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): December 3, 2018 (December 2, 2018)

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 o

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 o

Section 8 - Other Events

Item 8.01. Other Events.

On December 2, 2018, NewLink Genetics Corporation issued a press release titled "NewLink Genetics Presents Encouraging Updated Phase 1 Data with Indoximod Plus Chemotherapy in Frontline AML in an Oral Session at 2018 ASH Annual Meeting."

A copy of the press release is attached hereto as Exhibits 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 December 2, 2018, entitled "NewLink Genetics Presents Encouraging Updated Phase 1 Data with Indoximod Plus Chemotherapy in Frontline AML in an Oral Session at 2018 ASH Annual Meeting."

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: December 3, 2018

NewLink Genetics Corporation

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

NewLink GeneticsPresents Encouraging Updated Phase 1 Data with Indoximod Plus Chemotherapy in Frontline AML in an Oral Session at 2018 ASH Annual Meeting

- *Updated Phase 1 data for indoximod plus standard-of-care chemotherapy in newly diagnosed AML show post-induction minimal residual disease (MRD) negativity rate of 86% and post-consolidation MRD negativity of 100%*
- *Safety data from this study indicate the combination treatment regimen was well tolerated with no regimen limiting toxicities (RLTs) observed*

Ames, IA and San Diego, CA, December 2, 2018 -- NewLink Genetics Corporation (NASDAQ:NLNK) announced that updated Phase 1 data evaluating indoximod plus standard-of-care chemotherapy for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) were presented today by Ashkan Emadi, MD, PhD, Professor of Medicine and Associate Director for Clinical Research, University of Maryland Greenebaum Comprehensive Cancer Center, in an oral session today at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego, CA, from 9:30AM - 11:00AM PT, in Grand Hall B, Manchester Grand Hyatt.

This Phase 1 trial evaluated the initial safety and preliminary evidence of clinical activity of adding indoximod to standard 7+3 induction and high-dose cytarabine (HiDAC) consolidation chemotherapy for adult patients with newly diagnosed AML. The presentation highlighted an initial safety profile indicating that the treatment regimen was well tolerated with adverse events commensurate with chemotherapy alone. Evidence of clinical activity was observed for indoximod plus chemotherapy in newly diagnosed AML as supported by these Phase 1 data showing post-induction minimal residual disease (MRD) negativity rate of 86% and post-HiDAC1 MRD negativity of 100%.

“These data demonstrate the promising potential for indoximod in combination therapy for patients with newly diagnosed AML and the use of MRD status as a study endpoint,” said Dr. Ashkan Emadi. “We remain encouraged and look forward to additional data as this study proceeds.”

Fifty-seven patients were screened, and 38 patients initiated induction therapy on protocol. Five patients never received indoximod resulting in an intent-to-treat (ITT) population of 33 patients. Twenty-two patients received the pre-specified 80% of indoximod dosing required to be included in the per protocol (PP) analysis, 8 received less than 80% of the scheduled indoximod dosage, and 3 patients remained on induction treatment as of the date of data cut off. Of these 22 PP patients, 16/22 (73%) achieved complete morphological response (CR) and 6 were primary refractory. Of the patients who achieved CR, 14 had results available from MRD testing post-induction. MRD negativity was defined by a flow cytometry assay at a level of < 0.02% (Hematologics, Inc., Seattle, WA). Of those tested, 12/14 (86%) were MRD-negative. Of the 14 patients, 1 patient proceeded to transplant, and 13 began HiDAC consolidation therapy. Post-HiDAC consolidation, all 13 patients were tested for MRD status with all 13/13 (100%) reported to be MRD-negative. When benchmarked against available published studies, these initial data appear encouraging. For a more precise comparison, a contemporaneous multi-institutional dataset is being aggregated to benchmark these data against data generated from patients undergoing the same chemotherapy regimen without the addition of indoximod using the same MRD assay assessed at the same reference laboratory.

Safety data from this Phase 1 trial indicate that the combination therapy regimen was well tolerated. No RLTs were observed when combining indoximod with standard-of-care chemotherapy. Grade 3 or greater adverse hematologic events included febrile neutropenia, anemia, and thrombocytopenia while non-hematologic events included hypoxia, anemia, and pneumonia. The overall adverse event profile observed in this small sample size is consistent with that of 7+3 induction chemotherapy plus HiDAC consolidation alone.

About AML[1,2]

Adult acute myeloid leukemia (AML) is a cancer of the blood and bone marrow in which the bone marrow makes abnormal types of white blood cells, red blood cells, or platelets. AML is the most common type of acute leukemia in adults and tends to progress rapidly without treatment. In the US, approximately 19,000 patients per year are diagnosed with AML with only around 25% expected to survive longer than three years. Of those newly diagnosed patients, approximately half are categorized as young and fit for an aggressive chemotherapy treatment regimen.

[1] National Cancer Institute
[2] American Society of Clinical Oncology

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target, suppressing immune response and allowing for immune escape by degrading tryptophan with the resultant production of kynurenine. Indoximod reverses the immunosuppressive effects of low tryptophan and high kynurenine through mechanisms that include modulation of the AhR-driven transcription of genes that control immune function. This results in increased proliferation of effector T cells, increased differentiation into helper T cells rather than regulatory T cells, and downregulation of IDO expression in dendritic cells. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications including recurrent pediatric brain tumors, DIPG, and AML.

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focusing on developing 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 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 "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.

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