

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 15, 2015 (December 10, 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 December 10, 2015, NewLink Genetics Corporation (the "Company") announced that it reached the enrollment goal for NLG2101, a randomized Phase 2 study of indoximod in combination with taxane chemotherapy for patients with metastatic breast cancer. The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Also on December 10, 2015, the Company announced the presentation of preliminary safety data from NLG2101, a randomized Phase 2 clinical trial evaluating an IDO pathway inhibitor in combination with taxane-based chemotherapy for patients with breast cancer. The press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

On December 15, 2015, the Company announced the completion of enrollment in the Phase 3 **P**ILLAR (**P**ancreatic **I**mmunotherapy with algenpantucel-**L** for **L**ocally **A**dvanced non-**R**esectable cancer) clinical trial of algenpantucel-L for patients with borderline resectable or locally advanced unresectable pancreatic cancer. The press release is attached hereto as Exhibit 99.3 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 December 10, 2015, entitled "NewLink Genetics Reaches Enrollment Goal for Randomized Phase 2 Trial of Indoximod for Patients with Metastatic Breast Cancer"
99.2	Press Release, dated December 10, 2015, entitled "NewLink Genetics Corporation Presents Preliminary Safety Data From Randomized Phase 2 Trial of Indoximod, an IDO Pathway Inhibitor, at San Antonio Breast Cancer Symposium"
99.3	Press Release, dated December 15, 2015, entitled "NewLink Genetics Corporation Completes Enrollment of Phase 3 PILLAR Trial Evaluating Algenpantucel-L for Patients With Locally Advanced Pancreatic Cancer"

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 15, 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 Reaches Enrollment Goal for Randomized Phase 2 Trial of Indoximod for Patients with Metastatic Breast Cancer

AMES, Iowa, December 10, 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, announced today that this month it reached the enrollment goal for NLG2101, a randomized Phase 2 study of indoximod in combination with taxane chemotherapy for patients with metastatic breast cancer. Indoximod is a small-molecule indoleamine 2,3-dioxygenase (IDO) pathway inhibitor that has the potential to disrupt mechanisms by which tumors evade the immune system.

“We believe that IDO is an increasingly important target in immuno-oncology, and that targeting the IDO pathway will be a critical component of future immuno-oncology combination therapies,” said Charles Link, Jr., M.D., Chairman and CEO of NewLink Genetics. “Completing enrollment in the clinical trial for this combination chemoimmunotherapy is an important step forward in evaluating indoximod in breast cancer.”

IDO pathway inhibitors are a class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4, PD-1, and PD-L1 that represent potential breakthrough approaches to cancer therapy. The IDO pathway regulates immune response by suppressing T-cell activation, which enables local tumor immune escape. Recent studies have demonstrated that the IDO pathway is active in many cancers, both within tumor cells as a direct defense against T-cell attack and also within antigen presenting cells in tumor draining lymph nodes, whereby this pathway promotes peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

NewLink Genetics has a number of active programs directed at synthesizing inhibitors to the IDO pathway and, additionally, the company has discovered novel tryptophan-2,3-dioxygenase (TDO) specific inhibitors. 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. In addition, NewLink Genetics has entered into an exclusive worldwide license and collaboration agreement with Genentech, a member of the Roche Group, for the development of GDC-0919, which is currently in Phase 1 clinical development in patients with recurrent or advanced solid tumors.

About the NLG2101 Trial

NLG2101 is a Phase 2, 1:1 randomized study evaluating indoximod in 154 patients with ER/PR +/- and HER2- metastatic breast cancer who have not received any prior chemotherapy in the metastatic setting. The primary endpoint of NLG2101 is progression-free survival after treatment with docetaxel 75 mg/m² or paclitaxel 80 mg/m² with or without indoximod.

About NewLink Genetics Corporation and IDO Pathway Inhibitors

NewLink is 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. 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 Genetics 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 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, 2014 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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NewLink Genetics Reaches Corporation Presents Preliminary Safety Data from Randomized Phase 2 Trial of Indoximod, an IDO Pathway Inhibitor, at San Antonio Breast Cancer Symposium

AMES, Iowa/San Antonio, Texas, December 10, 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 the presentation of preliminary safety data from NLG2101, a randomized Phase 2 trial evaluating an IDO pathway inhibitor indoximod in combination with taxane-based chemotherapy for patients with breast cancer. The data were presented today at the 2015 San Antonio Breast Cancer Symposium.

NLG2101 is a randomized, double-blind, placebo-controlled Phase 2 trial of indoximod 1200 mg orally, twice daily in combination with docetaxel 75 mg/m² every 3 weeks or paclitaxel 80 mg/m² weekly in patients with metastatic ER/PR positive or negative, HER2 negative breast cancer. The trial, which reached its goal of 154 patients enrolled across multiple sites in the United States and Europe, is designed to evaluate the combination of indoximod and chemotherapy as first-line therapy for patients with metastatic breast cancer. The study's primary endpoint is progression-free survival, with secondary endpoints of overall survival, response rate per RECIST 1.1 criteria, safety, and immune response correlative assays.

