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NewLink Genetics to Present Phase 2 Data of Its HyperAcute(R) Lung Immunotherapy at AACR 102nd Annual Meeting 2011

AMES, Iowa, April 1, 2011 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation today announced that additional data from its Phase 2 clinical trial of the Company's investigational HyperAcute® Lung cancer immunotherapy will be presented during a poster session at the American Association for Cancer Research 102nd Annual Meeting 2011 in Orlando, Florida. A summary of the poster is below.

Title: Immunological findings in a phase II immunotherapy study using allogeneic lung cancer cells modified to express α(1,3) galactosyltransferase in advanced non-small cell lung cancer (NSCLC)

- Immunology 8 Poster Session, Wednesday, April 6, 2011, 8:00 AM - 12:00 PM Eastern Time
- Abstract #5507 (Exhibit Hall A4-C, Poster Section 32, Poster #5507)

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The single-arm, open-label Phase 1/2 clinical trial is fully enrolled with 54 patients for the treatment of refractory, recurrent or metastatic NSCLC. The trial is being conducted at the NCI. The primary endpoint of the study is to assess tumor response rate after administration of HyperAcute Lung and the secondary endpoint is to assess overall survival.

Interim results from the Phase 2 portion of the trial showed a median overall survival of 11.3 months, a one-year survival rate of 46%, good tolerability and a favorable safety profile. Based on analysis of data from comparable precedent clinical trials of similar patients, expected median overall survival would have been approximately eight months. NewLink anticipates initiating a Phase 2B/3 clinical trial in advanced NSCLC patients in the second half of 2011.

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 Lung Immunotherapy

NewLink's HyperAcute Lung investigational product consists of a group of three separate allogeneic lung tumor cell lines that were genetically modified to express α-Gal epitopes on their surface. These three cell lines are representative of the three major types of NSCLC. Each of the modified cell lines is grown in large cultures, harvested, irradiated, and packaged. Approximately 100 million cells of each HyperAcute Lung cell line are given by intradermal injection with each treatment.

About Lung Cancer

According to the American Cancer Society, lung cancer is the leading cause of cancer-related death in the United States. The NCI estimates that over 157,000 Americans will die of the disease in 2010, accounting for approximately 28% of all

cancer deaths. Lung cancer is most often diagnosed at advanced stages when it is difficult to treat. According to the American Cancer Society, about 85% to 90% of lung cancers are classified as NSCLC. The remainder is called small cell lung cancer. The American Cancer Society also reports that about 80% of NSCLC cases are detected when they have progressed to stages III or IV. The current expected overall survival for a nonresectable stage IIIB or IV NSCLC patient who has failed first line treatment is approximately eight months.

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 is also 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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