

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): September 28, 2015 (September 26, 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 September 26, 2015, NewLink Genetics Corporation (the "Company") presented early-stage clinical data from a Phase 1b study to determine the safety of indoximod, the Company's wholly owned indoleamine 2,3 dioxygenase (IDO) pathway inhibitor, in combination with ipilimumab for the treatment of patients with unresectable stage 3 or 4 melanoma, at the European Cancer Congress 2015 in Vienna, Austria (the "ECC").

On September 27, 2015, the Company presented early-stage clinical data from a phase 1a study of GDC-0919, an IDO checkpoint inhibitor being developed in collaboration with Genentech, a member of the Roche Group, at the ECC.

The press releases are attached hereto as Exhibits 99.1 and 99.2 and are 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 September 26, 2015, entitled “NewLink Genetics Corporation Announces Promising Phase 1b Data from the Combination of Indoximod and Ipilimumab in Melanoma at European Cancer Congress 2015 (ECC)” |
| 99.2 | Press Release, dated September 27, 2015, entitled “NewLink Genetics Corporation Announces Promising Clinical Data at European Cancer Congress 2015 (ECC)” |

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: September 28, 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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NewLink Genetics Corporation Announces Promising Phase 1b Data from the Combination of Indoximod and Ipilimumab in Melanoma at European Cancer Congress 2015 (ECC)

AMES, Iowa - September 26, 2015 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company at the forefront of developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer, today presented promising early-stage clinical data from a Phase 1b study of indoximod, its wholly owned indoleamine 2,3 dioxygenase (IDO) pathway inhibitor, in combination with ipilimumab for the treatment of patients with unresectable stage 3 or 4 melanoma at the European Cancer Congress 2015 (ECC) in Vienna, Austria.

The data reported today are from a Phase 1b safety study of nine patients to determine the safety of indoximod and to establish the dose for a Phase 2 study of indoximod in combination with ipilimumab, which is currently enrolling patients.

Indoximod is an orally available, small molecule, broad IDO pathway inhibitor that has shown the potential to interfere with multiple targets within the IDO pathway. IDO pathway inhibitors, such as indoximod, are designed to be used in combination with other therapeutic agents to maximize the body's immune response against tumors.

Combination therapy with indoximod and ipilimumab showed encouraging clinical activity in some patients. Of the seven patients evaluable for a response, one patient had a complete response and one patient had a partial response by RECIST criteria. Five patients in the study had progressive disease, and two patients are still awaiting follow up.

"We are pleased to present data from the successful completion of our Phase 1b trial evaluating the combination of indoximod and ipilimumab in patients with advanced melanoma," said Nicholas Vahanian, M.D., President and Chief Medical Officer. "The combination was well-tolerated and did not demonstrate any regimen-limiting immune-based toxicities, abnormalities in liver function tests or other toxicities that have been reported with this class of drugs. Based on these promising clinical results, we are already enrolling patients in the Phase 2 combination study."

The Phase 2 study, currently enrolling 38 patients, will utilize a revised study design with standard of care immune checkpoint inhibition (consisting of four cycles of concomitant ipilimumab, repeat cycles of nivolumab or repeat cycles of pembrolizumab) being given in combination with indoximod. The Phase 2 dose for indoximod has been established at 1,200 mg BID (twice daily), and the primary endpoint will be preliminary efficacy as measured by median progression-free survival.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company focused on discovering, developing and commercializing novel immuno-oncology products to improve treatment options for 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.

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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NewLink Genetics Corporation Announces Promising Clinical Data at European Cancer Congress 2015 (ECC)

AMES, Iowa - September 27, 2015 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer, announced promising early-stage clinical data from a phase 1a study of GDC-0919, an IDO checkpoint inhibitor being developed in collaboration with Genentech, a member of the Roche Group, was presented today at the European Cancer Congress 2015 (ECC) in Vienna, Austria.

The data reported today are from a Phase 1a study of the safety, pharmacokinetics and pharmacodynamics of GDC-0919 in 19 patients with recurrent or advanced solid tumors. The primary objectives of this study are to evaluate the safety and tolerability of GDC-0919 in patients with advanced solid tumors as well as to define the maximum tolerated dose (MTD) or maximum biologically effective dose and recommended Phase 2 dose. GDC-0919, a small molecule investigational immunotherapy designed to inhibit IDO1 for the treatment of immune tolerance associated with cancer, is intended as a combination therapy with other immunotherapies and oncology therapeutics.

The data showed an acceptable safety profile, disease stabilization and preliminary evidence of peripheral pharmacodynamic modulation.

GDC-0919 was well tolerated up to 800 mg BID (twice daily) on a 21/28 day cycle. Thirty seven percent of patients available for tumor assessments (7/17) achieved stable disease. The MTD was not reached.

Single and multiple dose exposure from 50 to 800 mg of GDC-0919 increased in approximately dose-proportional manner, and higher doses of GDC-0919 modulated plasma Kynurenine in a manner consistent with the half-life of GDC-0919.

The most common adverse events related to GDC-0919 were lower grade and included pruritus or itching (37%), fatigue, (26%) and decreased appetite (21%).

The study continues to evaluate safety, PK, activity and pharmacodynamics of GDC-0919 at a continuous dosing schedule (BID 28/28) to enable greater flexibility in future dosing regimens. GDC-0919 also is being evaluated in a Phase 1b study in combination with atezolizumab (PD-L1 inhibitor) in patients with recurrent or advanced solid tumors.

About NewLink Genetics' IDO Collaboration with Genentech

NewLink Genetics entered into an exclusive worldwide license agreement with Genentech in October 2014 for the development of GDC-0919, NewLink Genetics' IDO checkpoint inhibitor, previously known as NLG919. The parties also entered into a research collaboration for the discovery of next generation IDO/TDO compounds.

Under the terms of the agreement, NewLink Genetics received an upfront payment of \$150 million and will be eligible to receive in excess of \$1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating double-digit royalties on potential commercial sales of multiple products by Genentech.

Genentech continues to fund future research, development, manufacturing and commercialization costs and also provides research funding to NewLink Genetics for support of the research collaboration. NewLink Genetics retains the option for co-promotion rights for GDC-0919 and potential next generation IDO/TDO compounds in the U.S.

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