



June 1, 2012

Data From an Investigator-Initiated Phase 2 Study of NewLink Genetics' HyperAcute® Melanoma Immunotherapy Published in 2012 ASCO Annual Meeting Abstracts

HyperAcute Melanoma Demonstrates Activity in Stage III and Stage IV Patients

AMES, Iowa, June 1, 2012 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (Nasdaq:[NLNK](#)) today announced results from a Phase 2 investigator-initiated study of NewLink's HyperAcute® Melanoma immunotherapy product candidate in combination with pegylated interferon (Sylatron, Merck). The data were published in an abstract (No: e19008) at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL. This is in advance of presentations scheduled for Monday, June 4th at ASCO regarding NewLink's HyperAcute Pancreas (algenpantucel-L) and HyperAcute Lung (tergenpumatumucel-L) immunotherapy product candidates and IDO pathway inhibitor, NLG8189 (D-1mT) product candidate.

"Patients with metastatic melanoma have a poor outcome. We find it very encouraging that all of the patients in this study had immune responses to HyperAcute Melanoma including several patients who either had a complete objective response or have continued disease free survival after the resection of Stage III or IV disease," said Dr. Adam Riker, senior author of the abstract entitled, "Final results of a phase II immunotherapy trial for stage III and IV melanoma patients." "This promising data warrants further studies especially considering that this study employed only a short 12-week course of therapy at a relatively low dosage."

Phase 2 Study Design

Twenty-five patients (16 Stage IV patients and nine Stage III patients) with advanced melanoma were treated with 150 million cell injections weekly for 12 weeks in combination with an eight week course of pegylated interferon. Trial endpoints included clinical response, overall safety and correlative findings for observed anti-tumor effect.

Study Findings

Twenty-one of 25 patients completed the trial, with four stopping due to progressive disease. HyperAcute Melanoma was well tolerated without significant grade 3 or 4 toxicities associated with the vaccine. By RECIST criteria, of 16 stage IV patients there were two complete responders (CR), two with stable disease and three with no evidence of disease (NED) after resection. Among stage III patients, 3/9 remain disease free and one patient with slowly progressive disease remained alive for more than 30 months. The median overall survival in the study was 29 months, with 50% of the patients surviving for two years and 12/25 (48%) still alive. The anti-alpha-Gal antibody values increased after vaccination in 24/25 patients by up to 100-fold. All evaluable patients seroconverted, developing asymptomatic autoimmune antibodies. Anti-tyrosinase antibodies developed in seven of 23 patients correlating with one CR and one patient NED. Vitiligo developed in 4/25 patients, correlating with two complete responses and two patients stable continuing with no evidence of disease.

"The presence of vitiligo and durable complete responses provide further evidence for clinical activity of HyperAcute Melanoma," said Dr. Nicholas Vahanian, President and Chief Medical Officer of NewLink Genetics and added "We look forward to further evaluating our HyperAcute Melanoma immunotherapy in combination with recently approved anti-melanoma agents in additional advanced clinical studies."

"We believe that lessons we are learning from trials employing our proprietary HyperAcute technology in patients with lung and pancreatic cancer can be incorporated into improved study designs for patients with melanoma as we attempt to build upon these initial provocative clinical findings," stated Dr. Charles Link, CEO and Chief Scientific Officer of NewLink Genetics.

About HyperAcute Melanoma

New Link Genetics' HyperAcute Melanoma product candidate consists of a group of three allogeneic melanoma tumor cell lines that were modified to express the gene that makes alpha-GT. These three cell lines each possess collections of known melanoma antigens so that the immune response they stimulate will provide broad coverage. Each of the modified cell lines is grown separately in large cultures, then harvested, irradiated and packaged. Approximately 50 million cells of each

HyperAcute Melanoma cell line are given by intradermal injection with each treatment.

Upcoming ASCO Presentations:

NewLink Genetics is pleased that data from its HyperAcute product candidates and IDO pathway inhibitor therapies will be featured at ASCO. Presentations include:

HyperAcute® Pancreas

Session Title: Gastrointestinal (Noncolorectal) Cancer

Title: Addition of algenpantucel-L immunotherapy to standard of care (SOC) adjuvant therapy for pancreatic cancer.

Session: General Poster Session - Poster Board #: 41H

Date: Monday June 4, 2012

Time: 8:00 AM to 12:00 PM

Location: S Hall A2

HyperAcute® Lung

Session Title: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy

Title: Correlation of interferon-g (IFN) response with survival in a phase II hyperacute (HAL) immunotherapy trial for non-small cell lung cancer (NSCLC).

Session Type: General Poster Session - Poster Board #: 5D

Permanent Abstract ID: 2571

Date: Monday June 4, 2012

Time: 8:00 AM to 12:00 PM

Location: S Hall A2

D-1MT IDO Pathway inhibitor

Session Title: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy

Abstract Title: A phase I study of 1-methyl-d-tryptophan in patients with advanced malignancies

Session Type: Oral Abstract Session:

Permanent Abstract ID: 2501

Date: Monday June 4, 2012

Time: 3:00 PM to 6:00 PM

Location: E Arie Crown Theater

Presentation Time: 3:15 PM --- 3:30 PM

Session Title: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy

Abstract Title: A phase I study of 1-methyl-d-tryptophan in combination with docetaxel in metastatic solid tumors.

Session Type: General Poster Session: - Poster Board #: 11E

Permanent Abstract ID: TPS2620

Date: Monday June 4, 2012

Time: 8:00 AM to 12:00 PM

Location: S Hall A2

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 (algenpantucel-L) 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>). 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 (tergenpumatucl-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 for HyperAcute Melanoma and potential implications of the data contained in Abstract No: e19008 to be presented at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting for future clinical studies. 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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