September 7, 2017

Updated Data for Indoximod Plus KEYTRUDA® (pembrolizumab) Demonstrate Improvement of Response Rate for Patients with Advanced Melanoma

Pivotal Trial of Indoximod in Advanced Melanoma to Include Both PD-1 Inhibitors, KEYTRUDA (pembrolizumab) and OPDIVO® (nivolumab)

AMES, Iowa--(BUSINESS WIRE)-- NewLink Genetics Corporation (NASDAQ: NLNK) today announced updated data from the ongoing Phase 2 NLG2103 study of indoximod, NewLink Genetics' IDO pathway inhibitor, in combination with the PD-1 pathway inhibitor, KEYTRUDA (pembrolizumab). These data will be highlighted in an oral presentation at the Third International Cancer Immunotherapy Conference in Frankfurt/Mainz, Germany, on September 9, 2017 by Yousef Zakharia, M.D., Assistant Professor of Medicine, Division of Hematology, Oncology and Blood & Marrow Transplantation at the University of Iowa and Holden Comprehensive Cancer Center.

This Smart News Release features multimedia. View the full release here: http://www.businesswire.com/news/home/20170907005441/en/

Indoximod plus Pembrolizumab Data from Phase 2 Trial in Advanced Melanoma

n[1] = 51 patients	n (%)
ORR	**31 (61)**
CR	10 (20)
PR	21 (41)
SD	10 (20)
DCR	**41 (80)**
PD	10 (20)
mPFS (months)	**12.9**
PFS at 12 months	**56%**

overall response rate (ORR), complete response (CR), partial response (PR), stable disease (SD), disease control rate (DCR), progressive disease (PD), median progression-free survival (mPFS), progression-free survival (PFS)

[1] Update includes only those patients with cutaneous, mucosal and melanoma of unknown primary origin.

Data as presented at Third International Cancer Immunotherapy Conference

Indoximod plus pembrolizumab data from Phase 2 trial in advanced melanoma (Graphic: Business Wire)

The presentation entitled, "Combined Inhibition of the IDO and PD-1 Pathways Improves the Response Rate for Patients with Advanced Melanoma", showed an improvement over previously reported results presented at the AACR Annual Meeting 2017 for both the Complete Response rate (CR) and the Overall Response Rate (ORR) for patients[1] who received indoximod plus pembrolizumab. Evaluable patients were defined as those having at least one on-treatment imaging study.

Key findings in the updated data reported today:

- Improvement in Complete Response (CR) to 20% (10/51 patients) compared to CR of 12% (6/51 patients)
- The Progression-Free Survival (PFS) by RECIST criteria was 56% at one year with median PFS (mPFS) of 12.9 months

"We are encouraged by the progression-free survival and the improvement in complete responses observed in the trial," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer, and Chief Scientific Officer. "The updated data further support our decision to initiate a pivotal trial for patients with advanced melanoma."

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Indoximod in combination with pembrolizumab was well-tolerated. The most common all-grade adverse events were fatigue, headache, and nausea. Three patients experienced grade 3 serious adverse events (SAE) possibly attributed to indoximod. Three patients experienced SAEs that led to discontinuation of treatment. There were no treatment related deaths.

Pivotal Trial of Indoximod in Advanced Melanoma to Include Both PD-1 Inhibitors, KEYTRUDA (pembrolizumab) and OPDIVO (nivolumab)

The pivotal trial has been designed as a large-scale (600 patients) trial in Stage III unresectable and metastatic stage IV melanoma. The trial will have a one to one randomization between indoximod plus KEYTRUDA (pembrolizumab) or OPDIVO (nivolumab) compared to single agent PD-1 inhibitor. The co-primary endpoints of the study are PFS by RECIST criteria and Overall Survival (OS).

"Our team is excited to move forward with this pivotal trial," said Eugene Kennedy, M.D., Vice President of Clinical and Medical Affairs. "We believe that allowing physicians the choice of either pembrolizumab or nivolumab accurately reflects current clinical care and should aid in enrolling the trial by the end of 2018."

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape.

NewLink Genetics is currently evaluating indoximod in multiple combination studies for patients with various types of cancer including melanoma, acute myeloid leukemia, pancreatic cancer and prostate cancer.

About NewLink Genetics Corporation

NewLink Genetics is a late-stage biopharmaceutical company focusing on discovering, developing and commercializing 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. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, prostate cancer, acute myeloid leukemia, and pancreatic cancer. For more information, please visit http://www.newlinkgenetics.com.

KEYTRUDA® is a registered trademark of Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

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 fact, 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 any 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, 2016 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

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Investor Contact:
NewLink Genetics
Lisa Miller, 515-598-2555
Director of Investor Relations
lmiller@linkp.com
or
Media:
LaVoieHealthScience
Andrew Mastrangelo, 617-374-8800, ext. 108
AVP, Public & Media Relations
amastrangelo@lavoiehealthscience.com

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