

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): December 10, 2013 (December 10, 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 December 10, 2013, NewLink Genetics (NASDAQ:NLNK) announced the initiation of a first in human Phase 1 clinical trial of NLG919.

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 December 10, 2013, entitled "NewLink Genetics Initiates Phase 1 Clinical Trial of NLG919, a Novel Immune Checkpoint Inhibitor for Cancer Immunotherapy"

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: December 10, 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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99.1	Press Release, dated December 10, 2013, entitled "NewLink Genetics Initiates Phase 1 Clinical Trial of NLG919, a Novel Immune Checkpoint Inhibitor for Cancer Immunotherapy"



FOR IMMEDIATE RELEASE

NewLink Genetics Initiates Phase 1 Clinical Trial of NLG919, a Novel Immune Checkpoint Inhibitor for Cancer Immunotherapy

NLG919 is the Company's Second IDO Pathway Inhibitor to Enter Clinical Development in Patients with Recurrent Advanced Solid Tumors

Ames, IA - December 10, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced the initiation of a first in human Phase 1 clinical trial of NLG919. This is NewLink's second IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor that will initially be tested in patients with recurrent advanced solid tumors. NLG919 is a small-molecule, orally bioavailable, immune checkpoint inhibitor designed to counteract a fundamental mechanism by which tumors evade immune-mediated destruction.

NLG919 represents a novel class of compounds in NewLink's IDO pathway platform. This platform includes indoximod, NewLink's most advanced IDO pathway inhibitor, which is currently in Phase 2 clinical development for the treatment of breast cancer.

"NLG919 represents a second category of IDO pathway inhibitors to enter clinical development. It has demonstrated encouraging preclinical activity on its own, and interesting synergy in combination with indoximod, our most advanced IDO product candidate. By combining multiple immune checkpoint inhibitors, such as those targeting PD-1, CTLA-4 and IDO, we have the potential to provide more effective treatment options," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "IDO pathway inhibitors harness key mechanisms of the immune system to enhance the body's ability to fight cancer and boost the effect of other therapies. We believe the addition of NLG919 to our pipeline further solidifies NewLink as a leader in the field of IDO pathway inhibition."

The Phase 1 dose-escalation study is designed to evaluate the safety, pharmacokinetics, pharmacodynamics, and initial evidence of activity of NLG919 as determined by overall response rates in up to 36 patients with recurrent advanced solid malignancies. For more information about the study please refer to www.clinicaltrials.gov.

In preclinical studies, NLG919 has demonstrated encouraging activity in solid tumor models and shown that IDO pathway inhibition is critical to reversal of the local immune suppression which impairs immunological detection and destruction of tumors. NewLink has shown that NLG919 inhibits the IDO pathway by a complementary, yet different mechanism of action than indoximod. Furthermore, preclinical data showing that the combined activity of different checkpoint inhibitors, including distinct IDO inhibitors such as NLG919 and indoximod as well as other agents targeting the PD-1 and CTLA-4 pathways, can function synergistically against cancer.

About NLG919 and inhibition of the IDO pathway

IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitors represent a key class of immune checkpoint inhibitors and a potential breakthrough approach to cancer therapy. This approach uses anti-tolerogenic, small molecule drug 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, both within 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

tumors. When hijacked by developing cancers in this manner, IDO may facilitate the survival, growth, invasion, and metastasis of malignant cells that might otherwise be recognized and attacked by the immune system. NLG919 is currently in Phase 1 clinical development in patients with recurrent advanced solid tumors. In addition to NLG919, indoximod, NewLink's most advanced IDO pathway inhibitor, is in Phase 2 clinical studies for the treatment of breast cancer. NewLink has an active drug discovery program focused on the IDO pathway.

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>.

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, NLG919 and our other HyperAcute platforms 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.

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