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NewLink Updates Enrollment Information for Its Pivotal Phase 3 HyperAcute(R) Pancreas Immunotherapy (algenpantucel-L) Trial

AMES, Iowa, June 19, 2012 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (Nasdaq:NLNK) today announced that in the second quarter of 2012 it passed the midpoint in enrollment in its Phase 3 HyperAcute Pancreas immunotherapy product candidate (algenpantucel-L) trial as number of participating institutions reached to 74 sites around the US.

"Now that we have passed the midway point of trial enrollment, we are confident that the trial will be fully enrolled before the end of 2013," said Dr. Nick Vahanian, President and Chief Medical Officer of NewLink Genetics. He added, "We are very thankful for the support we have received from our patients and investigators and based on currently available data we anticipate reaching the trigger event for the first interim analysis in early 2013."

The current Phase 3 study is designed to evaluate the benefit of HyperAcute Pancreas in up to 722 patients who have undergone resection of pancreatic cancer. The clinical trial design was approved by the FDA under Special Protocol Assessment prior to opening in May 2010 and the HyperAcute Pancreas was granted Fast Track and Orphan Drug designation in the fourth quarter of 2010.

This Phase 3 trial was initiated based on encouraging results from the Company's Phase 2 study of HyperAcute Pancreas in patients who had undergone resection of pancreatic cancer. The Phase 2 results were recently updated and showed one, two and three year survival of 86% , 51% and 42% respectively, based on Kaplan-Meier analysis with a 33 months of median follow up. Demonstrating improvements of 37%, 59% and 121% over predicted one, two and three outcomes respectively based upon nomogram analysis of these same patients.

About algenpantucel-L

NewLink's algenpantucel-L immunotherapy product candidate consists of a group of two allogeneic pancreatic cancer tumor cell lines that were modified to express Alpha-Gal. These cell lines were chosen to provide a broad coverage of pancreatic cancer antigens. Each of the modified cell lines is grown in large cultures, harvested, irradiated and packaged. Approximately 150 million cells of each HyperAcute Pancreas cell line are given by intradermal injection with each treatment. A series of up to 14 treatments using both cell lines over a period of six months was used in NewLink's Phase 2 clinical trial. In NewLink's Phase 3 trial protocol, NewLink is adding an additional series of monthly, maintenance treatments, to be given during the next six months.

About algenpantucel-L clinical trials

About the Phase 2 Study

The multi-institutional, open-label, dose-finding, Phase 2 trial evaluated the use of algenpantucel-L in addition to chemotherapy with chemoradiotherapy in the adjuvant setting for resected pancreatic cancer. Adjuvant therapy was to start within seven weeks after surgery. The first cycle of treatment consisted of vaccination with either 100 million or 300 million cells per dose given intradermally on days 1 and 8. One week after the second vaccination, gemcitabine was administered at 1000mg/m^2/week for three weeks, on days one, eight, and 15, in conjunction with HyperAcute Pancreas immunotherapy dosed on days 1 and 15 of cycle two. Chemoradiotherapy was initiated one to two weeks after the completion of cycle two. Continuous infusion 5-FU was administered at 250 mg/m^2/day for the entire duration of radiation therapy. HyperAcute Pancreas immunotherapy was administered on days 1, 15, 29, and 43 of the chemoradiotherapy stage. A total of up to 14 vaccinations were dosed for patients who completed the entire study treatment.

About the Phase 3 Study

In May 2010, NewLink initiated its Phase 3 clinical trial for algenpantucel-L. This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating Stage I and Stage II surgically-resected pancreatic cancer patients, according to the American Joint Committee on Cancer classification system, or AJCC system, who have no detectable disease by a CT scan. The primary endpoint of the clinical trial is overall survival, with secondary endpoints of disease-free survival, safety, toxicity and immunological responses. The study plans to enroll up to 722 patients in order to achieve 680

evaluable patients. Current adjuvant standard-of-care regimens for post-resection pancreatic cancer patients include gemcitabine alone or a combination of gemcitabine plus 5-FU based chemoradiotherapy. In the Phase 3 clinical trial, 50% of the patients will receive standard adjuvant therapy with algenpantucel-L and 50% will receive standard adjuvant therapy without algenpantucel-L. Algenpantucel-L treated patients will receive up to 18 treatments given every two weeks over a period of approximately six months followed by six monthly injections. Patients in the study are being monitored with periodic imaging to check for recurrences for at least five years after surgery or until death occurs.

About Pancreatic Cancer

The American Cancer Society estimates that approximately 44,030 new cases of pancreatic cancer were diagnosed in the United States in 2011. Pancreatic cancer has generally been recognized as an aggressive form of cancer with non-specific initial symptoms, making it difficult to diagnose at an early stage. Due to the difficulty in diagnosis and the aggressive nature of this cancer, the National Cancer Institute estimates a 96% mortality rate is associated with this disease, and the American Cancer Society estimates one-year and five-year overall survival rates of about 24% and 5%, respectively.

Pancreatic cancer can generally be divided into three broad categories: (1) local disease, in which the cancer is confined to the pancreas and can be removed surgically, which is called resection; (2) locally advanced disease, in which the cancer has spread locally and may or may not be eligible for resection because it has invaded tissues that should not be removed, such as key nerves and arteries; and (3) metastatic disease, in which the tumor has spread beyond the region of the pancreas.

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, HyperAcute Pancreas cancer immunotherapy (algenpantucel-L) 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). This clinical trial is being performed under a Special Protocol Assessment with the U.S. Food and Drug Administration. NewLink and its collaborators have completed patient enrollment for a Phase 1/2 clinical trial evaluating its HyperAcute Lung cancer immunotherapy (tergenpumatucel-L) product candidate for non-small cell lung cancer and a Phase 2 clinical trial for its HyperAcute Melanoma cancer immunotherapy product candidate. NewLink also is developing NLG8189 (d-1-methyltryptophan, 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 NLG8189 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 of 1995. These statements include, but are not limited to, statements regarding the prospects of algenpantucel-L including the expected requirements and timing for completion of enrollment for NewLink's Phase 3 clinical trial and the timing of a future interim analysis of the data from the trail as well as potential implications of the previously reported data generated in NewLink clinical trials. 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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