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NewLink Genetics' Indoximod + PROVENGE® Results in Statistically Significant Improvement in Radiographic Progression-Free Survival (rPFS) for Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC) in Phase 2 Trial

AMES, Iowa, June 05, 2017 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today announces the presentation of results from a randomized 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. The abstract, 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)*, is being presented in a poster session by Gautam G. Jha, M.D., Adjunct Assistant Professor, Division of Hematology and Oncology, University of Minnesota, at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, IL this morning from 8:00-11:30 a.m. CT.

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. The indoximod treatment arm for the study showed a statistically significant improvement in radiographic progression-free survival (rPFS) when compared to placebo and was 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

"Given that PROVENGE alone has not shown any PFS benefit in multiple prior studies, this randomized, placebo controlled data, although limited in number of patients, is quite encouraging and has the potential to offer some measurable clinical benefits for patients," said Dr. Jha, principal investigator of this study.

An infographic accompanying this release is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/2b9ffc61-5de8-43b4-8a37-6f8cb3790234

Data reported at ASCO 2017 indicate that treatment with NewLink Genetics' proprietary IDO pathway inhibitor, indoximod, post PROVENGE therapy leads to significant improvement in rPFS when compared to placebo and is well tolerated.

"These results are additional evidence that indoximod has the potential to improve outcomes for patients in combination with therapies beyond the established checkpoint inhibitors," said Charles J. Link, Jr. M.D., Chairman and CEO of NewLink Genetics.

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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