UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 4, 2012 (June 4, 2012)

NewLink Genetics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2503 South Loop Drive **Ames, IA**	**50010**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(515) 296-5555**

Not applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 8 - Other Events

Item 8.01. Other Events.

On June 4, 2012, NewLink Genetics Corporation (Nasdaq: NLNK) ("NewLink") announced that its HyperAcute® Pancreas (algenpantucel-L) Immunotherapy will be featured today in a poster presentation (abstract number 4049) at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL. The abstract entitled "Addition of algenpantucel-L immunotherapy to standard of care (SOC) adjuvant therapy for pancreatic cancer" will be shown in S Hall A2 from 8:00AM to 12:00PM . The study results show 37%, 59% and 121% improvement in 1-, 2- and 3-year survival, respectively, as compared to standard-of-care.

The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference. The press release attached as Exhibit 99.1 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 NewLink's HyperAcute Pancreas immunotherapy product candidate, anticipated overall survival rates in the Phase 2 clinical trial of NewLink's HyperAcute Pancreas immunotherapy product candidate and potential implications of the data contained in a poster presentation (abstract number 4049) at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL., entitled "Addition of algenpantucel-L immunotherapy to standard of care (SOC) adjuvant therapy for pancreatic cancer." 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.

On June 4, 2012, NewLink also announced its HyperAcute® Lung (tergenpumatucel-L) immunotherapy will be featured today in a poster presentation (abstract number 2571) at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL. The abstract entitled "Correlation of interferon-g (IFN) response with survival in a phase II hyperacute (HAL) immunotherapy trial for non-small cell lung cancer (NSCLC)" will be shown in S Hall A2 from 8:00AM to 12:00 PM . The study presented by Dr. John C. Morris, Professor and Director of Thoracic Cancer Division at the University of Cincinnati, demonstrated a direct correlation between immune response and survival in non-small cell lung cancer patients. In addition, patient survival compared favorably to that seen in patients receiving other second-line chemotherapy agents, suggesting encouraging clinical benefit.

The press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

On June 4, 2012, NewLink also 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).

The press release is attached hereto as Exhibit 99.3 and incorporated herein by reference.

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated June 4, 2012 entitled "NewLink Genetics reports Two- and Three-year Overall Survival data from its Phase 2 HyperAcute® Pancreas (algenpantucel-L) Immunotherapy trial at the American Society of Clinical Oncology (ASCO) Annual Meeting"
99.2	Press release, dated June 4, 2012 entitled "NewLink Genetics HyperAcute® Lung (tergenpumatucel-L) Immunotherapy Demonstrates a Correlation Between Immune Response and Survival in Patients with Non-Small Cell Lung Cancer"
99.3	Press release, dated June 4, 2012 entitled "Data from Phase 1 and Phase 1B Studies of NewLink Genetics' IDO Pathway Inhibitor (NLG8189) Presented at 2012 ASCO Annual Meeting"

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: June 4, 2012

NewLink Genetics Corporation

By: /s/ Gordon H. Link, Jr.
Gordon H. Link, Jr.
Its: Chief Financial Officer

INDEX TO EXHIBITS

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Exhibit 99.1

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FOR IMMEDIATE RELEASE

NewLink Genetics reports Two- and Three-year Overall Survival data from its Phase-2 HyperAcute® Pancreas (algenpantucel-L) Immunotherapy trial at the American Society of Clinical Oncology (ASCO) Annual Meeting

AMES, Iowa, June 4, 2012 - NewLink Genetics Corporation (Nasdaq: NLNK) announces that its HyperAcute® Pancreas (algenpantucel-L) Immunotherapy will be featured today in a poster presentation (abstract number 4049) at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL. The abstract entitled “Addition of algenpantucel-L immunotherapy to standard of care (SOC) adjuvant therapy for pancreatic cancer” will be shown in S Hall A2 from 8:00AM to 12:00PM . The study results show 37%, 59% and 121% improvement in 1-, 2- and 3-year survival, respectively, as compared to standard-of-care.

