

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): June 6, 2016

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 June 6, 2016, NewLink Genetics Corporation (the "Company") announced data from two studies on two posters highlighting the combination therapeutic potential of indoximod, an indoleamine-(2,3)-dioxygenase (IDO) pathway inhibitor, at the 2016 American Society of Clinical Oncology Annual Meeting in Chicago.

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 June 6, 2016, entitled "NewLink Genetics Presents Clinical Data for IDO Pathway Inhibitor Indoximod Combinations at American Society of Clinical Oncology (ASCO) Annual Meeting"

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: June 6, 2016

NewLink Genetics Corporation

By: /s/ John B. Henneman III
John B. Henneman III
Its: Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated June 6, 2016, entitled "NewLink Genetics Presents Clinical Data for IDO Pathway Inhibitor Indoximod Combinations at American Society of Clinical Oncology (ASCO) Annual Meeting"



NewLink Genetics Presents Clinical Data for IDO Pathway Inhibitor Indoximod Combinations at American Society of Clinical Oncology (ASCO) Annual Meeting

In Two Study Posters, Indoximod Shows Promise in Combination Therapies for Melanoma and Pancreatic Cancer

AMES, Iowa, June 6, 2016 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK), a biopharmaceutical company focused on bringing novel immuno-oncology medicines to patients, yesterday presented data from two studies on two posters highlighting the combination therapeutic potential of indoximod, an indoleamine-(2,3)-dioxygenase (IDO) pathway inhibitor, at the [2016 American Society of Clinical Oncology Annual Meeting](#) in Chicago.

Both posters are available online [here](#).

Updates on Phase 1b/2 trial of the IDO inhibitor indoximod plus checkpoint inhibitors for the treatment of unresectable stage 3 or 4 melanoma

The trial design allows for the combination of indoximod with either ipilimumab or one of the PD-1 checkpoint inhibitors pembrolizumab or nivolumab. The combination of indoximod with other checkpoint inhibitors has been well tolerated thus far with no increase in toxicity noted in this Phase 1b/2 study. Overall, 40 patients had been enrolled in the combined Phase 1b/2 study long enough to have response data available at the time of data cut off. The poster data presented at ASCO were based on data via site reported RECIST criteria available from 28 subjects, the objective response rate, comprised of complete response plus partial response, for these patients is 36 percent (10 of 28) with three complete responses. Interestingly, the subset of 15 patients who received indoximod in combination with pembrolizumab had an objective response rate of 53 percent (8 of 15) with two complete responses (13 percent). The trial continues to enroll, with 55 patients currently enrolled in Phase 2.

“Although early, the 53 percent response rate in patients with metastatic melanoma treated with indoximod and pembrolizumab appears promising,” said Zakharia Yousef, M.D., Assistant Professor of Medicine, Division of Hematology, Oncology and Blood & Marrow Transplantation at the University of Iowa and Holden Comprehensive Cancer Center.

Phase 2 trial of the IDO pathway inhibitor indoximod plus gemcitabine/nab-paclitaxel for the treatment of metastatic pancreas cancer: interim analysis

The combination of indoximod and gemcitabine/nab-paclitaxel continues to be well tolerated by patients with metastatic pancreatic cancer. These data come from the Phase 1/2 trial in which treatment-naïve metastatic pancreatic cancer patients were treated with the combination therapy in continuous four week cycles. As of the data cut off for the analysis, a total of 45 patients (Phase 1 and 2) were enrolled in the trial long enough to potentially have cycle 4 imaging available by the ASCO presentation. Data via site reported RECIST criteria were available on 31 patients. At the time of this analysis, objective response rate was 45 percent (14 of 31) and multiple durable responses ≥ 6 months were observed. Two patients achieved a complete

response (6 percent), both at Cycle 8, showing delayed kinetics that may indicate an immune based mechanism. The trial continues to enroll patients and a biopsy cohort expansion is underway.

“The objective response rate, observance of complete responses, and delayed and durable response patterns are promising for this combination regimen for patients with metastatic pancreas cancer,” said Andrea Wang-Gillam, M.D., Ph.D., Assistant Professor of Medicine, Division of Oncology, Section of Medical Oncology, at Washington University School of Medicine.

Further Study of Indoximod Combinations Planned

“These are promising data as indoximod continues to demonstrate potential in combination therapies with other checkpoint inhibitors and with chemotherapies for different cancers, with encouraging rates for objective responses while being well-tolerated,” said Charles Link, Jr., M.D., Chairman and Chief Executive Officer. “We believe these data further support that the IDO pathway is one of the key immune checkpoint targets. We anticipate continued clinical progress in these and additional indoximod combinations during 2016.”

About Indoximod

Indoximod is an orally available small molecule that has shown the potential to interfere with multiple targets within the indoleamine 2,3-dioxygenase (IDO) pathway. It is designed to be used in combination with other therapeutic agents to maximize the body's immune response against a range of tumor types. Indoximod is currently in multiple Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreatic, melanoma and brain cancers and in Phase 1 clinical trials for the treatment of pediatric patients with primary malignant brain tumors.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company focused on discovering, developing and commercializing novel immunoncology products to improve treatment options for patients with cancer. NewLink Genetics' portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink Genetics' 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.newlinkgenetics.com>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink Genetics 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, enrollment in or results of its clinical trials for product candidates; its timing of release of data from 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 Genetics makes due to a number of important factors, including those risks discussed in “Risk Factors” and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2015 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink' Genetics' views as of the date of this press release. NewLink Genetics 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 Genetics' views as of any date subsequent to the date of this press release.

###

Corporate Contact:
Jack Henneman
Chief Financial Officer
(515) 598-2561
Investor@linkp.com

Investor Contact:
Donna LaVoie
LaVoieHealthScience
617-374-8800, ext. 107
dlavoie@lavoiehealthscience.com

Media:
David Connolly
LaVoieHealthScience
617-374-8800, ext. 108
dconnolly@lavoiehealthscience.com