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NewLink Genetics Launches Phase 3 Clinical Trial of algenpantucel-L Immunotherapy in Patients with Borderline Resectable or Locally Advanced Unresectable Pancreatic Cancer

AMES, Iowa, Oct. 10, 2012 /PRNewswire/ -- NewLink Genetics Corporation (Nasdaq: NLNK) announces launching of an open-label, randomized, multi-institutional Phase 3 study in patients with borderline resectable or locally advanced unresectable pancreatic cancer. The projected enrollment will be 280 subjects and patients will be randomized (1:1) to receive standard of care FOLFIRINOX plus or minus algenpantucel-L (HyperAcute®-Pancreas) immunotherapy. The primary endpoint of the study will be to evaluate overall survival. Secondary objectives include evaluation of progression free survival and immunological response.

"We are excited to initiate an additional Phase 3 clinical trial for algenpantucel-L to potentially expand into a new indication for locally advanced pancreatic cancer. We have made significant progress in our Phase 3 trial with algenpantucel-L for resected pancreas cancer patients since its launch in May of 2010," commented Dr. Charles Link, Chief Executive Officer of NewLink. He added, "There is an enormous unmet need in the pancreatic cancer market for both resectable and unresectable patients. The successful expansion of algenpantucel-L into a market segment for locally advanced disease would potentially more than double the patient population who might benefit from this immunotherapy treatment."

"We believe this new study will be favorably perceived by the clinicians as they will have a promising clinical trial to offer patients with this devastating disease," commented Dr. Nick Vahanian, Chief Medical Officer of NewLink Genetics. "We have more than 70 major cancer centers currently enrolling patients in our ongoing Phase 3 trial for resected pancreatic cancer patients. We believe these relationships will enable us to efficiently implement this new Phase 3 clinical trial, since the majority of locally advanced patients are evaluated at the same centers as the resectable 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.

About the Phase 3 Study

This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating patients with borderline resectable or locally advanced unresectable pancreatic cancer. The primary endpoint of the clinical trial is overall survival, with secondary endpoints of progression-free survival, safety, toxicity and immunological responses. The study plans to enroll up to 280 patients. Standard-of-care regimens for patients with borderline resectable or locally advanced unresectable pancreatic cancer patients include FOLFIRINOX (an abbreviation for a chemotherapy combination that includes the drugs leucovorin calcium, fluorouracil, irinotecan hydrochloride, and oxaliplatin). In the Phase 3 clinical trial, half of the patients will receive FOLFIRINOX with algenpantucel-L and the remainder will receive FOLFIRINOX without algenpantucel-L.

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, 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 recruiting patients in a Phase 2B/3 clinical trial in this indication. NewLink has completed patient enrollment in a 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 of 1995. These statements include, but are not limited to, statements regarding the prospects of algenpantucel-L and the prospects of NewLink's Phase 3 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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