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NewLink Genetics Launches Adaptive Design Phase 2B/3 Clinical Trial of tergenpumatucel-L Immunotherapy in Patients with Non-Small Cell Lung Cancer

AMES, Iowa, Oct. 3, 2012 /PRNewswire/ -- NewLink Genetics Corporation (Nasdaq: NLNK) announces the launching of an open-label, randomized, multi-institutional adaptive design Phase2B/3 study to evaluate efficacy of its tergenpumatucel-L (HyperAcute® Lung) product candidate in patients with progressive or relapsed Stage-IIIB/IV non-small cell lung cancer (NSCLC).

The Phase 2B portion of the study will evaluate two dosing schedules for tergenpumatucel-L versus docetaxel and the Phase 3 portion of the study will further assess efficacy of the selected dose against docetaxel. The primary endpoint of the study will be to evaluate survival in second-line therapy for patients with advanced non-small cell (stage IIIB/IV) lung cancer. Secondary objectives include progression free survival, evaluation of tumor response, and immunological response in treated patients.

"We are pleased to move another promising HyperAcute product candidate with encouraging survival data from Phase 2 into advanced-stage studies," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "Non-small cell lung cancer remains the leading cause of cancer death in the United States."

"Immunotherapies are emerging as one of the most promising next treatment paradigms for cancer patients by allowing the patient's immune system to fight their disease without significant new toxicities. We are excited to participate in this advanced study to evaluate NewLink's innovative HyperAcute Lung immunotherapy in NSCLC," said principal investigator of the study Dr. Ramaswamy Govindan, Professor of Medicine, Co-Director Section of Medical Oncology at the Alvin J Siteman Cancer Center, Washington University School of Medicine, St. Louis, MO.

"This trial design is based on Phase 2 non-small cell lung cancer data presented at the recent ASCO meeting demonstrating 11.2 months median survival in 2nd and 3rd line patients who failed prior treatment. Our correlative immunological data showing 21.9 vs. 7 months survival in certain patients capable of generating IFN-gamma responses versus patients who did not mount this response, suggest patients with the best immune responses may have significantly greater long term overall survival. If these types of data can be confirmed in the new larger, randomized study an important novel therapy will be made available for patients with very limited options. We are delighted to be one of the lead centers," commented principal investigator for the Phase -2 study and Co-PI for the Phase 3 study Dr. John C. Morris, Professor of Medicine, Director of Experimental Therapeutics, Thoracic Cancer and Head & Neck Cancer Programs at University of Cincinnati, Cincinnati, OH.

Although a number of therapies have been approved in lung cancer, the prognoses for patients remain poor. "This study is designed to test the hypothesis that patients treated with HyperAcute immunotherapies may be sensitized to subsequent treatments with chemotherapy while also evaluating whether survival benefits observed in our Phase 2 study can be reproduced in a large controlled Phase 3 study," commented Dr. Nick Vahanian, President, Chief Medical Officer, NewLink Genetics.

Adaptive Study Design

This Phase 2B/3 study will enroll patients having a better baseline immune system status relative to the patient population in the earlier Phase 2 study. In order to be eligible for the study, patients must have Stage IIIB or Stage IV recurrent or treatment refractory non-small cell lung cancer with good performance status (ECOG < 2) and no more than one prior chemotherapy failure. A lymphocyte count of > /= 1000/µL, platelets > /= 100,000/µL, hemoglobin > 10.0 gm/dL, albumin > /= 3.0 gm/dL and acceptable hepatic and renal function are required for enrollment.

Two hundred forty (240) patients will be randomized (2:1:1) to receive: Arm 1: Docetaxel 75 mg/m2 intravenously given every 3 weeks for 4 doses; Arm 2a: Tergenpumatucel-L at 300 million cells given by intradermal injection weekly for 11 weeks then every 2 months for 5 additional doses (up to a total of 16 immunizations); Arm 2b: Tergenpumatucel-L at 300 million cells given by intradermal injection every 2 weeks for 6 doses and then every month for 10 additional doses (up to a total of 16 immunizations).

Phase 3 Study Design

In the phase 3 portion of the study, patients will be randomized (1:1) to receive either docetaxel or tergenpumatucel-L at the dose level that was selected in the Phase 2B portion of the study. At the planned interim analysis a sample size re-estimation will be performed that will determine the final enrollment numbers for the trial.

About Non-Small Cell Lung Cancer

According to the American Cancer Society, lung cancer is the leading cause of cancer-related death in the United States. The NCI estimates that over 160,000 Americans will die of the disease in 2012, accounting for approximately 28% of all cancer deaths. It accounts for more deaths than the next four most common cancers combined. Despite improvements in diagnosis and treatment, the overall 5-year survival for all patients with lung cancer is a dismal 13-16%, and this declines to less than 2% in patients with metastatic disease. Lung cancer is most often diagnosed at advanced stages when it is difficult to treat. According to the American Cancer Society, about 85% to 90% of lung cancers are classified as NSCLC. The remainder is called small cell lung cancer. The American Cancer Society also reports that about 80% of NSCLC cases are detected when they have progressed to stages III or IV. The current expected overall survival for a nonresectable stage IIIB or IV NSCLC patient who has failed first line treatment is approximately eight months.

About tergenpumatucel-L

The HyperAcute-Lung Immunotherapy product candidate, tergenpumatucel-L, consists of three separate allogeneic lung tumor cell lines grown in large cultures, harvested, packaged and irradiated. These component cells are representative of the three major types of non-small cell lung cancer and have been engineered to express a foreign gene encoding the alpha-galactosyl transferase enzyme. This enzyme modifies the surface of the cells in tergenpumatucel-L to make them more easily recognized and attacked by the immune system. After vaccination with tergenpumatucel-L, some patients' immune systems respond by recognizing new lung cancer antigens in ways thought to be helpful in fighting their own tumor.

About NewLink Genetics Corporation

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. NewLink's lead product candidate, algenpatucel-L (HyperAcute Pancreas) cancer immunotherapy is being studied in a Phase 3 clinical trial in surgically resected pancreatic cancer patients (patient information is available at http://www.pancreaticcancer-clinicaltrials.com) under a Special Protocol Assessment with the U.S. Food and Drug Administration. NewLink and its collaborators have completed patient enrollment for a Phase 2 clinical trial evaluating its tergenpumatucel-L (HyperAcute Lung) cancer immunotherapy product candidate for non-small cell lung cancer and is now opening a Phase 2B/3 clinical trial in this indication. NewLink has completed patient enrollment in an initial Phase 2 clinical trial for its HyperAcute Melanoma cancer immunotherapy product candidate. NewLink also is developing indoximod (NLG8189 or D-1MT), a small molecule, orally bioavailable product candidate from NewLink's proprietary indoleamine (2, 3) dioxygenase, or IDO, pathway inhibitor technology. Through NewLink's collaboration with the National Cancer Institute, NewLink is studying indoximod in various chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. For more information please visit www.linkp.com.

Safe Harbor Statement

This press release contains "forward-looking statements" for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of1995. These statements include, but are not limited to, statements regarding the prospects of tergenpumatucel-L and the prospects of NewLink's Phase 2B/3 clinical trial. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties associated with clinical trials and the regulatory approval process. These and other factors are identified and described in more detail in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2011, as amended, and subsequent filings. The Company disclaims any intent or obligations to update these forward-looking statements.

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