NewLink Genetics Announces Initial Phase 1 Data with Indoximod Plus Radiation and Chemotherapy for Pediatric Patients with Diffuse Intrinsic Pontine Glioma (DIPG) Presented During AACR Plenary

April 15, 2018

Early data indicate indoximod has clinical activity when used in combination therapies beyond PD-1 inhibition

AMES, Iowa, April 15, 2018 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK), today reported initial data from NLG2105, a Phase 1 study evaluating indoximod, its IDO pathway inhibitor, in combination with radiation and chemotherapy for the treatment of pediatric patients with progressive brain tumors during the “Multimodality Immuno-oncology Approaches” session at the American Association for Cancer Research (AACR) 2018 Annual Meeting in Chicago.

The presentation reviewed NewLink Genetics’ trial evaluating the combination of indoximod with radiotherapy and chemotherapy for children with malignant brain tumors. Indoximod has immunostimulatory effects involving multiple immune cell types. Indoximod works by reversing the effects of low tryptophan by increasing proliferation of effector T cells, and directly reprogramming T regulatory cells into helper T cells. Initially, 29 heavily pretreated patients were enrolled in a dose-escalation protocol with initial data presented at the Society for Neuro-Oncology Conference, November 2017. Seventeen of the 29 patients were appropriate candidates for re-irradiation of their tumors and were treated with a combination therapy including indoximod plus conformational radiotherapy followed by maintenance indoximod combined with temozolomide chemotherapy. The other 12 patients were treated with immuno-chemotherapy consisting of indoximod and temozolomide. In aggregate, with further follow-up, the 29 subjects in the dose-escalation phase of the study had a median progression-free survival (mPFS) of 6.2 months and median time on study (time to regimen failure, TTRF) of 11.7 months. The treatment continued to be well tolerated with minimal toxicity attributed to indoximod.

“These early data, though from a small cohort of pediatric patients, demonstrate the potential of the indoximod plus radiochemotherapy combination without an increase in toxicity for these children,” said Dr. Theodore S. Johnson, M.D., Ph.D., Associate Professor of Pediatrics at Augusta University, lead investigator for the trial.

Once initial safety data were generated, an additional pilot cohort of newly-diagnosed patients with diffuse intrinsic pontine glioma (DIPG) was opened using indoximod during front-line radiotherapy (RT) followed by maintenance indoximod plus temozolomide. Six newly diagnosed DIPG patients initiated treatment, with all 6 having completed induction radioimmunotherapy. Treatment was well tolerated with symptomatic improvement in all 6 patients. Site-reported radiographic review indicated near resolution of tumor in one patient at the end of radiotherapy and observable improvement in 5 out of 6 patients overall. A seventh patient with progressive DIPG received re-RT combined with indoximod, which was well tolerated with symptomatic improvement and objective tumor reduction per site-reported assessment on post-RT MRI.

“These initial findings further support the potential for indoximod in combination with other agents,” said Charles J. Link, Jr., M.D., Chairman and Chief Executive Officer. “We look forward to working with our investigators toward gathering more data on the effects of indoximod on this deadly disease.”

NewLink will also present during poster session PO.IM02.07, Immunomodulatory Agents and Interventions 1, Abstract 3753, entitled: *Indoximod modulates AhR-driven transcription of genes that control immune function*, from 8:00 AM - 12:00 PM CT on Tuesday, April 17, 2018.

Separately, the Company has determined that it will not initiate the randomization portion of Indigo301, its study of indoximod in combination with pembrolizumab or nivolumab for patients with advanced melanoma. NewLink’s clinical team will evaluate the design, trial size and feasibility of an alternative randomized evaluation of indoximod in melanoma in the context of the failure of a competitor’s trial of its enzymatic IDO inhibitor in a similar clinical setting. The evaluation will include analysis of the full data set from the Company’s single-arm Phase 2 melanoma study, the differentiated mechanism of action of indoximod, and the opinions of experts in the field. The Company will present final results from its Phase 2 trial in melanoma and its single-arm Phase 2 trial in pancreatic cancer at an upcoming medical conference in the first half of 2018.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target involved in regulating the tumor microenvironment and immune escape. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1/PD-L1 agents, cancer vaccines, radiation and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies.

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. 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, 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 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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