

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): March 7, 2014 (March 7, 2014)

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

<b>Delaware</b> (State or other jurisdiction of incorporation)	<b>001-35342</b> (Commission File Number)	<b>42-1491350</b> (IRS Employer Identification No.)
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**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 March 7, 2014, NewLink Genetics (NASDAQ:NLNK) announced the continuation of the Phase 3 IMPRESS clinical study of algenpantucel-L for patients with surgically resected pancreatic cancer following the first of two planned interim data analyses.

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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release, dated March 7, 2014, entitled "NewLink Genetics' Independent Review Committee Recommends Study Continuation Without Modification after Completion of First Interim Analysis of IMPRESS Phase 3 Pancreatic Cancer Trial with Algenpantucel-L"

## **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: March 7, 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 March 7, 2014, entitled "NewLink Genetics' Independent Review Committee Recommends Study Continuation Without Modification after Completion of First Interim Analysis of IMPRESS Phase 3 Pancreatic Cancer Trial with Algenpantucel-L"



**NewLink Genetics' Independent Review Committee Recommends Study Continuation Without Modification after Completion of First Interim Analysis of IMPRESS Phase 3 Pancreatic Cancer Trial with Algenpantucel-L**

Ames, IA - 3/7/2014 -- 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 the continuation of the Phase 3 IMPRESS clinical study of algenpantucel-L for patients with surgically resected pancreatic cancer following the first of two planned interim data analyses.

As part of the planned interim analysis, scheduled to occur following 222 patient events, the independent data safety monitoring committee (DSMC) met to review available patient data. Following their review, the DSMC recommended that the study should proceed as planned, 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.

"As we have previously emphasized, continuation of this study was an anticipated outcome considering the high statistical threshold assigned to this first interim analysis under the special protocol assessment," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink.

"In any case, it is reassuring that no unexpected safety issues or other concerns were raised by the independent data safety monitoring committee," said Dr. Nicholas N. Vahanian, President and Chief Medical Officer of NewLink Genetics. "Now, with the first interim analysis behind us, we look forward to continuing the study and to gathering additional, more mature data in support of our mission to provide improved treatment options for patients with pancreatic cancer."

**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 tergenpumatucel-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>.

## 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 timing for completion of enrollment of our Phase 3 clinical trial for our HyperAcute Pancreas cancer immunotherapy; the timing of release of clinical data from ongoing clinical studies; its plans related to moving additional indications into clinical development; the prospects of algenpantucel-L and any of our other product candidates and related clinical 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, 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:

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