

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 3, 2013 (June 1, 2013)

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

Delaware
(State or other jurisdiction
of incorporation)

001-35342
(Commission
File Number)

42-1491350
(IRS Employer
Identification No.)

2503 South Loop Drive
Ames, IA
(Address of principal executive offices)

50010
(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 1, 2013, NewLink Genetics (NASDAQ:NLNK) announced results from a Phase 2 clinical study with tergenpumatucel-L.

The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

On June 3, 2013, NewLink Genetics (NASDAQ:NLNK) announced results from two clinical studies with indoximod, an orally administered small molecule drug candidate that inhibits the IDO pathway.

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

On June 3, 2013, NewLink Genetics (NASDAQ:NLNK) also announced results from a Phase 2 clinical study with its drug candidate algenpantucel-L.

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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated June 1, 2013, entitled “NewLink Genetics Presents Positive Phase 2 Data on Novel Immunotherapy, Tergenpumatucel-L, in Non-Small Cell Lung Cancer at the ASCO 2013 Annual Meeting”
99.2	Press Release, dated June 3, 2013, entitled “NewLink Genetics Presents Results from Two Phase 1 Studies with Immunotherapy Agent, Indoximod, at the ASCO 2013 Annual Meeting”
99.3	Press Release, dated June 3, 2013, entitled “NewLink Genetics' Algenpantucel-L Shows Encouraging Disease-Free and Overall Survival in Phase 2 Study in Resected Pancreatic Cancer”

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 3, 2013

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

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FOR IMMEDIATE RELEASE

NewLink Genetics Presents Positive Phase 2 Data on Novel Immunotherapy, Tergenpumatumucel-L, in Non-Small Cell Lung Cancer at the ASCO 2013 Annual Meeting

Data Demonstrate Favorable Outcomes for Tergenpumatumucel-L as a Single Agent and Potential to Enhance Salvage Chemotherapy Efficacy in Previously Treated Patients

Ames, IA - June 1, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), an oncology-focused biopharmaceutical company specializing in immunotherapy, today announced results from a Phase 2 clinical study with tergenpumatumucel-L. The study evaluated the safety and activity of tergenpumatumucel-L in 28 previously treated patients with metastatic or recurrent non-small cell lung cancer (NSCLC). All patients in the study received tergenpumatumucel-L as a single agent, which resulted in long term stable disease (³ 16 weeks) in 8 of the 28 patients, including one patient who survived 50 months. Median overall survival of 11.3 months with tergenpumatumucel-L as a single agent was also encouraging in this patient population. Sixteen of the patients whose disease progressed following tergenpumatumucel-L therapy received salvage chemotherapy. The partial response rate was 31 percent (5/16) and an additional 25 percent (4/16) achieved stable disease, suggesting that tergenpumatumucel-L enhanced the response rate of the salvage chemotherapy. The safety and tolerability of tergenpumatumucel-L was demonstrated in the study with no serious drug related (grade 4) adverse events reported; the most frequent drug related adverse events reported in the study were skin reactions at the injection sites.

NewLink is currently conducting a Phase 2b/3 trial comparing tergenpumatumucel-L to docetaxel for patients with previously treated NSCLC. This study will compare the response rates of follow-on chemotherapy for patients whose disease progresses in either the docetaxel or tergenpumatumucel-L arm to further investigate tergenpumatumucel-L's potential to produce a chemo-sensitization effect. Tergenpumatumucel-L is the second most advanced product in clinical testing from NewLink's HyperAcute platform technology.

“Lung cancer continues to be the leading cause of cancer-related deaths in this country. Response rates to currently available cytotoxic chemotherapies in previously treated patients are typically less than 10 percent with median survival being less than 8 months. Immune therapies such as tergenpumatumucel-L have the promise of improving the outcomes without producing excessive toxicities. If Phase 3 trials confirm these results, tergenpumatumucel-L would fill a significant unmet need for these patients,” said Ramaswamy Govindan, MD, Professor of Medicine, Division of Oncology, Washington University School of Medicine.

“Our Phase 2 trial data demonstrate the potential of tergenpumatumucel-L to improve survival while enhancing response rates to subsequent therapies,” said Nicholas Vahanian, M.D., President and Chief Medical Officer of NewLink Genetics. “Combined with results from studies of HyperAcute products for other indications, these data show that our HyperAcute technology has the potential to effectively stimulate the human immune system to recognize and destroy cancer cells.”

The Phase 2 data were discussed in a poster presentation entitled “Potential chemo-sensitization effect of tergenpumatumucel-L immunotherapy in treated patients with advanced non-small cell lung cancer (NSCLC),” by NewLink Genetics researchers and collaborators at the 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO).

About HyperAcute Immunotherapy

NewLink's HyperAcute immunotherapy platform creates novel biologic products that are designed to stimulate the human immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human cancer cells that are tumor specific, but not patient specific. These cells have been modified to express alpha-gal, a carbohydrate for which humans have pre-existing immunity. These alpha-gal-modified cells stimulate a rapid and powerful human immune response that trains the body's natural defenses to seek out and destroy cancer cells. The objective of HyperAcute immunotherapies is to elicit an antitumor response by "educating" the immune system to attack a patient's own cancer cells. HyperAcute immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins. We believe these unique properties of HyperAcute products result in the stimulation of a robust immune response.

