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 23, 2019

NewLink Genetics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2503 South Loop Drive **Ames, IA**	**50010**
(Address of principal executive offices)	(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 ☐

Section 8 - Other Events

Item 8.01. Other Events.

On May 23, 2019, NewLink Genetics Corporation issued a press release titled "NewLink Genetics Presents Updated NLG802 Results at the Immuno-Oncology 2019 World Congress."

A copy of the press release is attached hereto as Exhibit 99.1 and is 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 23, 2019, entitled "NewLink Genetics Presents Updated NLG802 Results at the Immuno-Oncology 2019 World 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 23, 2019

NewLink Genetics Corporation

By: /s/ Carl W. Langren
Carl W. Langren
Its: Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

NewLink Genetics Presents Updated NLG802 Results at the Immuno-Oncology 2019 World Congress

- *NLG802, a prodrug of indoximod, produced significantly higher pharmacokinetic (PK) exposure in patients compared to molar equivalent of indoximod while maintaining encouraging safety profile*
- *Notable response in 5th line pancreatic cancer patient re-challenged with chemotherapy after NLG802 treatment ended*

AMES, Iowa, May 23, 2019 (GLOBE NEWSWIRE) - NewLink Genetics Corporation (NASDAQ:NLNK) today announced the abstract (Poster 61) entitled, "A Phase 1 Clinical Trial of NLG802, a Prodrug of Indoximod with Enhanced Pharmacokinetic Properties," was presented at the Immuno-Oncology 2019 2nd World Congress in Barcelona, Spain.

The Phase 1 dose-escalation study evaluated the safety, toxicity and PK of NLG802 to determine the maximum tolerated dose (MTD) or maximum biologically achievable dose (MBAD). Data from the study was used to recommend a Phase 2 dose (RP2D) of NLG802.

NLG802 was administered orally at five dose levels up to 1452 mg BID in 26 patients with recurrent advanced solid tumors. At the time of analysis for this presentation, five (19%) patients remain on study, 14 (54%) alive, and four patients withdrew from follow-up. Six patients achieved a best response of stable disease per RECIST 1.1 criteria, with 1 patient having durable stable disease greater than nine months. No subject experienced a dose-limiting toxicity within the first 28-day cycle. The most frequently reported adverse events (AE) regardless of attribution were fatigue (54%), nausea (46%), vomiting (35%), decreased appetite (31%), and diarrhea (23%).

PK results were also reported from this study. After continuous twice-daily dosing with NLG802 at all levels, significantly higher PK exposure was observed. At 1452 mg BID, the highest dose administered, NLG802 produced a 6-fold increase in C_{max} and a 4.7-fold increase in AUC compared with molar equivalent indoximod dosing.

The treatment regimen was well tolerated with no NLG802-related serious adverse events (SAE) reported. MTD/MBAD had not been reached, and recommended Phase 2 dose (RP2D) was established at 1452 mg BID based on achieving preclinical exposure levels required for pharmacodynamic effects of indoximod.

An interesting response was observed during this study involving a patient with metastatic pancreatic cancer who had failed three prior lines of therapy (gemcitabine plus nab-paclitaxel, FOLFIRI, and irinotecan HCl plus gemcitabine). NLG802 was administered to this patient as 4th line therapy and was discontinued after five weeks upon disease progression. The patient was subsequently re-challenged with gemcitabine plus nab-paclitaxel. Imaging three months after re-challenge showed a partial response (PR) with 75% reduction in total tumor burden. In addition, the CA19-9 levels dropped 94% from levels prior to this line of therapy. No objective responses were observed after any earlier rounds of chemotherapy prior to administration of NLG802. This suggests that prior treatment with NLG802 may have contributed to the response ultimately observed in this patient.

"These results corroborate earlier data demonstrating NLG802's ability to produce significantly higher exposure levels in patients compared with molar equivalent dosing of indoximod, while maintaining tolerability," said Eugene P. Kennedy, MD, Chief Medical Officer of NewLink Genetics. "We are encouraged by these results, which reinforce our belief that NLG802 has the potential to be an important component of an immuno-oncology treatment regimen."

The poster can be accessed through the NewLink Genetics website at www.NewLinkGenetics.com in the "Investors & Media" section under "Posters & Presentations" or by clicking here.

About NLG802

NLG802, an orally-available prodrug of indoximod, was specifically engineered to increase the bioavailability of indoximod by leveraging existing mechanisms of absorption, increasing the exposure of indoximod approximately 5-fold. NewLink Genetics is currently evaluating NLG802 in a Phase 1 dose-escalation clinical trial in cancer patients to assess the safety and pharmacokinetics of NLG802.

About NewLink Genetics Corporation

NewLink Genetics is a clinical-stage biopharmaceutical company focusing on developing novel oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors, indoximod and its prodrug NLG802, are immuno-oncology drug candidates designed to harness multiple components of the immune system to combat cancer. The IDO Pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape. NewLink Genetics' drug candidate, NLG207 (formerly CRLX101), a nanoparticle formulation of camptothecin, a topoisomerase 1 inhibitor, is under development to combat refractory malignancies. For more information, please visit www.NewLinkGenetics.com and follow us on Twitter @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 "will be," "may," "appear to," "has potential to," "look forward to," "are designed 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, 2018 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 & Media Contact:

Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
lmiller@linkp.com