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Data From Phase 1 and Phase 1B Studies of NewLink Genetics' IDO Pathway Inhibitor (NLG8189) Presented at 2012 ASCO Annual Meeting

NLG8189 Demonstrates Good Safety Profile and Bioavailability With Early Evidence of Activity

AMES, Iowa, June 4, 2012 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (Nasdaq:NLNK) today announced that data from Phase 1 and Phase 1B studies evaluating NLG8189 (D-1MT, 1-methyl-D-tryptophan or d-1-Methyltryptophan) will be presented in an oral presentation at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL in the E Arie Crown Theater from 3:15 to 3:30PM. The data show that NLG8189 is safe and well tolerated, with a favorable pharmacokinetic profile demonstrating good oral bioavailability. In addition, NLG8189 reached targeted therapeutic levels in the absence of serious toxicity. Interestingly, symptoms of hypophysitis (inflammation of pituitary) were observed in some patients suggesting early signs of biological activity. Furthermore, NLG8189 demonstrated a favorable safety profile in combination with Taxotere, as well as in combination with adenoviral autologous dendritic cell (DC) vaccines, with promising early signs of activity. These studies were conducted in conjunction with the National Cancer Institute (NCI).

Dr. Hatem Soliman, author of the abstract entitled "A phase I study of 1-methyl-d-tryptophan in combination with docetaxel in metastatic solid tumors" and also presenter of an oral abstract, commented, "In light of this favorable safety profile of NLG8189 and signs of activity we are especially interested in expanding our understanding of the mechanism underlying this compound's effect on the key immunomodulatory IDO pathway. The high response rate to chemotherapy after treatment with vaccine and NLG8189 suggests chemosensitization is occurring. In particular, we observed that 75% (6 out of 8 patients) responded to a combination of carboplatin and gemcitabine follow-on regimen including one complete response in a fifth line therapy."

Phase 1 and Phase 1B Study Designs

NewLink/NCI have completed Phase 1 single-agent pharmacokinetic/safety studies of the drug. Currently, two Phase 1B/2 clinical trials are enrolling patients to evaluate NLG8189 in combination with other cancer therapies. The initial Phase 1 dose escalation study evaluated 48 patients in escalating doses from 200 mg to 2,000 mg BID. The first Phase 1B clinical trial has primary endpoints assessing safety and efficacy of NLG8189 in combination with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. The second Phase 1B clinical trial has primary endpoints assessing safety and efficacy of escalating doses of NLG8189 in combination with Taxotere for patients with advanced stage solid tumors for which Taxotere is the standard-of-care, such as metastatic breast, prostate, ovarian and lung cancers. Furthermore, in breast cancer patients who had already received multiple prior chemotherapy regimens before treatment with DC vaccine and NLG8189, a 50% objective response rate was found when patients were next administered further salvage chemotherapy. This response rate was unexpected in patients who were so heavily pretreated and suggests that a chemosensitization effect occurred.

Study Findings

Initial Phase 1 studies confirmed that the drug has early signs of activity, good oral bioavailability, a favorable half-life that allows drug accumulation to levels estimated to be within the therapeutic range and that it is tolerated very well by patients. The adverse events were generally mild and self-limited, including several cases of measurable but easily managed hypophysitis that developed in immunologically sensitized patients, an indication that NLG8189 can elevate immune activation above baseline to clinically detectable levels. In the Phase 1B study of Taxotere plus NLG8189, patients with advanced solid tumors were shown to tolerate the drug combination at the maximum dose and are now being treated with this new drug combination and followed for efficacy. Similarly, the study combining Ad-p53 vaccine/NLG8189 has reached its maximum dose without limiting toxicity and is now collecting efficacy data.

"We have been encouraged by the data from the Phase 1 studies as we see very favorable safety and pharmacokinetic profiles for this drug," said Dr. Nicholas Vahanian, President and Chief Medical Officer of NewLink Genetics. He added "The evidence of biologic activity is encouraging, especially given that the immune-related events observed in several patients are a side effect that has correlated with positive clinical outcomes in studies of other immune-modulatory agents such as ipilimumab. It has always been our strategy to develop NLG8189 as a component of combination treatment with other anti-cancer agents and to explore how the potential chemosensitization observed in these studies might be further exploited."

About NLG8189

NLG8189 is a small-molecule, orally bioavailable product candidate based on NewLink's proprietary IDO pathway inhibitor technology. Preclinical experiments have demonstrated a strong, synergistic anti-tumor effect without increased toxicity when NLG8189 was administered in combination with a number of currently available chemotherapeutic agents. IDO pathway inhibitors, including NLG8189, represent a potential breakthrough approach to cancer therapy using small-molecule, anti-toleragenic product candidates intended to combat the mechanisms by which tumors evade immune-mediated destruction. IDO is an enzyme that regulates immune response by suppressing T-cell function and creating local tumor immune escape. Recent studies have demonstrated that IDO is overexpressed in many cancers, within both tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor draining lymph nodes whereby IDO promotes peripheral tolerance to tumor-associated antigens ("TAAs"). When hijacked by developing cancers in this manner, IDO may facilitate the survival, growth, invasion, and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system as foreign.

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 (tergenpumatucel-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, 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 NLG8189 and potential implications of the data contained in Abstract No: NCT01191216 and in the oral abstract presentation entitled "A phase I study of 1-methyl-d-tryptophan in patients with advanced malignancies" 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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