

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 4, 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))

Section 8 - Other Events

Item 8.01. Other Events.

On April 4, 2017, NewLink Genetics Corporation (the "Company") issued a press release titled "Interim Phase 2 Data Demonstrate Robust Response Rate with Indoximod in Combination with Keytruda® (pembrolizumab) for Patients with Advanced Melanoma at AACR Plenary"

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 4, 2017, entitled "Interim Phase 2 Data Demonstrate Robust Response Rate with Indoximod in Combination with Keytruda® (pembrolizumab) for Patients with Advanced Melanoma at AACR Plenary"

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 4, 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 April 4, 2017, entitled “Interim Phase 2 Data Demonstrate Robust Response Rate with Indoximod in Combination with Keytruda® (pembrolizumab) for Patients with Advanced Melanoma at AACR Plenary”



Interim Phase 2 Data Demonstrate Robust Response Rate with Indoximod in Combination with Keytruda® (pembrolizumab) for Patients with Advanced Melanoma at AACR Plenary

- 59% Objective Response Rate (ORR) and 80% Disease Control Rate (DCR) in 51 Patients with Non-ocular Melanoma -

AMES, Iowa, April 4, 2017 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK), a biopharmaceutical company focused on bringing novel immuno-oncology therapies to patients with cancer, today reported interim results from NLG2103, a Phase 2 study evaluating its IDO pathway inhibitor, indoximod, in combination with checkpoint inhibitors for the treatment of patients with advanced melanoma.

These data report on a cohort of 60 evaluable patients (including patients with ocular melanoma) who received the combination of indoximod plus pembrolizumab which demonstrated a 52% (31/60) ORR and a 73% (44/60) DCR. Patients with non-ocular melanoma achieved a 59% (30/51) ORR and an 80% (41/51) DCR. The combination was generally well tolerated with low rates of Grade 3 or higher adverse events. These data will be presented today in the Clinical Trials Plenary Session at the American Association for Cancer Research (AACR) 2017 Annual Meeting in Washington, D.C.

“These data are impressive and demonstrate the potential of this combination to improve response rates of the currently available therapy for patients with advanced melanoma. Importantly, our combination therapy was well tolerated without an appreciable increase in toxicity,” said Dr. Yousef Zakharia, M.D., Assistant Professor of Medicine, Division of Hematology, Oncology and Blood & Marrow Transplantation at the University of Iowa and Holden Comprehensive Cancer Center, a leading investigator on the trial.

Nicholas Vahanian, M.D., President and Chief Medical Officer said, “These new data further underscore the potential for indoximod in combination with other agents. The ORR and DCR are highly encouraging and further validate indoximod as a promising IDO pathway inhibitor.”

Charles J. Link, Jr., M.D., Chairman and Chief Executive Officer said, "Currently approved immunotherapies are transforming cancer treatment. We believe targeting the IDO pathway is key to enhancing the efficacy of existing and future treatment regimens. NewLink Genetics has two distinct IDO pathway inhibitors in development that represent separate and independent opportunities. We expect further clinical validation of the IDO pathway as an immuno-oncology target throughout 2017.”

[NLG2103](#) is a Phase 2 study evaluating the addition of indoximod to the standard of care checkpoint inhibitors approved for patients with advanced melanoma (pembrolizumab, ipilimumab, or nivolumab). The interim data represent a cohort of 60 evaluable patients who received indoximod plus pembrolizumab. Evaluable patients were defined as those having at least one on-treatment imaging study. The primary outcome measure of the trial is objective response rate (ORR) and secondary outcome measures include disease control rate (DCR) and evaluation of safety and tolerability.

Key findings:

- The ORR, by site reported RECIST criteria, for all patients was 52% (31/60) with a 73% (44/60) DCR.
- Patients with non-ocular melanoma achieved a 59% (30/51) ORR and a DCR of 80% (41/51).
- The majority of responses reported have been durable.
- The occurrence of Grade 3 or greater adverse events was low with no apparent increase for the combination over what would be expected with pembrolizumab alone.

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. These include 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>.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. ([Source](#))

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

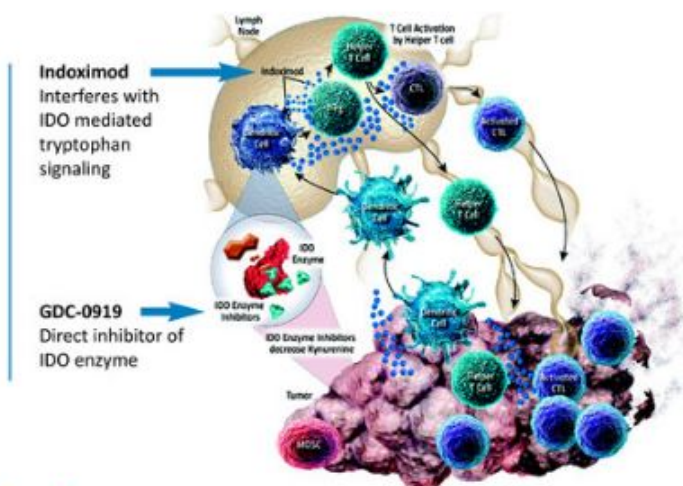
- ▶ IDO (indoleamine 2,3-dioxygenase) is an intracellular enzyme that regulates immune responses and when the pathway is active, results in an immuno-suppressive phenotype rather than an activated anti-tumor phenotype¹
- ▶ Tumors hijack the IDO pathway, a normal part of the immune system, to facilitate 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. *Oncolimmunology*. 2012;1(9):1460-1468.
² Johnson TS. *Immunol Invest*. 2012;41(6-7):765-797.

Targeting the IDO Pathway Two Strategies for Inhibition

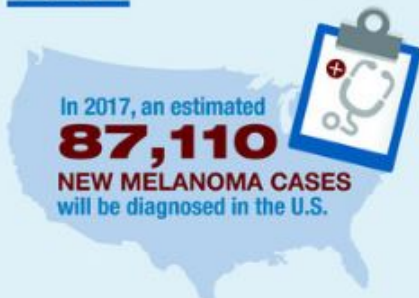
- ▶ Indoximod
 - Acts directly on immune cells to reverse IDO pathway mediated suppression
- ▶ GDC-0919
 - Direct IDO enzymatic inhibitors, block tryptophan metabolism^{1,2}
- ▶ Available data indicate similar activity with both approaches³

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

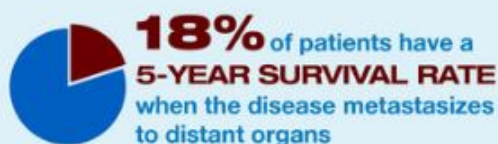


Melanoma

METASTATIC OR ADVANCED MELANOMA IS THE DEADLIEST FORM OF THE DISEASE



In 2017, an estimated **9,730 people** WILL DIE OF MELANOMA



Source: American Cancer Society, *Cancer Facts & Figures*, 2017