

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): April 2, 2013 (April 2, 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 April 2, 2013, NewLink Genetics (NASDAQ:NLNK) announced the initiation of a double-blind, randomized, placebo-controlled Phase 2 clinical study of its first IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor, indoximod, in patients with metastatic breast cancer. The Phase 2 clinical study will evaluate indoximod as a new approach to treating cancer by administering this novel IDO pathway inhibitor, designed to counteract a key mechanism by which tumors evade immune-mediated destruction, in combination with a conventional cytotoxin, docetaxel.

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 April 2, 2013, entitled "NewLink Genetics Initiates Phase 2 Trial of IDO Pathway Inhibitor, Indoximod, for the Treatment of Metastatic Breast 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: April 2, 2013

### **NewLink Genetics Corporation**

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

## INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated April 2, 2013, entitled "NewLink Genetics Initiates Phase 2 Trial of IDO Pathway Inhibitor, Indoximod, for the Treatment of Metastatic Breast Cancer"



Contact:  
Gordon Link  
Chief Financial Officer  
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FOR IMMEDIATE RELEASE

## **NewLink Genetics Initiates Phase 2 Trial of IDO Pathway Inhibitor, Indoximod, for the Treatment of Metastatic Breast Cancer**

*Clinical Trial Designed to Evaluate Novel IDO Pathway Inhibitor in Combination with Docetaxel*

Ames, IA - April 2, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced the initiation of a double-blind, randomized, placebo-controlled Phase 2 clinical study of its first IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor, indoximod, in patients with metastatic breast cancer. The Phase 2 clinical study will evaluate indoximod as a new approach to treating cancer by administering this novel IDO pathway inhibitor, designed to counteract a key mechanism by which tumors evade immune-mediated destruction, in combination with a conventional cytotoxin, docetaxel. This Phase 2 clinical study follows the successful Phase 1b dose-escalation study of indoximod in patients with advanced solid tumors in which a favorable safety profile and promising early signs of activity were observed. Indoximod is the most advanced product candidate to enter clinical trials based on NewLink's proprietary IDO pathway inhibitor platform for small-molecule, orally bioavailable cancer immunotherapies.

“There is significant unmet need for new approaches that may offer more effective treatment options for patients with metastatic breast cancer, a leading cause of death in women in the United States,” said Hatem Soliman, MD, a medical oncologist specializing in breast cancer in The Center for Women's Oncology at Moffitt Cancer Center and the principal investigator for this study. “Indoximod has demonstrated promising safety, pharmacokinetic and biologic activity in earlier clinical studies and we look forward to increasing our understanding of its potential in metastatic breast cancer with this robust Phase 2 study designed to evaluate the activity of indoximod in combination with a conventional chemotherapy across a number of clinically relevant endpoints.”

“Indoximod, an IDO pathway inhibitor is an immune check point inhibitor akin to the recently developed antibodies targeting CTLA-4 and PD-1. IDO can be expressed within both tumor cells and/or antigen presenting cells to create local immune suppression to impair immunological detection and destructions of tumors,” commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. “We are excited about the promising approach of using novel therapies, like indoximod, to harness key mechanisms of the immune system to enhance the body's cancer-fighting abilities and enhance the effect of other therapies. NewLink intends to pursue this strategy as we advance other clinical candidates from our IDO pathway inhibitor platform as well as our novel candidates from our HyperAcute immunotherapy platform.”

This randomized, double-blind, placebo-controlled Phase 2 clinical study is designed to evaluate the safety and efficacy of indoximod in combination with docetaxel as compared to docetaxel alone in up to 120 patients with metastatic breast cancer. Study endpoints include progression-free survival, objective response rate, median overall survival and

evaluation of pharmacodynamic tumor markers, in addition to safety. For more information about the study please refer to [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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

IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitors, also known as one of the key class of checkpoint inhibitors, represent a potential breakthrough approach to cancer therapy using small-molecule, anti-toleragenic product candidates intended to counteract a key mechanism by which tumors evade immune-mediated destruction. IDO is an enzyme that regulates immune response by suppressing T-cell function and enabling 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. Indoximod is currently in multiple Phase 1B/2 studies targeting breast cancer. These include combination studies with docetaxel and with an autologous p-53 Dendritic Cell vaccine. In addition to its clinical product candidate indoximod, NewLink has an active program directed at synthesizing other IDO pathway inhibitors.

### ***About NewLink Genetics Corporation***

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for cancer patients. 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. NewLink's lead product candidate, algenpantucel-L (HyperAcute® Pancreas) is being studied in a Phase 3 clinical trial in surgically resected pancreatic cancer patients (under a Special Protocol Assessment with the U.S. FDA) as well as in a separate study in locally advanced pancreatic cancer patients. NewLink has recently launched an adaptive design Phase 2B/3 clinical trial of tergenpumatucel-L (HyperAcute® Lung) in patients with non-small cell lung cancer. NewLink is developing indoximod, a small-molecule, orally bioavailable product candidate from NewLink's proprietary indoleamine-(2,-3)-dioxygenase pathway inhibitor technology. NewLink is studying indoximod in various chemotherapy and immunotherapy combination studies independently and in collaboration with the National Cancer Institute. 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, indoximod and our other HyperAcute product candidates and related clinical trials. 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 risks relating to: the initiation of clinical trials and the completion of enrollment; adverse general economic and industry conditions; and those risks discussed in "Risk Factors" and elsewhere in NewLink's Quarterly 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.*