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Data from Clinical Studies of NewLink Genetics' Two Distinct IDO Pathway Inhibitors to Be Presented at ASCO 2017

AMES, Iowa, May 17, 2017 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced that abstracts from two clinical studies of its IDO pathway inhibitors, indoximod and navoximod (GDC-0919), used in combination with other agents, are now available on the website of the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

An infographic accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/b945495b-6286-4184-881f-b4ea49aa46b4

"The IDO pathway is a key immuno-oncology target and NewLink Genetics has two separate and distinct 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. Navoximod is our direct enzymatic inhibitor of IDO and is partnered with Genentech/Roche," said Charles J. Link, Jr., M.D., Chief Executive Officer and Chief Scientific Officer of NewLink Genetics.

Indoximod in combination with the therapeutic cancer vaccine, PROVENGE®

Results from a randomized, double-blind, placebo-controlled, multi-institutional Phase 2 investigator initiated study with indoximod in combination with the therapeutic cancer vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer will be presented as a poster (Abstract number 3066) by Gautam Gopalji Jha, M.D., Adjunct Assistant Professor, Division of Hematology and Oncology, University of Minnesota, at ASCO in Chicago on Monday, June 5, 2017, 8:00 a.m. - 11:30 a.m. CT, titled, *A phase 2 randomized, double-blind study of sipuleucel-T followed by IDO pathway inhibitor, indoximod or placebo in the treatment of patients with metastatic castration resistant prostate cancer (mCRPC).*

In the study, forty-six patients were randomized into two arms to receive either twice daily oral indoximod (n=22) or placebo (n=24) for 6 months beginning the day after the third and final PROVENGE infusion. Conclusions indicate that treatment with the IDO pathway inhibitor, indoximod, post PROVENGE therapy, leads to significant improvement in radiographic progression free survival (rPFS) when compared to placebo and is well-tolerated.

Key findings presented from the study include:

- Statistically significant improvement in median rPFS was 10.3 months in the treatment arm compared to 4.1 months in the placebo arm ($p = 0.011$)
- Median Overall Survival (OS) has not yet been reached
- Patients tolerated therapy with indoximod with no significant differences in adverse events between the two arms
- There was no statistical difference in the primary endpoint of ELISPOT assay immune response to PA2024, the PROVENGE-related fusion protein, in the 35 of 46 patients who had clinical samples available for testing

"These data further support the hypothesis that targeting the IDO Pathway in combination with a broad backbone of treatment regimens including chemotherapy, anti-PD-1 antibodies and therapeutic vaccines across multiple indications has the potential to provide meaningful clinical benefit without compromising tolerability," commented Nicholas N. Vahanian, M.D., President and Chief Medical Officer of NewLink Genetics.

Navoximod in combination with TECENTRIQ® (atezolizumab) in multiple solid tumors

Initial data from a Phase 1b dose-escalation study of navoximod in combination with TECENTRIQ® for patients with locally advanced or metastatic solid tumors conducted by our partner, Genentech/Roche, will be presented in an oral presentation (Abstract number 105) by Howard A. "Skip" Burris, III, M.D., President Clinical Operations and Chief Medical Officer, Sarah Cannon Research Institute, at ASCO in Chicago on Sunday, June 4, 2017, 10:24 a.m. CT. The presentation is titled, *A*

phase 1b dose-escalation study of combined inhibition of IDO1 (GDC-0919) and PD-L1 (atezolizumab) in patients with locally advanced or metastatic solid tumors.

This Phase 1b, open-label, dose-escalation study is designed to characterize safety and tolerability. Secondary objectives include identifying a maximum tolerated dose (MTD) and recommended Phase 2 dose, and evaluating pharmacokinetics, pharmacodynamics, and anti-tumor activity. Patients were given TECENTRIQ (1200 mg IV every 3 weeks) and escalating doses of navoximod (orally twice daily, for 21 days) using a standard 3+3 design. Initial results from this study (n=52, non-selected heterogeneous population during the dose escalation) found the combination was generally well-tolerated, with peripheral IDO1 modulation, and some early activity signals. Patients were previously treated with prior systemic therapies with a median number of 3 and a range of 1-9. Two patients also received prior immunotherapy.

The design of the trial includes the initial dose-escalation phase reported in this abstract, followed by disease-specific expansion cohorts (enrollment target is 305 patients) for patients with select tumor types including non-small-cell lung cancer (NSCLC), renal cell cancer (RCC), urothelial bladder cancer (UBC), triple negative breast cancer (TNBC), to further evaluate safety, response, and peripheral and tumor pharmacodynamics. Updates for this study will continue to be reported by Genentech/Roche.

Dr. Vahanian continued, "We are encouraged by the clinical profile for the combination of navoximod and atezolizumab from the first phase of this combination trial and look forward to the data for the disease-specific expansion cohorts which are currently accruing patients."

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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