first-line CRPC, instead of second-line CRPC."

The Phase 3 trial evaluating durable pain palliation has been designed in collaboration with internationally recognized experts in the treatment of patients with CRPC (previously referred to as hormone-refractory prostate cancer) including Dr. Tomasz Beer at the University of Oregon and Dr. Sebastian Hotte at Juravinski Cancer Centre, in Hamilton, Ontario, Canada. This will be a randomized, controlled, international trial in approximately 300 men with metastatic CRPC who responded to first-line docetaxel therapy, but subsequently have progression of disease, including prostate cancer-related pain, and are able to receive docetaxel retreatment as second-line chemotherapy. Patients will be randomized to receive treatment with either OGX-011 and docetaxel/prednisone or docetaxel/prednisone alone. The primary endpoint of the trial will be to determine whether a greater proportion of patients in the arm treated with OGX-011 and docetaxel/prednisone experiences durable pain palliation as compared to patients in the arm treated with docetaxel/prednisone alone. It is expected that approximately 50 clinical sites in the United States and Canada will participate in this trial.

"Patients with pain due to metastatic prostate cancer generally require narcotic medications that are dosed to provide maximum pain relief; however, unacceptable side effects such as sedation and severe constipation remain dose-limiting. Because of this, patients frequently continue to suffer from pain despite 'optimally dosed' narcotics," said Cindy Jacobs, M.D., Ph.D., OncoGenex' Executive Vice-President and Chief Medical Officer. "Thus, pain is a common, often unremitting and disabling symptom of advanced prostate cancer, and pain control is a key measurement of clinical benefit."

The planned initiation of this Phase 3 trial evaluating pain palliation is supported by encouraging Phase 2 data from patients receiving OGX-011 plus docetaxel as second-line chemotherapy - additional data was presented at the 2009 Annual Meeting of the American Urological Association (AUA). Based on the 27 patients who had prostate cancer-related pain and received OGX-011 plus docetaxel as second-line chemotherapy, 12 patients or 44% of patients, experienced pain palliation for 3 months or longer. The majority of pain responses occurred within the first two cycles of OGX-011 plus docetaxel. These data compare favorably even when compared to pain responses observed after first-line chemotherapy. This is clinically relevant because patients receiving second-line treatment have more advanced disease and are thought to have more profound or resistant prostate cancer-related pain.

About OGX-011

OGX-011 is designed to inhibit the production of clusterin, a protein that is associated with cancer treatment resistance and is currently being evaluated in Phase 2 clinical trials in prostate, lung and breast cancer. OncoGenex Pharmaceuticals announced preliminary data on December 3, 2008 that OGX-011 showed an overall survival advantage in a randomized, controlled Phase 2 trial in first-line treatment of metastatic castrate resistant prostate cancer, in which the median survival for patients receiving OGX-011 in combination with docetaxel and prednisone was 27.5 months, compared to 16.9 months in patients receiving docetaxel and prednisone alone. Updated survival results will be presented at the 2009 Annual Meeting of the American Society of Clinical Oncology.

At the 2008 Annual Meeting of the American Society of Clinical Oncology, OncoGenex reported Phase 2 data with OGX-011 in combination with second-line treatment of metastatic castrate resistant prostate cancer showing better than expected survival results, reductions in levels of clusterin, durable reductions in pain, and a decline in PSA, a protein that is often elevated in patients with prostate cancer.

Based on clinical results to date, OncoGenex intends to conduct Phase 3 registration trials with OGX-011 in metastatic castrate resistant prostate cancer, subject to the receipt of additional funding. The U.S. Food & Drug Administration (FDA) has currently agreed on the design of two Phase 3 registration trials, via the Special Protocol Assessment (SPA) process, of OGX-011 in combination with second-line chemotherapy. One trial design investigates overall survival as the primary endpoint; the other trial design investigates pain palliation as the primary endpoint. OGX-011 has received Fast Track designation from the FDA for the treatment of progressive metastatic prostate cancer in combination with docetaxel.

OncoGenex holds an exclusive license for patents related to clusterin inhibition obtained from the University of British Columbia based on discoveries made by researchers at the Prostate Centre at Vancouver General Hospital. OGX-011 utilizes second-generation antisense technology, licensed from Isis Pharmaceuticals (NASDAQ: ISIS), to effectively target and inhibit production of clusterin protein in tumor cells. OncoGenex and Isis partnered in the successful discovery and initial development of OGX-011 and, in 2008, amended their agreement to provide OncoGenex with sole rights to OGX-011 and sole responsibility for development costs and partnering decisions, subject to financial obligations to Isis.

About the Special Protocol Assessment and Agreement Process

Under a Special Protocol Assessment (SPA), a company and the FDA can reach an agreement on the design and size of a clinical trial to support a regulatory submission. This agreement can be in writing and cannot be changed after the clinical trial begins except: (i) with written agreement of the company and the FDA; or (ii) if the director of the FDA reviewing division determines that "a substantial scientific issue essential to determining the safety or effectiveness of the drug" was identified after testing began.

About OncoGenex Pharmaceuticals

OncoGenex Pharmaceuticals is a biopharmaceutical company committed to the development and commercialization of new therapies that address unmet needs in the treatment of cancer. OncoGenex has a deep oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. OGX-011, the lead candidate currently completing five Phase 2 clinical studies in prostate, lung and breast cancers, is designed to inhibit the production of a specific protein associated with treatment resistance; OGX-427 is in Phase 1 clinical development; SN2310 has completed enrollment in a Phase 1 clinical trial; and CSP-9222 and OGX-225 are currently in pre-clinical development. More information is available at www.oncogenex.com.

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 statements concerning the potential survival benefit of OGX-011, anticipated clinical development activities, timing of these activities, the ability of future trials to demonstrate clinical benefit and the potential for regulatory approvals. 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.

The potential risks and uncertainties associated with forward-looking statements include, among others, the possibility that any benefit in patient survival will not be maintained or will become less substantial as patient survival follow up continues, risks that clinical trials will not be successful or confirm earlier clinical trial results, including the risk that the survival benefit will not be confirmed by a Phase 3 clinical trial, risks associated with obtaining funding from third parties or completing a financing necessary to support the costs and expenses of a Phase 3 clinical trial, the timing and costs of clinical trials and regulatory approvals will be different than management currently anticipates, risks relating to the development, safety and efficacy of therapeutic drugs and potential applications for these products and the risk factors set forth in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for fiscal year 2008 and. The Company

undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof.

SOURCE: OncoGenex Pharmaceuticals, Inc.

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