

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 2, 2014 (June 2, 2014)

**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 2, 2014, NewLink Genetics (NASDAQ:NLNK) announced additional data with its drug candidate algenpantucel-L that is currently under development for multiple indications in pancreatic cancer.

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

On June 2, 2014, NewLink Genetics (NASDAQ:NLNK) announced continuing progress with its IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor program at the American Society for Clinical Oncology (ASCO) 2014 annual meeting.

The press release is attached hereto as Exhibit 99.2 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 2, 2014, entitled "NewLink Genetics Presents Algenpantucel-L Clinical Data in Poster Discussion Session at ASCO 2014 Annual Meeting"
99.2	Press Release, dated June 2, 2014, entitled "NewLink Genetics Demonstrates Continuing IDO Pathway Inhibitor Progress at ASCO 2014 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 2, 2014

### **NewLink Genetics Corporation**

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

## INDEX TO EXHIBITS

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**NewLink Genetics Presents Algenpantucel-L Clinical Data in Poster Discussion Session at ASCO 2014 Annual Meeting**

*Algenpantucel-L Shows Improved Overall Survival in Pancreatic Cancer Patients with Increased Anti-Calreticulin Antibody  
Patient Characteristics for Algenpantucel-L IMPRESS Phase 3 Clinical Study Subjects Consistent with Expectations*

Ames, IA - June 2, 2014 -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutics to improve treatment options for patients with cancer, today announced additional data with its drug candidate algenpantucel-L that is currently under development for multiple indications in pancreatic cancer.

Additional immunological correlative data from the NLG0205 Phase 2 study of adjuvant algenpantucel-L for treatment of resected pancreatic cancer patients was discussed at a poster presentation in Chicago during the 50<sup>th</sup> Annual meeting of the American Society of Clinical Oncology (ASCO). The NLG0205 Phase 2 clinical study evaluated algenpantucel-L plus standard-of-care adjuvant therapy (gemcitabine and 5-FU based chemoradiotherapy) in 69 patients with resected pancreatic cancer where one year disease-free survival was 62 percent and overall one year survival was 86 percent. Newlink presented data demonstrating that increased anti-calreticulin antibody (anti-CALR Ab) levels following algenpantucel-L treatment correlate with a statistically significant improvement in overall survival. Specifically, the data show median overall survival was 35.8 months in patients with elevated levels of anti-CALR Ab versus 19.2 months in patients without elevated levels(p=0.03).

Furthermore, the company presented additional patient demographic data from its ongoing IMPRESS phase 3 pivotal trial. The company evaluated the characteristics of “*High Risk vs Low Risk*” populations including age, gender, disease, nodal status, CA19-9 levels, resection margin, tumor location and tumor size for all 722 patients enrolled in the IMPRESS study. Specifically, IMPRESS has enrolled a significant majority (92%) of patients with high risk characteristics that were defined as being node positive or having tumor size  $\geq 2.5$  cm. The patient demographic profile and stage of disease severity were shown to be highly similar across all parameters when compared with the previously reported U.S.-based, multi-center RTOG 9704 clinical study of adjuvant therapy in this patient population, supporting projected survival rates for the control arm of the IMPRESS study.

Characteristics	IMPRESS (n=722)	RTOG 9704 (n=221)
Age (median)	65	61
Gender (male)	52%	53%
Tumor location (head)	80%	85%
Tumor location (body)	20%	15%
CA19-9 ( $\geq 180$ )	9%	9%
Tumor Grade (poor/undifferentiated)	35%	30%
Nodal Status (N+)	70%	68%
Tumor Size (median) $\geq 3.0$ cm	55%	59%
<u>High risk status:</u> N+ or $\geq 2.5$ cm	92%	N/A
<u>Low risk status:</u> N0, $\leq 2.5$ cm, R0/R1	8% (low risk)	N/A

“Algenpantucel-L is the most advanced program to emerge through our HyperAcute platform, and we are highly encouraged by this additional data supporting our belief that algenpantucel-L may provide a much needed survival benefit for pancreatic cancer patients” said Charles J. Link, Jr., M.D., Chairman and Chief Executive Officer of NewLink. “We also presented patient population characteristics from our IMPRESS Phase 3 clinical study with algenpantucel-L which were consistent, across the board, with those previously reported in the RTOG 9704 clinical study, supporting our expectations regarding survival rates for patients enrolled in the control arm of the IMPRESS study.”

“During the last few years, despite some recent reports of novel therapeutic agents showing promise in pancreatic cancer, overall benefits are marginal at best and unfortunately offer only limited survival advantage achieved with significant toxicities“ said Dr. Nick Vahanian, President and Chief Medical Officer of NewLink Genetics. He added, “In fact, during the last 3 decades there has been such limited progress made in fighting pancreatic cancer that reports of 1-2 months of survival benefit are still considered significant. We hope our data will shift treatment paradigms by helping to demonstrate the promise of immunotherapy in treating pancreatic cancer patients.”

