

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 17, 2018

**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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

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**Section 8 - Other Events**

**Item 8.01. Other Events.**

On April 17, 2018, NewLink Genetics Corporation issued a press release titled "NewLink Genetics Describes the Differentiated Mechanism of Action of Indoximod in AACR Poster Presentation."

A copy of the press release and the accompanying slides are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

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**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 17, 2018, entitled " <a href="#">NewLink Genetics Describes the Differentiated Mechanism of Action of Indoximod in AACR Poster Presentation</a> "
99.2	<a href="#">MOA Slides</a>

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**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 17, 2018

**NewLink Genetics Corporation**

By: /s/ John B. Henneman III

John B. Henneman III

Its: Chief Financial Officer



## **NewLink Genetics Describes the Differentiated Mechanism of Action of Indoximod in AACR Poster Presentation**

AMES, Iowa, April 17, 2018 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today presented a poster entitled "[Indoximod modulates AhR-driven transcription of genes that control immune function](#)" in the Immunomodulatory Agents and Interventions session at the American Association for Cancer Research (AACR) 2018 Annual Meeting in Chicago.

"The data demonstrate that indoximod has a unique mechanism of action, remarkably differentiated from IDO enzymatic inhibitors. This different mechanism may contribute to antitumor immune responses in the IDO pathway and through activity independent of IDO," said Charles J. Link, Jr., M.D., Chairman and Chief Executive Officer.

The data suggest that indoximod regulates the differentiation of helper T cells toward an immuno-stimulatory helper function and downregulates genes that control the differentiation of T cells into immuno-suppressive regulatory T cells (Tregs) in an AhR dependent manner. This leads to an increase in the ratio of helper T cells to Tregs. Additionally, it was shown that indoximod reduces the level of IDO protein in dendritic cells *in vitro*, leading to increased stimulation of CD8 T cell proliferation and reduced production of kynurenine. Moreover, indoximod stimulation of mTOR in T cells appears to increase the proliferation of effector T cells in an IDO and TDO-independent manner. Through this mechanism, indoximod may be able overcome the effects of Trp degradation mediated by both IDO and TDO. Thus, in addition to opposing immunosuppression mediated by the IDO pathway, indoximod may drive antitumor immune responses independent from IDO.

In summary, indoximod has immunostimulatory effects involving 4 main cell types: CD8<sup>+</sup> T cells, T helper cells, T regulatory cells, and dendritic cells. Indoximod appears to function through three main mechanisms to inhibit the IDO pathway:

- Reversing the effects of low tryptophan by increasing proliferation of effector T cells
- Increasing the ratio of T helper to T regulatory cells by both favoring differentiation of activated CD4 T cells into helper T cells and directly reprogramming T regulatory cells into helper T cells
- Downregulating IDO expression in dendritic cells

### **About Indoximod**

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immunology target involved in regulating the tumor microenvironment and immune escape. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1/PD-L1 agents, cancer vaccines, radiation and chemotherapy across solid and liquid tumors.

### **About NewLink Genetics Corporation**

NewLink Genetics is a late-stage biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are designed to harness multiple components of the immune

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system to combat cancer. For more information, please visit [www.newlinkgenetics.com](http://www.newlinkgenetics.com) and follow us on Twitter [@NLNKGenetics](https://twitter.com/NLNKGenetics).

### **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 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, 2017 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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#### Investor Contact:

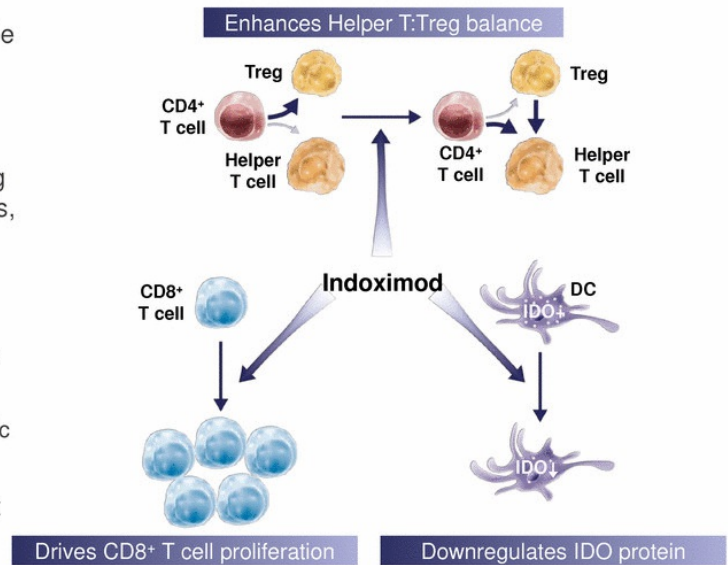
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## Indoximod Mechanism of Action

