

NEWLINK GENETICS CORP

FORM 8-K (Current report filing)

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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): May 18, 2017

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))
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Section 8 - Other Events

Item 8.01. Other Events.

On May 18, 2017, NewLink Genetics Corporation (the "Company") issued a press release titled "Data from Clinical Study of NewLink Genetics' IDO Pathway Inhibitor, Indoximod, to Be Presented at the 22nd European Hematology Association Congress."

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.

Exhibit Number	Description
99.1	Press Release, dated May 18, 2017, entitled “Data from Clinical Study of NewLink Genetics’ IDO Pathway Inhibitor, Indoximod, to Be Presented at the 22 nd European Hematology Association Congress”

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: May 18, 2017

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 May 18, 2017, entitled "Data from Clinical Study of NewLink Genetics' IDO Pathway Inhibitor, Indoximod, to Be Presented at the 22 nd European Hematology Association Congress"



Data from Clinical Study of NewLink Genetics’ IDO Pathway Inhibitor, Indoximod, to Be Presented at the 22nd European Hematology Association Congress

AMES, Iowa, May 18, 2017 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today announced that an abstract describing data from a clinical study of its IDO pathway inhibitor, indoximod, in combination with chemotherapeutic agents for patients with newly diagnosed acute myelogenous leukemia (AML), is now available on the website of the [European Hematology Association \(EHA\) Annual Congress](#).

“These data to be presented at the EHA Congress further highlight clinical results presented at AACR in April and to be presented at ASCO in June, supporting the hypothesis that the IDO pathway is central to immune suppression in cancer,” said Charles J. Link, Jr., M.D., Chief Executive Officer and Chief Scientific Officer. “NewLink Genetics has two separate and distinct types of IDO pathway inhibitors in clinical development. Indoximod, which is wholly owned by NewLink Genetics, has a proposed differentiated mechanism within the IDO pathway and acts as a tryptophan mimetic having a direct effect on immune cells to reverse immune suppression used by cancer to protect itself.”

Indoximod in combination with chemotherapeutic agents

Initial results from the Phase 1b portion of a Phase 1b/randomized Phase 2a trial of indoximod in combination with chemotherapeutic agents, idarubicin and cytarabine, for patients with newly diagnosed AML will be presented as an e-poster (Abstract number E-912) by Ashkan Emadi, M.D., Ph.D., Associate Professor of the University of Maryland Greenebaum Comprehensive Cancer Center, at EHA in Madrid on Friday, June 23, 2017, 9:30 AM to Saturday, June 24, 7:00 PM CET and is titled: *Indoximod in Combination with Idarubicin and Cytarabine for Upfront Treatment of Patients with Newly Diagnosed Acute Myeloid Leukemia (AML): Phase 1 Report*.

This [study](#) uses a conventional remission induction and consolidation protocol for patients with newly diagnosed AML. Indoximod is given orally starting on day 8 of induction onward. The Phase 1 portion evaluated three dose levels of indoximod (600 mg, 1000 mg, 1200 mg) in combination with the standard of care 7+3 chemotherapy. Twelve patients were enrolled, as of March 1, 2017. The results indicate indoximod does not appear to add significant toxicity to standard remission induction and consolidation therapy for patients with newly diagnosed AML. Initial data suggest a low rate of minimal residual disease (MRD-neg) after one cycle of induction chemotherapy.

Nicholas N. Vahanian, M.D., President and Chief Medical Officer added, “Importantly, these data support further clinical investigation of our IDO pathway inhibitors in combination with currently available therapies, such as chemotherapy for patients with newly diagnosed Acute Myeloid Leukemia (AML).”

Key findings presented from the study include:

- Combination treatment with indoximod and conventional remission induction and consolidation therapy was well tolerated without adding significant toxicity

- Five of 6 (83%) evaluable patients treated with indoximod (600 mg or 1000 mg) achieved complete remission, with no evidence of minimal residual disease

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape.

NewLink Genetics is currently evaluating indoximod in multiple combination studies for patients with various types of cancer including melanoma, acute myeloid leukemia, pancreatic cancer and prostate cancer.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' product candidates are designed to harness multiple components of the immune system to combat cancer. 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 fact, 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 results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development; 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, 2016 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.

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IDO Pathway and Cancer

Key Immuno-Oncology Target

- ▶ IDO (indoleamine 2,3-dioxygenase) is an intracellular enzyme that regulates immune responses and when the pathway is active, results in an immuno-suppressive phenotype rather than an activated anti-tumor phenotype¹
- ▶ Tumors hijack the IDO pathway, a normal part of the immune system, to facilitate immune escape²
- ▶ Used in combination with other cancer therapies, IDO pathway inhibitors are being evaluated in multiple tumor types to potentially improve outcomes for patients with cancer

¹ Mertz, R. *Oncoimmunology*. 2012;1(9):1460-1468.
² Johnson TS. *Immunal Invest*. 2012;41(6-7):765-797.

Targeting the IDO Pathway

Two Strategies for Inhibition

- ▶ Indoximod
 - Acts directly on immune cells to reverse IDO pathway mediated suppression
- ▶ Navoximod (GDC-0919)
 - Direct IDO enzymatic inhibitor, blocks tryptophan metabolism^{1,2}
- ▶ Available data indicate similar activity with both approaches³

¹ Mautino, M. *AACR* 2013, Abstract 491.
² Jochems, C. *Oncotarget*. 2016;7(25):37762-37772.
³ Mautino, M. *AACR* 2013, Abstract 5023.

