May 31, 2011

NewLink Genetics to Present Data on Its HyperAcute(R) Prostate and Melanoma Immunotherapies at the American Society of Clinical Oncology Annual Meeting

AMES, Iowa, May 31, 2011 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation today announced that data from its investigational HyperAcute® Prostate cancer immunotherapy and investigational HyperAcute® Melanoma immunotherapy clinical trials will be presented at the American Society of Clinical Oncology (ASCO) 2011 Annual Meeting to be held June 3-7, 2011 in Chicago, Illinois. A summary of the company's poster presentations is below and full abstracts can be accessed on the ASCO website at www.asco.org.

HyperAcute® Melanoma immunotherapy

Title: Combination immunotherapy for high-risk and advanced melanoma patients. (Abstract #8534)

- Poster Session: Melanoma/Skin Cancers, Monday, June 6, 2011, 8:00 AM – 12:00 PM CT, McCormick Place S403
- Discussion: Monday, June 6, 2011, 11:30 AM – 12:30 PM CT, McCormick Place S406
- First Author: A. I. Riker, NewLink Louisiana State University Health Sciences Center, New Orleans, LA

The single-arm, open-label, Phase 2, investigator-sponsored clinical trial is fully enrolled with 25 patients for the treatment of high risk, resected stage III, recurrent, refractory or stage IV melanoma. The study evaluated the combination of HyperAcute Melanoma vaccine (NLG-12036, NewLink Genetics) combined with pegylated interferon (PEG-Intron).

HyperAcute® Prostate immunotherapy

Title: Effect of cellular vaccination of prostate cancer patients on IgG responses to peptide epitopes predicted from prostate tumor–associated autoantigens. (Abstract #2558)

- Poster Session: Developmental Therapeutics - Clinical Pharmacology and Immunotherapy, Monday, June 6, 2011, 8:00 AM - 12:00 PM CT, McCormick Place Hall A
- First Author: G. P. Hemstreet, University of Nebraska Medical Center, Omaha, NE

About HyperAcute Immunotherapy

NewLink's HyperAcute immunotherapy technology is designed to stimulate the human immune system by exploiting a natural barrier present in humans that protects against infection being transmitted from other mammals. This barrier is related to the enzyme, alpha (1,3) galactosyl transferase, or α-GT, which is expressed in the cells of lower mammals but not present in human or other Old World primate cells. The presence of this enzyme results in the incorporation of a non-human form of carbohydrate called alpha (1,3) galactosyl carbohydrates, or α-Gal, on the surface of expressing cells. Introducing α-Gal expressing cells to the human or primate immune system activates an immune response resulting from pre-existing antibodies against α-Gal. Antibodies directed against the α-Gal epitope are potentially the most abundant natural antibody in humans and represent approximately 1% of circulating human antibodies.

NewLink's HyperAcute cancer immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes α-Gal epitopes. This exposure to α-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which α-Gal is present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, NewLink believes the resulting cellular fragments bound by anti-α-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to tumor-associated antigens common to both the immunotherapy and the patient's tumor cells.

About HyperAcute Melanoma Immunotherapy

NewLink's HyperAcute Melanoma 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, harvested, packaged and irradiated. Approximately 50 million cells of each HyperAcute Melanoma cell line

are given by intradermal injection with each treatment.

About Melanoma

Melanoma is an often lethal form of skin cancer. If it is not recognized and treated early, the cancer can advance and spread to other parts of the body, where it becomes hard to treat and can be fatal. While it is not the most common skin cancer, it causes the most deaths. The American Cancer Society estimates that in 2009 there were 8,650 deaths from melanoma in the United States and there will be approximately 68,000 new cases of melanoma in the United States in 2010.

About HyperAcute Prostate Cancer Immunotherapy

NewLink's HyperAcute Prostate investigational product consists of two separate allogeneic prostate cancer cell lines that were selected based on antigen profiles and modified to express the gene that makes _alpha-GT. Each of the modified cell lines is grown in large cultures, harvested, packaged and irradiated.

About Prostate Cancer

Prostate cancer is one of the most common forms of cancer affecting men. According to the American Cancer Society, there were over 217,000 patients diagnosed with prostate cancer in the United States in 2010. 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 31%, 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 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, is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients. 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 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 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 D-1MT in various chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. For more information please visit www.linkp.com.

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