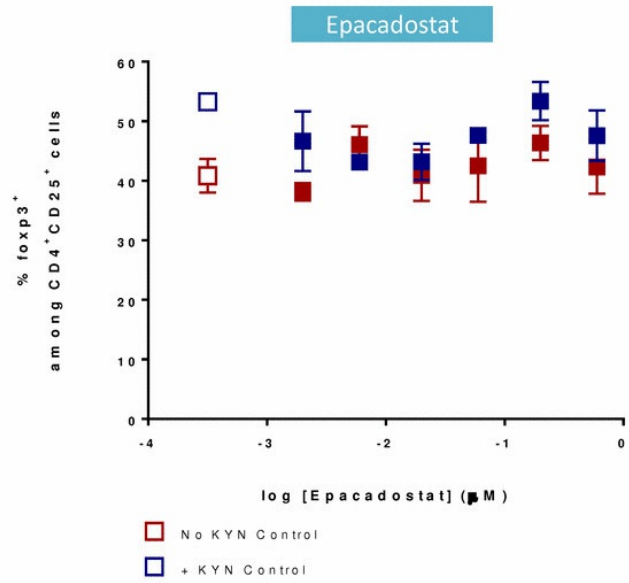
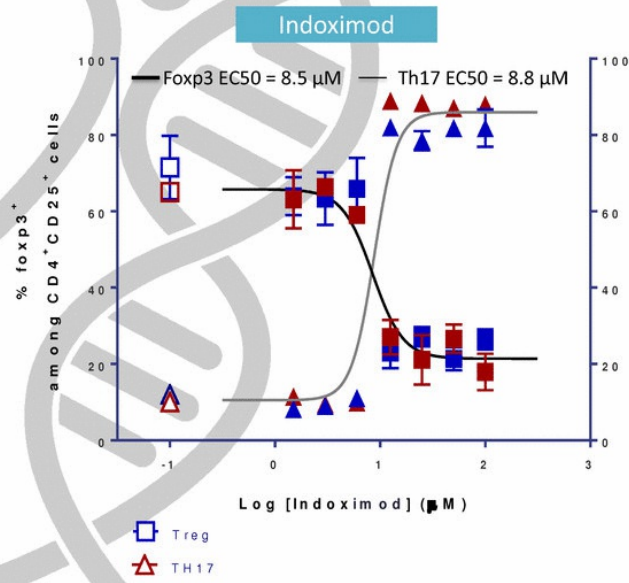
- Indoximod is an orally administered, small-molecule IDO pathway inhibitor that reverses the immunosuppressive effects of low tryptophan and high kynurenine that result from IDO activity
- Indoximod has immunostimulatory effects involving 4 main cell types: CD8<sup>+</sup> T cells, CD4<sup>+</sup> T helper cells, T regulatory cells, and dendritic cells
  - Indoximod reverses the effects of low tryptophan by increasing proliferation of effector T cells
  - Indoximod drives differentiation into T helper cells vs regulatory T cells
  - Indoximod downregulates IDO expression in dendritic cells
- Potential synergy has been shown with checkpoint blockade, chemotherapy, radiation and vaccines



IDO, indoleamine 2,3-dioxygenase; Treg, T regulatory cell; DC, dendritic cell.  
 1. Brincks EL, et al. Poster presented at the AACR Annual Meeting, April 14-18, 2018. Abstract 3753.

# Indoximod vs Epacadostat: A Differentiated Mechanism of Action

## Indoximod Drives Differentiation of Helper vs Regulatory T Cells



AACR Poster #3753 (Brincks, EL, et al, 2018)