NewLink's lead product candidate, algenpantucel-L (HyperAcute pancreas), is being studied in a Phase 3 trial (IMPRESS: "Immunotherapy for Pancreatic Resectable cancer Survival Study") under a Special Protocol Assessment with the U.S. Food and Drug Administration. This trial involves up to 722 patients with surgically resected pancreatic cancer. Algenpantucel-L is also being tested in a second Phase 3 study (PILLAR: "Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable"), involving patients with locally advanced pancreatic cancer.

NewLink has several HyperAcute product candidates focused on other tumor types in various stages of development, including tergenpumatumucel-L, which is in an adaptive design, randomized Phase 2B/3 clinical trial currently accruing up to 240 patients with non-small cell lung cancer.

About NewLink Genetics Corporation

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. 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 to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. For more information please visit <http://www.linkp.com>. Patient information is available at <http://www.pancreaticcancer-clinicaltrials.com>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the prospects of algenpantucel-L, tergenpumatumucel-L, indoximod and our other HyperAcute and/or IDO pathway product candidates and related trials; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2012, Quarterly Report on Form 10-Q for the period ended March 31, 2013, Form S-3 Registration Statement filed December 28, 2012 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink's views as of any date subsequent to the date of this press release.

Contact:

Media:

Gina Nugent

The Yates Network

gina@theyatesnetwork.com

Investors:

Gordon Link

Chief Financial Officer

515-598-2925

glink@linkp.com



FOR IMMEDIATE RELEASE

NewLink Genetics Presents Results from Two Phase 1 Studies with Immunotherapy Agent, *Indoximod*, at the ASCO 2013 Annual Meeting

Data Demonstrate Evidence of Indoximod's Safety and Anti-Tumor Activity When Used in Combination with Other Anti-Cancer Agents in Metastatic Solid Tumors

Ames, IA - June 3, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), an oncology-focused biopharmaceutical company specializing in immunotherapy, today announced results from two clinical studies with indoximod, an orally administered small molecule drug candidate that inhibits the IDO pathway. Indoximod was tested in a Phase 1 study in combination with docetaxel and in a Phase 1B/2 study in combination with dendritic cell cancer vaccine (AD.p53DC). In both studies, data indicated that indoximod was well tolerated when combined with these anti-cancer agents. The data also indicated promising signs of anti-tumor activity. Based on these results, NewLink has recently advanced indoximod into two separate Phase 2 cancer trials in patients with metastatic breast cancer.

The Phase 1 trial of indoximod in combination with docetaxel was conducted in patients that failed prior treatments to determine the maximum tolerated dose and evaluate the safety and activity for the combination of indoximod and docetaxel. The data showed that in 22 evaluable patients, 18 percent (4/22) exhibited a partial response and 41 percent (9/22) had stable disease. Data indicated that the combination therapy was well tolerated with no increase in expected toxicities or unexpected drug-drug interactions. Further, the pharmacokinetic profile of the combination therapy was similar to the profile of each drug as a single agent. Based on these results, a randomized Phase 2 clinical study was initiated evaluating the potential of indoximod in combination with docetaxel in patients with metastatic breast cancer using 1200 mg twice per day (BID) of indoximod and 75 mg/m² of docetaxel once every three weeks.

The Phase 1B/2 trial of indoximod in combination with a dendritic cell cancer vaccine (AD.p53DC) was conducted in 32 patients with metastatic solid tumors who failed prior treatments, 22 of whom had metastatic breast cancer. The primary objective of the study was to determine the maximum tolerated dose of the two agents when combined. Data indicated that the combination therapy was well tolerated and established the Phase 2 dose for the combination. Stable disease was observed in three patients during the initial treatment phase of the study. Of the 22 patients in the study with metastatic breast cancer, 11 patients that showed tumor progression after treatment with indoximod plus vaccine were subsequently treated with gemcitabine-based chemotherapy. Six of these 11 patients (54 percent) achieved an objective response, including a complete response in one patient who had received four prior chemotherapies. Based on these results, a Phase 2 clinical study was initiated evaluating the potential of indoximod in combination with the cancer vaccine in patients with metastatic breast cancer using 1600 mg BID of indoximod and the vaccine. This trial will also evaluate the impact of salvage therapy for patients using carboplatin and gemcitabine.

"Taken together, we believe the data from these trials demonstrate the significant potential of indoximod and its action as an IDO pathway inhibitor to disrupt the mechanisms by which cancer evades a patient's immune system and to boost the effect of other therapies, including cytotoxic agents and cancer vaccines for the treatment of solid tumors," commented Charles J. Link, Jr., MD, Chairman and Chief Executive Officer of NewLink Genetics.

Both studies were discussed in poster presentations at the 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO) by NewLink researchers and collaborators. The first poster presentation was entitled "A phase 1 study of indoximod in combination with docetaxel in metastatic solid tumors." The second poster presentation was entitled "A phase I study of ad.p53 DC vaccine in combination with indoximod in metastatic solid tumors."

