

NEWLINK GENETICS CORP

FORM 8-K (Current report filing)

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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): June 5, 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 June 5, 2017, NewLink Genetics Corporation (the "Company") issued a press release titled "NewLink Genetics' Indoximod + PROVENGE® Results in Statistically Significant Improvement in Radiographic Progression-Free Survival (rPFS) for Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC) in Phase 2 Trial."

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 5, 2017, entitled “NewLink Genetics’ Indoximod + PROVENGE® Results in Statistically Significant Improvement in Radiographic Progression-Free Survival (rPFS) for Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC) in Phase 2 Trial”

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 5, 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 June 5, 2017, entitled “NewLink Genetics’ Indoximod + PROVENGE® Results in Statistically Significant Improvement in Radiographic Progression-Free Survival (rPFS) for Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC) in Phase 2 Trial”



NewLink Genetics' Indoximod + PROVENGE[®] Results in Statistically Significant Improvement in Radiographic Progression-Free Survival (rPFS) for Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC) in Phase 2 Trial

AMES, Iowa, June 5, 2017 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today announces the presentation of results from a randomized Phase 2 investigator initiated study with indoximod in combination with the therapeutic cancer vaccine, PROVENGE (sipuleucel-T), for patients with metastatic castration resistant prostate cancer. The abstract titled, *A phase 2 randomized, double-blind study of sipuleucel-T followed by IDO pathway inhibitor, indoximod, or placebo in the treatment of patients with metastatic castration resistant prostate cancer (mCRPC)*, is being presented in a poster session by Gautam G. Jha, M.D., Adjunct Assistant Professor, Division of Hematology and Oncology, University of Minnesota, at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, IL this morning from 8:00-11:30 a.m. CT.

In the [study](#), forty-six patients were randomized into two arms to receive either twice daily oral indoximod (n=22) or placebo (n=24) for 6 months beginning the day after the third and final PROVENGE infusion. The indoximod treatment arm for the study showed a statistically significant improvement in radiographic progression-free survival (rPFS) when compared to placebo and was well tolerated.

Key findings presented from the study include:

- Statistically significant improvement in median rPFS was 10.3 months in the treatment arm compared to 4.1 months in the placebo arm ($p = 0.011$)
- Median Overall Survival (OS) has not yet been reached
- Patients tolerated therapy with indoximod with no significant differences in adverse events between the two arms
- There was no statistical difference in the primary endpoint of ELISPOT assay immune response to PA2024, the PROVENGE-related fusion protein, in the 35 of 46 patients who had clinical samples available for testing

“Given that PROVENGE alone has not shown any PFS benefit in multiple prior studies, this randomized, placebo controlled data, although limited in number of patients, is quite encouraging and has the potential to offer some measurable clinical benefits for patients,” said Dr. Jha, principal investigator of this study.

Data reported at ASCO 2017 indicate that treatment with NewLink Genetics' proprietary IDO pathway inhibitor, indoximod, post PROVENGE therapy leads to significant improvement in rPFS when compared to placebo and is well tolerated.

“These results are additional evidence that indoximod has the potential to improve outcomes for patients in combination with therapies beyond the established checkpoint inhibitors,” said Charles J. Link, Jr. M.D., Chairman and CEO of NewLink Genetics.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immunoncology 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>.

PROVENGE[®] is a registered trademark of Dendreon/Valeant Pharmaceuticals International, Inc.

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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Indoximod Post PROVENGE Therapy in Metastatic Castration Resistant Prostate Cancer

Radiographic Progression-Free Survival

