

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): May 30, 2014 (May 30, 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 May 30, 2014, NewLink Genetics (NASDAQ:NLNK) announced data from a Phase 2 clinical study of its dorgenmeltucel-L HyperAcute® immunotherapy in combination with pegylated interferon-alpha 2b in patients with advanced metastatic, progressive, refractory or recurrent melanoma.

The press release is attached hereto as Exhibit 99.1 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 May 30, 2014, entitled "NewLink Genetics Dorgenmeltucel-L HyperAcute Immunotherapy for Melanoma Demonstrates Clinical Efficacy with Tumor Regression and Immune Activation"

## 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: May 30, 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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99.1	Press Release, dated May 30, 2014, entitled “NewLink Genetics Dorgenmeltucel-L HyperAcute Immunotherapy for Melanoma Demonstrates Clinical Efficacy with Tumor Regression and Immune Activation”



**NewLink Genetics Dorgenmeltucel-L HyperAcute Immunotherapy for Melanoma Demonstrates Clinical Efficacy with Tumor Regression and Immune Activation**

*Data Demonstrating Promising Combination Immunotherapy with Dorgenmeltucel-L and Pegylated Interferon-alpha for Advanced Melanoma Patients in the Upcoming Publication of The Ochsner Journal*

Ames, IA - May 30, 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 data from a Phase 2 clinical study of its dorgenmeltucel-L HyperAcute® immunotherapy in combination with pegylated interferon-alpha 2b in patients with advanced metastatic, progressive, refractory or recurrent melanoma. The study will be featured in the upcoming edition of The Ochsner Journal, Volume 14, Number 2, Summer 2014, Academic Division of Ochsner Clinic Foundation. The treatment regimen consisted of 12 weekly vaccinations with 150 million cell dosage of dorgenmeltucel-L in combination with short course, pegylated interferon-alpha 2b given during weeks 5 through 12. These data demonstrated that the combination was capable of inducing complete and durable clinical responses with tumor regression and immune activation.

The study enrolled 25 patients, 21 of which completed the trial and were evaluable for response. The upcoming publication will highlight that of the 16 patients with stage IV disease, two had a complete response (CR) per Response Evaluation Criteria in Solid Tumors (RESIST), one had stable disease (SD), and four had no evidence of disease (NED) after resection. Furthermore, of the nine patients with stage II/III disease, three remained NED, and one stage IIC patient had slow progressive disease (PD) with a single site resected, this patient is currently NED. The median overall survival was 29 months, with 60% of the patients surviving for longer than one year. Of the 25 patients enrolled, 12 (48%) were still alive. All evaluable patients (21/21) seroconverted, developing autoimmune antibodies. Importantly, 4 of 25 patients developed vitiligo, correlating with two CR patients by RECIST criteria and two NED patients. Dorgenmeltucel-L HyperAcute immunotherapy in combination with pegylated interferon-alpha 2b was shown to be safe and well-tolerated in this study with no serious adverse events reported.

“These data demonstrated a complete response rate of 12.5% in patients with metastatic disease, which is on par with some early data from checkpoint inhibitors. Moreover, the complete responses observed were durable. In addition, 4 of the 16 patients with metastatic disease who were resected did not experience disease recurrence during the follow up period. The two patients who achieved complete responses also had more targeted autoimmunity manifested by vitiligo and did not demonstrate any off target autoimmunity as has been observed with checkpoint inhibitors,” stated Adam I. Riker, MD, FACS, Director, Advocate Cancer Institute, Advocate Christ Medical Center, the principal investigator of the current phase 2 study.

“A significant unmet need remains for improved treatment options for high-risk resected and metastatic melanoma patients,” said Nicholas Vahanian, M.D., President and Chief Medical Officer of NewLink. “We are highly encouraged by these data indicating that NewLink’s dorgenmeltucel-L in combination with pegylated interferon-alpha 2b provides the potential for better clinical outcomes including the potential for complete tumor regression and immune activation leading to increased survival. These initial results were obtained with only 12 weeks of vaccine given at 150 million cell dosages of dorgenmeltucel-L. We believe that higher doses and longer duration of therapy may improve outcomes. For example, we currently use 300 million cells per treatment and schedules of a year or more in duration with our more advanced pancreatic and lung cancer trials. We believe that HyperAcute vaccines, like dorgenmeltucel-L, could provide more targeted effects that could be amplified by checkpoint inhibitors. Thus to test this crucial combination,

we recently launched a new melanoma trial combining dorgenmeltucel-L with ipilimumab. This trial employs dorgenmeltucel-L at doses of 300 million cells with a vaccine treatment schedule of two years,” said Dr. Vahanian.

Dorgenmeltucel-L HyperAcute immunotherapy consists of melanoma cell lines that have been genetically modified to express alpha-gal carbohydrates on cell surface molecules. Alpha-gal has been shown to stimulate an immune response against melanoma-specific antigens in the tumor cell lines enabling the patient's immune system to target and destroy their melanoma cells.

### **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, dorgenmeltucel-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.*

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