

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): November 23, 2015

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))

Section 8 - Other Events

Item 8.01. Other Events.

On November 23, 2015, NewLink Genetics Corporation (the "Company") announced a trial update from a Phase 1b/2 study of indoximod in combination with temozolomide presented on November 20 at the 20th Annual Scientific Meeting of the Society for Neuro-Oncology in San Antonio, Texas

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.

Exhibit Number	Description
99.1	Press Release, dated November 23, 2015, entitled “NewLink Genetics Corporation Announces Clinical Data on Indoximod/Temozolomide Combination in Glioblastoma at Society for Neuro-Oncology 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: November 23, 2015

NewLink Genetics Corporation

By: /s/ John B. Henneman III

John B. Henneman III

Its: Chief Financial Officer

INDEX TO EXHIBITS

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99.1	Press Release, dated November 23, 2015, entitled “NewLink Genetics Corporation Announces Clinical Data on Indoximod/Temozolomide Combination in Glioblastoma at Society for Neuro-Oncology Meeting”



NewLink Genetics Corporation Announces Clinical Data on Indoximod/Temozolomide Combination in Glioblastoma at Society for Neuro-Oncology Meeting

AMES, Iowa, Nov. 23, 2015 -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK), a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor platforms, to improve the lives of patients with cancer, today announced a trial update from a Phase 1b/2 study of indoximod in combination with temozolomide presented on November 20 at the 20th Annual Scientific Meeting of the Society for Neuro-Oncology in San Antonio, Texas.

Indoleamine 2,3-dioxygenase (IDO) is a key immuno-modulatory enzyme that allows tumors to thwart the host immune response and therefore is an important research target. IDO is expressed in a large proportion of solid tumors, including 50-90% of glioblastoma tumors. Indoximod is NewLink Genetics' proprietary product candidate that has shown the potential to interfere with multiple targets within the IDO pathway and thereby to unleash the immune system to fight cancer.

The update presented is from a Phase 1b/2 study of indoximod in combination with temozolomide in patients with advanced glioblastoma who have previously demonstrated that their tumors are refractory to temozolomide. The completed Phase 1b portion of the study, which enrolled 12 patients, continues to show that the combination has an acceptable safety profile, confirming data previously presented. This Phase 1b portion of the study also demonstrated preliminary efficacy of the combination therapy. A six-month progression free survival (PFS) rate of 25% was observed, which compares favorably to the historical rate of 15% for refractory glioblastoma. In addition, the patient previously reported as having achieved a radiographically confirmed partial response (PR) remains on study treatment and has thus far demonstrated a durable response of greater than eight months, with an overall survival on trial of 20 months.

The Phase 2 portion of the study, which aims to determine the preliminary efficacy of the combination therapy, has enrolled 40 of a planned 132 patients as of the data cutoff. Nine of the 40 patients have been enrolled for more than six months and seven are evaluable as to outcome. One of these seven patients has demonstrated a radiographically confirmed PR after previously being refractory to treatment with temozolomide. The objective response occurred after having stable disease on treatment for six months. Of note, the onsets of the two partial responses, one in Phase 1b and one in Phase 2, were delayed, suggesting a possible immunotherapy-based mechanism of response.

"It is encouraging to see some promising early signs of activity of this combination of an immunotherapy with standard chemotherapy in recurrent GBM, which is a disease with huge unmet need," said Howard Colman, MD, PhD, Associate Professor of Neurosurgery and Director of Medical Neuro-Oncology at the Huntsman Cancer Institute at the University of Utah and an author of the study.

"I am particularly impressed with the potential early signals of an immune-mediated effect, as evidenced by the delayed onset and durability of the responses observed," said Olivier Rixe, MD, PhD, Professor of Medicine and Associate Director for Clinical Research at the University of New Mexico Comprehensive Cancer Center and an author of the study. "This is one of the first clinical trials testing an immune

checkpoint inhibitor in glioblastoma. It shows that indoximod is the first such therapy to produce an objective response in glioblastoma.”

"We are pleased with the preliminary safety and efficacy data on the combination of indoximod and temozolomide in glioblastoma obtained so far in this study," said Nicholas Vahanian, M.D., President and Chief Medical Officer. "We look forward to learning more about indoximod in our clinical studies in glioblastoma and four other cancer types, as well as about our six other immunology products currently in clinical testing."

About NewLink Genetics Corporation

NewLink is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immunology product candidates, including both cellular immunotherapy and checkpoint inhibitor platforms, to improve the lives of patients with cancer. NewLink Genetics' portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink Genetics' product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. For more information, please visit <http://www.newlinkgenetics.com>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, 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 NewLink Genetics' financial guidance for 2015; enrollment in or 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; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; 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, 2014 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink 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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