NewLink Genetics Announces Oral Presentation at the 2018 American Society of Hematology (ASH) Annual Meeting

November 1, 2018

AMES, Iowa, Nov. 01, 2018 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) announced today that an abstract with data pertaining to the use of the Company's investigational immuno-oncology molecule, indoximod, in combination therapy for patients with newly diagnosed acute myeloid leukemia (AML) has been accepted for an oral presentation at the 60th American Society of Hematology (ASH) Annual Meeting and Exposition to be held at the San Diego Convention Center, San Diego, CA, December 1-4th, 2018.

"We are pleased to have an abstract accepted for oral presentation at this year's ASH Annual Meeting," said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. "Our updated Phase 1 data for indoximod plus standard-of-care chemotherapy support the potential for improved outcomes for newly diagnosed AML patients."

- Abstract #332 entitled, *Indoximod combined with standard induction chemotherapy is well tolerated and induces a high rate of complete remission with MRD-negativity in patients with newly diagnosed AML: results from a Phase 1 trial,* Emadi, A., et al*,* to be presented during oral session 616 entitled, "Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Combination Therapy," on Sunday, December 2, 2018, from 9:30-11:00 AM PT, at the ASH Annual Meeting

As of July when the abstract was submitted, 31 newly diagnosed AML patients were consented, with 25 included in the intent-to-treat (ITT) analysis, and 19 meeting qualifications for the per-protocol (PP) analysis. Per-protocol patients were defined as those who took at least 80% of the scheduled indoximod doses. Of 25 ITT patients, 21 (84%) achieved complete response (CR), and 15 of 19 PP patients (79%) achieved CR. Twelve of the 15 PP CR patients had a minimal residual disease (MRD) sample submitted at the end of induction at the time of abstract submission. MRD negativity was defined by a flow cytometry assay at a level of < 0.02% (Hematologics, Inc., Seattle, WA). Ten of these 12 patients (83%) were MRD negative. As to the other three patients, 2 died of complications of AML treatment prior to a MRD marrow sample being submitted while one patient's results were pending. Of the 12 patients who had MRD samples submitted at the end of induction, one patient went directly to bone marrow transplant without undergoing consolidation therapy and was therefore taken off protocol. Of the remaining 11 patients, all 11 (100%) were MRD negative at the end of consolidation, the pre-specified endpoint of the protocol.

Data from the abstract suggest that a high percentage of newly diagnosed AML patients treated with indoximod plus standard-of-care (SOC) chemotherapy achieved CR and showed no evidence of minimal residual disease, or were MRD negative. In addition, data show that indoximod was well tolerated.

The abstract may be found on the ASH Annual Meeting website.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target, suppressing immune response and allowing for immune escape by degrading tryptophan with the resultant production of kynurenine. Indoximod reverses the immunosuppressive effects of low tryptophan and high kynurenine through mechanisms that include modulation of the AhR-driven transcription of genes that control immune function. This results in increased proliferation of effector T cells, increased differentiation into helper T cells rather than regulatory T cells, and downregulation of IDO expression in dendritic cells. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications including recurrent pediatric brain tumors, DIPG, and AML.

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focusing on developing 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. For more information, please visit www.newlinkgenetics.com and follow us on Twitter @NLNKGenetics.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink Genetics that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "may," "appear to," "has potential to," "look forward to," 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 NewLink's clinical trials for product candidates 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, 2017 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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