About IDO pathway inhibition

NewLink's IDO pathway platform is focused on developing small molecule drugs that disrupt mechanisms by which tumors evade a patient's immune system. IDO pathway inhibitors are another class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4 and PD-1 that are potential breakthroughs in cancer therapy. NewLink's IDO pathway inhibitors are orally administered small molecules that can be used in combination with other cancer therapeutics.

The IDO pathway regulates immune response by suppressing T-cell function and enabling local tumor immune escape. Recent studies have demonstrated that the IDO pathway is active in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor draining lymph nodes resulting in peripheral tolerance to tumor associated antigens (TAAs). Cancers may use the IDO pathway to facilitate survival, growth, invasion and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system.

NewLink is actively developing two IDO pathway inhibitors. The most advanced is indoximod, which is being studied in various chemotherapy and immunotherapy combination clinical studies. The second IDO pathway inhibitor, NLG919, has shown promising preclinical results and is expected to enter clinical trials by the end of 2013.

About NewLink Genetics Corporation

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. 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 to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. For more information please visit <http://www.linkp.com>. Patient information is available at <http://www.pancreaticcancer-clinicaltrials.com>.

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FOR IMMEDIATE RELEASE

NewLink Genetics' Algenpantucel-L Shows Encouraging Disease-Free and Overall Survival in Phase 2 Study in Resected Pancreatic Cancer

Median Overall Survival was More than Double in Patients with Elevated Levels of Anti-Mesothelin Antibodies Compared to Those without Elevated Levels

Data Presented in Oral Presentation at the ASCO 2013 Annual Meeting

Ames, IA - June 3, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), an oncology-focused biopharmaceutical company specializing in immunotherapy, today announced results from a Phase 2 clinical study with its drug candidate algenpantucel-L. The open-label, two-armed, multi-center study evaluated algenpantucel-L plus standard-of-care adjuvant therapy (gemcitabine and 5-FU-modulated radiation therapy) in 69 patients with resected pancreatic cancer. The study defined disease-free survival at one year as its primary endpoint, and overall survival, safety and immunological correlative analysis as the secondary endpoints. The data from the study showed that one year disease-free survival was 62 percent, while overall survival was 86 percent. Data presented on elevated levels of three separate biomarkers (antibodies to mesothelin, CEA and/or alpha-gal) correlated with a statistically significant improvement in overall survival. Specifically, the data showed median overall survival was 42 months in patients with elevated levels of anti-mesothelin antibodies versus 20 months in patients without elevated levels. Moreover, the subset of patients that showed increases in two or more of the aforementioned biomarkers had median overall survival greater than 42 months (median overall survival not reached for this subset of patients).

All patients are beyond 3 years of follow-up with study data showing three-year long-term disease-free survival and overall survival are 26 percent and 39 percent, respectively. The safety and tolerability of algenpantucel-L was favorable with no serious drug-related (grade 4) adverse events reported; the most frequent drug-related adverse events reported in the study were skin reactions at the injection sites. A Phase 3 study with algenpantucel-L for patients with surgically resected pancreatic cancer, the IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) study, is currently underway.

“The results of this study are very encouraging. The side effects of algenpantucel-L are minimal and quite tolerable. If the encouraging survival rates are confirmed in the randomized Phase 3 trial, it may very well change the standard of care and bring immunotherapy into the mainstream of pancreas cancer treatments,” commented George A. Fisher, M.D., Ph.D., Professor of Medicine (Oncology) at Stanford University School of Medicine and leader of the Gastrointestinal Oncology Program at Stanford.

“Algenpantucel-L is the most advanced program to emerge from our HyperAcute platform, and we are highly encouraged by these study results, which provide evidence that algenpantucel-L is stimulating and educating the immune system to recognize and attack cancer,” said Charles J. Link, Jr., M.D., Chairman and Chief Executive Officer of NewLink. “We are particularly interested in the data indicating that elevated levels of three separate biomarkers - antibodies to mesothelin, CEA and/or alpha-gal in combination - correlate with a statistically significant improvement in overall survival.”

The data were discussed in an oral presentation entitled “*Effect of algenpantucel-L immunotherapy for pancreatic cancer on anti-mesothelin antibody (Ab) titers and correlation with improved overall survival,*” by NewLink researchers and collaborators at the 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO).

About HyperAcute Immunotherapy

NewLink's HyperAcute immunotherapy platform creates novel biologic products that are designed to stimulate the human immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human cancer cells that are tumor specific, but not patient specific. These cells have been modified to express alpha-gal, a carbohydrate for which humans have pre-existing immunity. These alpha-gal-modified cells stimulate a rapid and powerful human immune response that trains the body's natural defenses to seek out and destroy cancer cells. The objective of HyperAcute immunotherapies is to elicit an antitumor response by “educating” the immune system to attack a patient's own cancer cells. HyperAcute immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins. We believe these unique properties of HyperAcute products result in the stimulation of a robust immune response.

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