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Interim Phase 2 Data Demonstrate Robust Response Rate with Indoximod in Combination with Keytruda® (pembrolizumab) for Patients with Advanced Melanoma at AACR Plenary

59% Objective Response Rate (ORR) and 80% Disease Control Rate (DCR) in 51 Patients with Non-ocular Melanoma

AMES, Iowa, April 04, 2017 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on bringing novel immuno-oncology therapies to patients with cancer, today reported interim results from NLG2103, a Phase 2 study evaluating its IDO pathway inhibitor, indoximod, in combination with checkpoint inhibitors for the treatment of patients with advanced melanoma.

An infographic accompanying this release is available at
http://www.globenewswire.com/NewsRoom/AttachmentNg/f025a8a3-f8c5-4cf6-972b-e57312023126

These data report on a cohort of 60 evaluable patients (including patients with ocular melanoma) who received the combination of indoximod plus pembrolizumab which demonstrated a 52% (31/60) ORR and a 73% (44/60) DCR. Patients with non-ocular melanoma achieved a 59% (30/51) ORR and an 80% (41/51) DCR. The combination was generally well tolerated with low rates of Grade 3 or higher adverse events. These data will be presented today in the Clinical Trials Plenary Session at the American Association for Cancer Research (AACR) 2017 Annual Meeting in Washington, D.C.

"These data are impressive and demonstrate the potential of this combination to improve response rates of the currently available therapy for patients with advanced melanoma. Importantly, our combination therapy was well tolerated without an appreciable increase in toxicity," said Dr. 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, a leading investigator on the trial.

Nicholas Vahanian, M.D., President and Chief Medical Officer said, "These new data further underscore the potential for indoximod in combination with other agents. The ORR and DCR are highly encouraging and further validate indoximod as a promising IDO pathway inhibitor."

Charles J. Link, Jr., M.D., Chairman and Chief Executive Officer said, "Currently approved immunotherapies are transforming cancer treatment. We believe targeting the IDO pathway is key to enhancing the efficacy of existing and future treatment regimens. NewLink Genetics has two distinct IDO pathway inhibitors in development that represent separate and independent opportunities. We expect further clinical validation of the IDO pathway as an immuno-oncology target throughout 2017."

NLG2103 is a Phase 2 study evaluating the addition of indoximod to the standard of care checkpoint inhibitors approved for patients with advanced melanoma (pembrolizumab, ipilimumab, or nivolumab). The interim data represent a cohort of 60 evaluable patients who received indoximod plus pembrolizumab. Evaluable patients were defined as those having at least one on-treatment imaging study. The primary outcome measure of the trial is objective response rate (ORR) and secondary outcome measures include disease control rate (DCR) and evaluation of safety and tolerability.

Key findings:

- The ORR, by site reported RECIST criteria, for all patients was 52% (31/60) with a 73% (44/60) DCR.
- Patients with non-ocular melanoma achieved a 59% (30/51) ORR and a DCR of 80% (41/51).
- The majority of responses reported have been durable.
- The occurrence of Grade 3 or greater adverse events was low with no apparent increase for the combination over what would be expected with pembrolizumab alone.

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. These include melanoma, acute myeloid leukemia, pancreatic cancer and prostate cancer.

About NewLink Genetics Corporation
NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' product candidates are designed to harness multiple components of the immune system to combat 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. (Source)

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, among others, statements about 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; 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, 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 rely on these forward-looking statements as representing NewLink Genetics' views as of any date subsequent to the date of this press release.

E-Media kit here

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