Time points (years)	NLG0205 Overall Survival	Expected** Overall Survival	Percent Increase in Survival
1	86%	63%	37%
2	51%	32%	59%
3	42%*	19%	121%

*Based on Kaplan-Meier estimate
**Brennan et al., nomogram

Dr. Jeffrey M. Hardacre, the study's Principal Investigator, from the University Hospitals Seidman Cancer Center and Case Western Reserve University, Cleveland, OH stated, “As a surgeon who regularly treats patients suffering from pancreatic cancer, and being accustomed to the dismal prognosis for these patients, I am highly encouraged with the exceptional overall survival data from this study.”

“Given that the primary endpoint in our pivotal Phase 3 study targeting similar patients is overall survival,

this data supports our cautious optimism," said Dr. Nicholas Vahanian, President and Chief Medical Officer of NewLink Genetics.

Key data from the 69 patient Phase 2 algenpantucel-L trial demonstrated:

The primary endpoint of the study, 12-month disease free survival (DFS), was 62%. The median DFS was 14.1 months. Subgroup analysis showed that patients receiving 300 million cells/dose had a 12-month DFS of 81%, while those receiving 100 million cells/dose had a 12-month DFS of 51% (p=0.02, Fisher's Exact). Prognostic criteria did not significantly differ between the two groups.

Overall 12-month survival was 86%. The predicted 12 month overall survival in our study was 63%. Subgroup analysis showed that patients receiving 300 million cells/dose had an overall 12-month survival of 96%, while those receiving 100 million cells/dose had an overall 12-month survival of 79% (p=0.053, Fisher's Exact). Two-year overall survival in our study was 51% with a predicted survival of 32% and 3-year overall survival was 42% with a predicted survival of 19%. Predicted survivals were computed using prognostic factors gathered for each patient and calculated using a nomogram published by Brennan et al from Memorial Sloan Kettering Cancer Center. Over the 33 month median follow up period of the study, the percentage improvement in overall survival rate compared to nomogram analysis increased over time. These data are consistent with recent studies of active immunotherapies (Sipuleucel-T and Ipilimumab) in that immune benefits appear greater in some patients over time.

Prominent eosinophil responses have been observed with the majority of patients demonstrating measurable increases in peripheral blood eosinophilia. In addition to eosinophilic infiltrates at the injection site in all tested patients, 70% developed eosinophilia, with 30% showing persistent eosinophilia for up to 2 years.

The HyperAcute Pancreas immunotherapy product candidate, also referred to as algenpantucel-L, demonstrated good tolerability and a favorable safety profile with no grade four adverse events considered attributable to the immunotherapy. The predominant adverse events related to the immunotherapy were grade one or two injection site reactions, all treated with conservative local therapies.

Anecdotally, three patients with cancer recurrence after receiving algenpantucel-L obtained complete radiographic responses with the use of subsequent chemotherapy. As of May 16, 2012, all three patients remain in remission with no evidence of disease for periods ranging from six to 36 months. "We are presenting data from three different HyperAcute products at ASCO this year and each of these has generated intriguing data that provide insights into the activity and mechanisms associated with the treatment of patients with HyperAcute immunotherapies," stated Dr. Charles Link, CEO and Chief Scientific Officer of NewLink Genetics. "These observations include survival advantages that improve over time, objective responses, novel immunological findings and chemosensitization."

