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Data from Clinical Study of NewLink Genetics' IDO Pathway Inhibitor, Indoximod, to Be Presented at the 22nd European Hematology Association Congress

AMES, Iowa, May 18, 2017 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced that an abstract describing data from a clinical study of its IDO pathway inhibitor, indoximod, in combination with chemotherapeutic agents for patients with newly diagnosed acute myelogenous leukemia (AML), is now available on the website of the European Hematology Association (EHA) Annual Congress.

An infographic accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/8a3b562f-28b3-4526-baaf-95974cd8eb4f

"These data to be presented at the EHA Congress further highlight clinical results presented at AACR in April and to be presented at ASCO in June, supporting the hypothesis that the IDO pathway is central to immune suppression in cancer," said Charles J. Link, Jr., M.D., Chief Executive Officer and Chief Scientific Officer. "NewLink Genetics has two separate and distinct types of IDO pathway inhibitors in clinical development. Indoximod, which is wholly owned by NewLink Genetics, has a proposed differentiated mechanism within the IDO pathway and acts as a tryptophan mimetic having a direct effect on immune cells to reverse immune suppression used by cancer to protect itself."

Indoximod in combination with chemotherapeutic agents

Initial results from the Phase 1b portion of a Phase 1b/randomized Phase 2a trial of indoximod in combination with chemotherapeutic agents, idarubicin and cytarabine, for patients with newly diagnosed AML will be presented as an e-poster (Abstract number E-912) by Ashkan Emadi, M.D., Ph.D., Associate Professor of the University of Maryland Greenebaum Comprehensive Cancer Center, at EHA in Madrid on Friday, June 23, 2017, 9:30 AM to Saturday, June 24, 7:00 PM CET and is titled: *Indoximod in Combination with Idarubicin and Cytarabine for Upfront Treatment of Patients with Newly Diagnosed Acute Myeloid Leukemia (AML): Phase 1 Report*.

This study uses a conventional remission induction and consolidation protocol for patients with newly diagnosed AML. Indoximod is given orally starting on day 8 of induction onward. The Phase 1 portion evaluated three dose levels of indoximod (600 mg, 1000 mg, 1200 mg) in combination with the standard of care 7+3 chemotherapy. Twelve patients were enrolled, as of March 1, 2017. The results indicate indoximod does not appear to add significant toxicity to standard remission induction and consolidation therapy for patients with newly diagnosed AML. Initial data suggest a low rate of minimal residual disease (MRD-neg) after one cycle of induction chemotherapy.

Nicholas N. Vahanian, M.D., President and Chief Medical Officer added, "Importantly, these data support further clinical investigation of our IDO pathway inhibitors in combination with currently available therapies, such as chemotherapy for patients with newly diagnosed Acute Myeloid Leukemia (AML)."

Key findings presented from the study include:

- Combination treatment with indoximod and conventional remission induction and consolidation therapy was well tolerated without adding significant toxicity
- Five of 6 (83%) evaluable patients treated with indoximod (600 mg or 1000 mg) achieved complete remission, with no evidence of minimal residual disease

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 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.

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.

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