These data were presented in a discussed poster presentation entitled “Anti-Calreticulin Antibody Titers Correlate with Improved Overall Survival in a Phase 2 Clinical Trial of Algenpantucel-L Immunotherapy for Patients with Resected Pancreatic Cancer,” by NewLink researchers and collaborators at the 2014 Annual Meeting of the American Society of Clinical Oncology (ASCO).

Patient enrollment (n=722) is complete in the IMPRESS study (Immunotherapy for Pancreatic Resectable cancer Survival Study). Following completion of the first interim analysis in March of this year, the NewLink Genetics' Independent Data Safety Monitoring Committee (DSMC) reviewed patient data and, as anticipated, recommended study continuation without modification. A second interim analysis is planned upon reaching 333 patient events and, if needed, a final analysis is planned at 444 patient events.

### ***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 immuno-oncology 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>.

### **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 and efficacy of algenpantucel-L, tergenpumatumucel-L, and our other HyperAcute product candidates and related clinical trials, plans to develop and commercialize our product candidates; ongoing and planned preclinical studies and clinical trials, the timing for completion of enrollment and outcomes of our other ongoing clinical studies; 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, 2013, Quarterly Report on Form 10-Q for the period ended March 31, 2014, 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.*

#### **Investor Contact:**

Gordon Link  
Chief Financial Officer  
515-598-2925  
[glink@linkp.com](mailto:glink@linkp.com)

#### **Media Contact:**

Gina Nugent  
The Yates Network  
[gina@theyatesnetwork.com](mailto:gina@theyatesnetwork.com)





## **NewLink Genetics Demonstrates Continuing IDO Pathway Inhibitor Progress at ASCO 2014 Annual Meeting**

*Five Combination Studies in Four Different Cancers Representing One of the Broadest Immuno-Oncology Combination Efforts in Biotech Space*

Ames, IA - June 2, 2014 -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on discovering, developing, and commercializing novel immunotherapeutics to improve treatment options for patients with cancer, demonstrated continuing progress with its IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor program at the American Society for Clinical Oncology (ASCO) 2014 annual meeting. In a series of presentations, NewLink researchers and collaborators presented multiple on-going clinical studies with its IDO pathway inhibitor candidates, expanding the immuno-oncology regimens being evaluated to include combinations with other immunotherapies, cancer vaccines, and chemotherapy. These presentations were highlighted by ASCO as trials in progress posters, demonstrating continued interest for innovative ongoing studies in IDO- mediated checkpoint inhibition.

Combination clinical studies presented that highlight NewLink's IDO pathway inhibitor product candidates include:

- Phase 1/2 study of NewLink's most advanced IDO pathway inhibitor, indoximod, in combination with ipilimumab (Yervoy) for unresectable stage 3 or 4 melanoma,
- Phase 1/2 study of indoximod in combination with temozolomide (Temodar) for primary malignant brain tumors,
- Phase 2 study of indoximod in combination with docetaxel (Taxotere) in metastatic breast cancer,
- Phase 2 study of indoximod after sipuleucel-T (Provenge) in metastatic castration-resistant prostate cancer,
- Phase 1 study of NLG919, the second product candidate from NewLink's IDO pathway inhibitor technology platform, for solid tumors.

"We believe NewLink is well positioned to continue to lead in the immune-oncology field as we now have 2 IDO pathway inhibitors from our rich IDO/TDO product pipeline in the clinic and our HyperAcute® platform products are continuing to make progress in the clinic across multiple indications," commented Dr. Nick Vahanian, President and Chief Medical Officer.

"With the initiation of these clinical studies we have significantly expanded the immuno-oncology combinations being evaluated with our IDO pathway inhibitor program, representing one of the broadest efforts in the biotech space. We plan to continue our efforts for even further expansion of our IDO program to additional indications by pursuing combination studies with chemotherapies and vaccines or other immune/check point modulators" commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "IDO pathway inhibition has previously demonstrated promising synergies and a good safety profile in preclinical studies in combination with other immunotherapies, cancer vaccines, and chemotherapy and we look forward to reporting on the anti-cancer activity of these combinations as our clinical data mature. We are also beginning to explore the potential of TDO inhibitors as stand-alone therapy and in combination with IDO inhibitors."

### ***About inhibition of the IDO pathway***

IDO pathway inhibitors are another class of immune check point inhibitors akin to the recently developed antibodies targeting CTLA-4 and PD-1 that represent potential breakthrough approaches to cancer therapy. The IDO pathway regulates immune response by suppressing T-cell activation which enables 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 whereby this pathway promotes

peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system. NewLink has a number of active programs directed at synthesizing inhibitors to the IDO pathway and additionally has discovered novel tryptophan-2,3-dioxygenase (TDO) specific inhibitors that are potential anti-cancer compounds which could function individually or in combination with IDO inhibition.

### **About NewLink Genetics Corporation**

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### **Investor Contact:**

Gordon Link  
Chief Financial Officer  
515-598-2925  
[glink@linkp.com](mailto:glink@linkp.com)

### **Media Contact:**

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[gina@theyatesnetwork.com](mailto:gina@theyatesnetwork.com)