About the Phase 2 Study

The multi-institutional, open-label, dose-finding, Phase 2 trial evaluated the use of algenpantucel-L in addition to chemotherapy with chemoradiotherapy in the adjuvant setting for resected pancreatic cancer. Adjuvant therapy was to start within seven weeks after surgery. The first cycle of treatment consisted of vaccination with either 100 million or 300 million cells per dose given intradermally on days one and eight. One week after the second vaccination, gemcitabine was administered at 1000mg/m^2/week for three weeks, on days one, eight, and 15, in conjunction with HyperAcute immunotherapy dosed on days one and 15 of cycle two. Chemoradiotherapy was initiated one to two weeks after the completion of cycle two. Continuous infusion 5-FU was administered at 250 mg/m^2/day for the entire duration of radiation

therapy. HyperAcute immunotherapy was administered on days one, 15, 29, and 43 of the chemoradiotherapy stage. A total of up to 14 vaccinations were dosed for patients who completed the entire study treatment.

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 Alpha-GT, which is expressed in the cells of lower mammals but not present in human cells. The presence of this enzyme results in the incorporation of a non-human form of carbohydrate called alpha (1,3) galactosyl carbohydrates, or Alpha-Gal, on the surface of expressing cells. Introducing Alpha-Gal expressing cells to the human immune system activates an immune response resulting from pre-existing antibodies against Alpha-Gal. Antibodies directed against the Alpha-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 Alpha-Gal epitopes. This exposure to Alpha-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which Alpha-Gal is present by activating complement, an important component of the immune system capable of cell destruction. After destruction, NewLink believes the resulting cellular fragments bound by anti-Alpha-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 Algenpantucel-L (HyperAcute Pancreas immunotherapy product candidate)

NewLink's algenpantucel-L immunotherapy product candidate consists of a group of two allogeneic pancreatic cancer tumor cell lines that were modified to express Alpha-Gal. These cell lines were chosen to provide a broad coverage of pancreatic cancer antigens. Each of the modified cell lines is grown in large cultures, harvested, irradiated and packaged. Approximately 150 million cells of each HyperAcute Pancreas cell line are given by intradermal injection with each treatment. A series of up to 12 treatments using both cell lines over a period of six months was used in our Phase 2 clinical trial. In our Phase 3 protocol, we are adding an additional series of six maintenance treatments, to be given during the next six months.

About Pancreatic Cancer

The American Cancer Society estimates that approximately 44,030 new cases of pancreatic cancer were diagnosed in the United States in 2011. Pancreatic cancer has generally been recognized as an aggressive form of cancer with non-specific initial symptoms, making it difficult to diagnose at an early stage. Due to the difficulty in diagnosis and the aggressive nature of this cancer, the National Cancer Institute estimates a 96% mortality rate is associated with this disease, and the American Cancer Society estimates one-year and five-year overall survival rates of about 24% and 5%, respectively.

Pancreatic cancer can generally be divided into three broad categories: (1) local disease, in which the cancer is confined to the pancreas and can be removed surgically, which is called resection; (2) locally advanced disease, in which the cancer has spread locally and may or may not be eligible for resection because it has invaded tissues that should not be removed, such as key nerves and arteries; and (3) metastatic disease, in which the tumor has spread beyond the region of the pancreas.

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 (algenpantucel-L) 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 (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 NLG8189 NewLink's HyperAcute Pancreas immunotherapy product candidate, anticipated overall survival rates in the Phase 2 clinical trial of NewLink's HyperAcute Pancreas immunotherapy product candidate and potential implications of the data contained in a poster presentation (abstract number 4049) at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL., entitled “Addition of algenpantucel-L immunotherapy to standard of care (SOC) adjuvant therapy for pancreatic cancer.” 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.

Exhibit 99.2

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FOR IMMEDIATE RELEASE

NewLink Genetics HyperAcute® Lung (tergenpumatucel-L) Immunotherapy Demonstrates a Correlation Between Immune Response and Survival in Patients with Non-Small Cell Lung Cancer

AMES, Iowa, June 4, 2012 - NewLink Genetics Corporation (Nasdaq: NLNK) announced its HyperAcute® Lung (tergenpumatucel-L) immunotherapy will be featured today in a poster presentation (abstract number 2571) at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting being held in Chicago, IL. The abstract entitled “Correlation of interferon-g (IFN) response with survival in a phase II hyperacute (HAL) immunotherapy trial for non-small cell lung cancer (NSCLC)” will be shown in S Hall A2 from 8:00AM to 12:00 PM . The study presented by Dr. John C. Morris, Professor and Director of Thoracic Cancer Division at the University of Cincinnati, demonstrated a direct correlation between immune response and survival in non-small cell lung cancer patients. In addition, patient survival compared favorably to that seen in patients receiving other second-line chemotherapy agents, suggesting encouraging clinical benefit.

