

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 19, 2013 (December 19, 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 19, 2013, NewLink Genetics (NASDAQ:NLNK) announced the launch of a first in human Phase 1 clinical trial of HyperAcute™ Renal immunotherapy in patients with metastatic renal cell cancer.

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 19, 2013, entitled "NewLink Genetics Launches Phase 1 Clinical Trial of Its HyperAcute™ Renal Immunotherapy in Patients with Metastatic Renal Cell 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: December 19, 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 December 19, 2013, entitled "NewLink Genetics Launches Phase 1 Clinical Trial of Its HyperAcute™ Renal Immunotherapy in Patients with Metastatic Renal Cell Cancer"



FOR IMMEDIATE RELEASE

NewLink Genetics Launches Phase 1 Clinical Trial of Its HyperAcute™ Renal Immunotherapy in Patients with Metastatic Renal Cell Cancer

Ames, IA - December 19, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced that it had launched a first in human Phase 1 clinical trial of HyperAcute Renal immunotherapy in patients with metastatic renal cell cancer. HyperAcute Renal Immunotherapy is comprised of two allogeneic renal cell cancer cell lines engineered to express the murine alpha(1,3)GT gene.

“HyperAcute Renal represents our sixth HyperAcute immunotherapy to advance into clinic,” commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. “As with pancreatic cancer and algenpantucel-L, we believe renal cell cancer may also be particularly well suited to HyperAcute Renal immunotherapy. We continue to develop new HyperAcute immunotherapies as we approach the initial interim analysis of our pivotal IMPRESS trial for algenpantucel-L, our lead HyperAcute immunotherapy for patients with resected pancreatic cancer.”

The Phase 1 dose-escalation study is designed primarily to determine the safety of HyperAcute Renal immunotherapy cells administered by intradermal injection in up to 20 patients with recurrent or refractory, metastatic clear-cell renal cancer. For more information about the study please refer to www.clinicaltrials.gov.

About Renal Cell Carcinoma (RCC)

Renal cell carcinoma (RCC) accounts for 85-90% of all kidney cancers. Worldwide, approximately 208,500 new cases of kidney cancer are diagnosed each year, which represents approximately 2-3% of all adult malignancies. The incidence of kidney cancer has been increasing annually by approximately 2%. In the United States (US), the estimated new kidney cancer cases and deaths in 2013 are about 65,150 and 13,680, respectively. Approximately 75% of RCC patients present with clinically localized or locally advanced disease at initial diagnosis. For these patients, surgical resection of renal tumors via partial or radical nephrectomy is the current standard treatment. Unfortunately, approximately 20-40% of patients with localized disease will eventually develop local recurrence or distant metastasis post nephrectomy.

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 has several HyperAcute product candidates focused on other tumor types in various stages of development, including algenpantucel-L (HyperAcute pancreas), that is being studied in a fully enrolled 722 patient Phase 3 trial (IMPRESS: "Immunotherapy for Pancreatic Resectable cancer Survival Study") under a Special Protocol Assessment with the U.S. Food and Drug Administration and tergenpumatumel-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. 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.

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 tergenpumatumucel-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, HyperAcute Renal, 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.

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