

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): July 2, 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 July 2, 2018, NewLink Genetics Corporation issued a press release titled "NewLink Genetics Announces Positive Updated Phase 1 Data with Indoximod Plus Radio-Immunotherapy for Pediatric Patients with DIPG Presented at ISPNO 2018."

A copy of the press release is attached hereto as Exhibits 99.1 and is 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 July 2, 2018, entitled " <a href="#">NewLink Genetics Announces Positive Updated Phase 1 Data with Indoximod Plus Radio-Immunotherapy for Pediatric Patients with DIPG Presented at ISPNO 2018.</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: July 2, 2018

**NewLink Genetics Corporation**

By: /s/ John B. Henneman III

John B. Henneman III

Its: Chief Financial Officer



## **NewLink Genetics Announces Positive Updated Phase 1 Data with Indoximod Plus Radio-Immunotherapy for Pediatric Patients with DIPG Presented at ISPNO 2018**

Ames, Iowa, July 2, 2018 --[NewLink Genetics Corporation](#) (NASDAQ:NLNK), reported that updated Phase 1 [data](#) evaluating indoximod plus front-line radiation and maintenance chemotherapy for the treatment of pediatric patients with newly diagnosed diffuse intrinsic pontine glioma (DIPG) were presented Sunday, July 1, at the International Symposium of Pediatric Neuro-Oncology ([ISPNO](#)) 2018 Annual Meeting in Denver.

Data were presented on ten newly diagnosed DIPG patients, all of whom had initiated therapy at the time of this assessment. All (10/10) demonstrated initial symptomatic improvement. Eight of ten had completed radiation, with the remaining 2 of 10 patients continuing radiotherapy. While a subset of the patient cohort developed inflammatory and other adverse symptomology, a common occurrence in this patient population, these symptoms were actively managed. Currently, 9/10 patients remain on study, with the longest time on study of 8.5 months. These data include more mature follow-up on the 6 patients previously presented at AACR 2018.

“These data continue to demonstrate the potential for indoximod plus radiochemotherapy as a combination treatment regimen which may improve disease related symptoms for these pediatric patients with an otherwise dire prognosis,” said Dr. Theodore S. Johnson, M.D., Ph.D., Associate Professor of Pediatrics at Augusta University, lead investigator for the trial. “We remain encouraged and look forward to additional data as the study proceeds.”

This DIPG cohort is a subset of [NLG2105](#), a Phase 1 study evaluating indoximod, NewLink’s IDO pathway inhibitor, in combination with radiation and chemotherapy for pediatric patients with malignant brain tumors. The DIPG cohort has been expanded from an initial pilot study based on early safety and efficacy data and is currently enrolling with a target of 30 DIPG patients.

### **About Diffuse Intrinsic Pontine Glioma (DIPG)**

Diffuse intrinsic pontine glioma, or DIPG, is a rare, aggressive brain tumor found in the brain stem that almost exclusively affects children. Every year in the United States, approximately 200-400 children, ages ranging from 4 to 11, are diagnosed with DIPG. As the tumor grows, it puts pressure on the nerves that control essential bodily functions. Children experience symptoms including, but not limited to: vision issues, arm and leg weakness and difficulty speaking, breathing and heartbeat resulting in death. The median survival time is 9 months, with only 1% of all children diagnosed with DIPG surviving more than 5 years.<sup>1</sup>

<sup>1</sup> Defeat DIPG Foundation

### **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 chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications such as AML, DIPG and melanoma.

### **About NewLink Genetics Corporation**

NewLink Genetics is a clinical 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 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 contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "may," "appear to," "has potential to," "look forward to," 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 NewLink's clinical trials for product candidates 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, 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.*

Investor Contact:

Lisa Miller  
Director of Investor Relations  
NewLink Genetics  
515-598-2555  
[lmiller@linkp.com](mailto:lmiller@linkp.com)

Media Contact:

Sharon Correia  
VP, Integrated Communications  
LaVoieHealthScience  
617-374-8800, ext. 105  
[scorreia@lavoiehealthscience.com](mailto:scorreia@lavoiehealthscience.com)