“The overall survival data is particularly remarkable when compared to current standard-of-care, which primarily utilizes cytotoxic chemotherapy agents with their associated debilitating side effects” commented Dr. Nick Vahanian, President, Chief Medical Officer, NewLink Genetics.

“These data suggest an intriguing relationship between a patient's immunological response to tergenpumatucel-L and overall survival,” said Dr. John C. Morris. He added, “Survival of the late stage patients in this study compares favorably with that seen in approved agents and there is emerging data to suggest that patient response to some of these agents may be enhanced by prior treatment with tergenpumatucel-L.”

Phase 1B/2 Study Design

Seventeen patients were treated in the Phase 1 portion of the study and 37 patients were treated in the

phase 2 portion. Patients had metastatic or recurrent NSCLC and had failed first-line chemotherapy**.** Twenty-eight of the 37 phase 2 patients were evaluable for clinical response. All phase 2 patients received 300 million cells per injection every two weeks for up to eight scheduled doses. Serum samples were collected before and after immunization and then at two-month follow-up visits. Peripheral blood mononuclear cells (PBMC) were collected prior to immunization and after the fourth and eighth vaccinations. Response was determined using RECIST criteria.

Results

There were 28 patients in the phase 2 portion of the study evaluable for response. Among these patients median overall survival was 11.3 months. Eight patients (28.5%) demonstrated stable disease after 16 weeks of treatment, including one patient that initially progressed and later regressed, surviving over 40 months. Eighteen patients with pre-immunization and post-immunization serum samples were tested for elevations in interferon-gamma response to drug. Eleven of these 18 responded with increased interferon-gamma, and the overall survival of these patients was 21.9 months. The increase in overall survival of patients with increased interferon gamma compared to non-responders was statistically significant with a p-value of 0.044. Six of the 11 responders showed reactivity to CL4-H522, a cellular target not present in HyperAcute Lung, suggesting cross priming to shared antigens.

Safety and Tolerability

No serious adverse events were reported as definitely or probably attributable to HyperAcute Lung. The most frequently observed adverse events attributable to the therapy were skin reactions at the site of injection. These were generally either acute inflammatory reactions or delayed-type hypersensitivity reactions that resolved without intervention in the vast majority of cases.

Dr. Charles Link, CEO and Chairman of NewLink stated that, “We are gratified that in addition to seeing positive clinical data with our HyperAcute-Lung product candidate, this study provides us with meaningful insight into the fundamental mechanisms by which this class of immunotherapies work.”

About HyperAcute Lung

The HyperAcute Lung product candidate, tergenpumatucel-L, consists of a group of three separate allogeneic lung tumor cell lines grown in large cultures, then harvested, packaged and irradiated. These cells are representative of the three major types of NSCLC and are modified to express the gene encoding the alpha galactosyl transferase enzyme. This enzyme modifies the surface of the cells in tergenpumatucel-L to make them more easily recognized and attacked by the immune system. After vaccination with tergenpumatucel-L, some patients' immune systems respond by recognizing new lung cancer antigens in ways thought to be helpful in fighting their own tumor.

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 (patient information is available at http://

www.pancreaticcancer-clinicaltrials.com) under a Special Protocol Assessment with the U.S. Food and Drug Administration. NewLink and its collaborators have completed patient enrollment for a Phase 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 NLG8189, 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.

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FOR IMMEDIATE RELEASE

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 - 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.

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