Preliminary evaluable safety data from 128 patients, when considered in a blinded fashion pooling control and treatments arms of the study, suggests that the regimen is generally well tolerated. The addition of indoximod to standard of care chemotherapy for metastatic breast cancer did not increase expected adverse events known to be associated with the administered chemotherapies. Additionally, no unexpected safety signals were reported with the combination of indoximod with docetaxel or paclitaxel, suggesting that there is no additional or unique toxicity with the addition of indoximod to chemotherapy.

Objective responses were achieved in an earlier Phase 1 trial combining indoximod and docetaxel in patients with metastatic solid tumors, including breast tumors.

"I believe this is an exciting chemoimmunotherapy combination regimen for patients with metastatic breast cancer," said Shou-Ching Tang, M.D., Ph.D., Professor of Medicine, Leader, Breast Cancer Multidisciplinary Team at Augusta University. "These data suggest that indoximod may become a valuable addition to standard breast cancer treatment regimens due to the potential for enhancing a patient's immune system to fight cancer without additive toxicity. I eagerly await the full results of this trial evaluating a promising immune check point inhibitor in combination with chemotherapy."

The data, presented during the poster session "Treatment: Immunotherapy," correspond to the abstract (P2-11-09) entitled, "A phase 2 randomized trial of the IDO pathway inhibitor indoximod in combination with taxane based chemotherapy for metastatic breast cancer: preliminary data."

Indoximod is an orally available small molecule that has shown the potential to interfere with multiple targets within the indoleamine 2,3-dioxygenase (IDO) pathway. It is designed to be used in combination with other therapeutic agents to maximize the body's immune response against a range of tumor types. Indoximod is currently in multiple Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreatic,

melanoma and brain cancers and in Phase 1 clinical trials for the treatment of pediatric patients with primary malignant brain tumors.

About NewLink Genetics Corporation

NewLink Genetics is 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. 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>.

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NewLink Genetics Corporation Completes Enrollment of Phase 3 PILLAR Trial Evaluating Algenpantucel-L for Patients with Locally Advanced Pancreatic Cancer

AMES, Iowa, December 15, 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, announced today the completion of enrollment in the Phase 3 PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable cancer) clinical trial of algenpantucel-L for patients with borderline resectable or locally advanced unresectable pancreatic cancer. Total enrollment in the study exceeded 300 patients.

"I am delighted to be part of this important study, with the potential for helping patients with pancreatic cancer in clear need of pioneering immunotherapies like algenpantucel-L," said Harish Lavu, M.D., Associate Professor of Surgery at Thomas Jefferson University and a lead investigator for PILLAR.

"Completion of enrollment in this large phase 3 trial combined with our previous success enrolling 722 patients with resected pancreatic cancer in the IMPRESS registration trial demonstrates our ongoing commitment to patients with this disease," said Charles Link, Jr., M.D., Chairman and CEO of NewLink Genetics. "With the addition of our trial of indoximod, one of our IDO pathway inhibitors, in combination with chemotherapy for patients with metastatic pancreatic cancer, we now have clinical trials in all stages of this disease for which patients have very limited treatment options."

About the PILLAR Trial

PILLAR is a Phase 3, 1:1 randomized trial assessing overall survival for patients with borderline resectable or locally advanced unresectable pancreatic cancer treated with a regimen of FOLFIRINOX or gemcitabine/nab-paclitaxel in combination with algenpantucel-L cellular immunotherapy versus standard of care chemotherapy alone.

About HyperAcute[®] Cellular Immunotherapy

NewLink Genetics' HyperAcute[®] Cellular Immunotherapy platform creates novel biologic products that are designed to stimulate the human immune system to recognize and attack cancer cells. HyperAcute Cellular Immunotherapy product candidates are composed of human cancer cells that are tumor specific, but not patient specific. These cells have been modified to express alpha-gal, a carbohydrate for which humans have pre-existing immunity. These alpha-gal-modified cells stimulate a rapid and powerful human immune response that educates the body's natural defenses to seek out and destroy cancer cells. The objective of HyperAcute immunotherapies is to elicit an antitumor response by "educating" the immune system to attack a patient's own cancer cells. HyperAcute immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins. We believe these unique properties of HyperAcute Cellular Immunotherapy products result in the stimulation of a robust immune response.

NewLink's lead product candidate, algenpantucel-L, is also being studied in a Phase 3 trial (IMPRESS: "Immunotherapy for Pancreatic Resectable cancer Survival Study") under a Special Protocol Assessment with the U.S. Food and Drug Administration. This trial involves 722 patients with surgically resected pancreatic cancer.

NewLink has several HyperAcute Cellular Immunotherapy product candidates focused on patients with multiple tumor types including lung cancer, melanoma and renal cell cancer.

About NewLink Genetics Corporation

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