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Clinical Data from NewLink Genetics' HyperAcute Prostate Cancer Immunotherapy Published in Journal of Immunotherapy

- Data Continues to Support the use of NewLink's HyperAcute® Immunotherapy to Elicit a Response in Tumor-Specific Antigens Common to both the Immunotherapy and the Patient's Tumor Cells -

AMES, Iowa, Dec. 13, 2012 /PRNewswire/ -- NewLink Genetics Corporation (Nasdaq: NLNK) today announced that the results of a Phase 1 dose escalation study with its proprietary HyperAcute Prostate Cancer Immunotherapy were published in the *Journal of Immunotherapy.* The article, entitled "Cellular Immunotherapy Study of Prostate Cancer Patients and Resulting IgG Responses to Peptide Epitopes Predicted From Prostate Tumor-associated Autoantigens," is featured in the current edition of the Journal.

The study was conducted at the University of Nebraska Medical Center and included eight patients. Patients were scheduled to receive a priming dose on day one, followed by eleven boost doses every two weeks and patients received up to 12 intradermal vaccinations at doses ranging from 30 million to 500 million cells per injection. Patients were tested for safety, immunological and clinical responses arising after immunotherapy.

The study demonstrated that the immunotherapy was safe, and that the first immunization differentially increased the anti-alphaGal IgG response in all patients compared with baseline levels. These data indicated that administration of HyperAcute-Prostate immunotherapy increases the immune response against alphaGal epitopes, demonstrating the immunogenicity of the vaccine in prostate cancer patients.

The patients that received the highest dose of immunotherapy developed antibody responses against prostate tumor-associated antigens that were not seen in a control group of untreated volunteers. Data demonstrated that 37.5 percent (3/8) of patients responded with Prostate Specific Antigen (PSA) level stabilization for more than 100 days.

The adverse events data reported in this publication confirm the safety of this immunotherapy, consistent with previous studies on the safety of alpha-Gal-expressing allogeneic vaccines (HyperAcute immunotherapy) in the treatment of lung, melanoma and pancreatic cancers. Median overall survival for the study was 25.1 months with one patient with bone metastases surviving for more than 70 months.

"The favorable safety profile of this agent combined with evidence of vaccine induced immunologic responses in patients clearly suggests this therapy should be studied in a large controlled trial," said Dr. George P. Hemstreet, III, University of Nebraska Medical Center, the Principal Investigator for the study.

NewLink Genetics is currently evaluating its lead immunotherapy product candidate algenpantucel-L (HyperAcute-Pancreas) in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients.

About HyperAcute Prostate Cancer Immunotherapy

NewLink's HyperAcute Prostate Cancer immunotherapy product candidate consists of two allogeneic prostate cancer tumor cell lines modified to express alpha-Gal. These cell lines were chosen to provide a broad coverage of prostate cancer antigens. Each of the modified cell lines is grown in large cultures, harvested, packaged and irradiated. Each of the two vaccine components was administered separately.

About Prostate Cancer

Prostate cancer is one of the most common forms of cancer affecting men. The American Cancer Society estimates that 241,740 new cases of prostate cancer will occur in the US during 2012. Increased screening over the past few decades has enabled physicians to detect prostate cancer in its early, more treatable stages. Nonetheless, while overall five-year survival rates for cases of prostate cancer approach 100%, the outlook for advanced, metastasized cases is poor, with a five-year survival rate of 29% according to the American Cancer Society.

About NewLink Genetics Corporation

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for cancer patients. 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 to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. NewLink's lead product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in a Phase 3 clinical trial in surgically resected pancreatic cancer patients (under a Special Protocol Assessment with the U.S. FDA) as well as in a separate study in locally advanced pancreatic cancer patients. NewLink has recently launched an adaptive design Phase 2B/3 clinical trial of tergenpumatucel-L (HyperAcute Lung) in patients with non-small cell lung cancer. NewLink is developing indoximod (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. NewLink is studying indoximod in various chemotherapy and immunotherapy combination studies independently and in collaboration with the National Cancer Institute. For more information please visit http://www.linkp.com. Patient information is available at http://www.pancreaticcancer-clinicaltrials.com

Safe Harbor Statement

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan,""target," "potential," "will,""could," "should,""seek," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about the prospects of NewLink's HyperAcute product candidates and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2011, in its Quarterly Report on Form 10-Q for the period ended September 30, 2012, and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink's views as of any date subsequent to the date of this press release.

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