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NewLink Genetics Outlines 2018 Business Priorities to Support Phase 3 Pivotal Trial of Indoximod Plus PD-1 Inhibitors

NewLink Genetics updates financial and clinical guidance

AMES, Iowa, Jan. 08, 2018 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced Indigo301, the name of its upcoming Phase 3 trial of indoximod plus PD-1 inhibitors for patients with advanced melanoma, and outlined 2018 business priorities to support this trial. In addition, the company updated clinical and financial guidance and provided preliminary unaudited financial information for year-end 2017.

These updates were made in conjunction with the 36th Annual JP Morgan Healthcare Conference that begins today in San Francisco. NewLink Genetics' Chairman and Chief Executive Officer, Charles J. Link, Jr., M.D., will discuss the Company's continued execution of its corporate strategy and 2018 priorities as part of a live presentation on Thursday, January 11, 2018, at 11:00 AM PT/2:00 PM ET. The slide presentation with updated guidance has been posted on the Company's website and may be found here. The oral presentation will be webcast and available on the NewLink Genetics website under the Investors & Media tab under Events & Presentations.

Indigo301 is a randomized Phase 3 study of indoximod or placebo plus KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab) for patients with unresectable or metastatic melanoma. The choice of PD-1 inhibitors will be at the physician's discretion, mirroring the general clinical setting. The study will consist of a planned 624 patients enrolled at approximately 100 sites in multiple countries and will include co-primary endpoints of Progression-Free Survival (PFS) and Overall Survival (OS), with a secondary endpoint of Objective Response Rate (ORR).

"NewLink has focused its business priorities on the execution of Indigo301 for patients with advanced melanoma," said Dr. Link. "We will also initiate a randomized Phase 2 trial in collaboration with AstraZeneca for patients with metastatic pancreatic cancer, and we anticipate clinical data from additional development programs."

To expedite the enrollment of Indigo301, NewLink Genetics has expanded the planned number of trial sites both within and outside of the US and plans several clinical recruitment initiatives to engage with the oncology community with the goal to enroll the majority of patients in 2018. As a result of these clinical planning efforts, NewLink Genetics is accordingly updating its guidance for clinical trials as follows:

Clinical Guidance and Milestones

- Enroll the majority of Indigo301 trial by the end of 2018
- Phase 2 results for indoximod + PD-1 blockade in advanced melanoma expected in 2018
- Phase 2 results for indoximod + gem/nab-paclitaxel in pancreatic cancer expected 1H 2018
- Phase 2 randomized AstraZeneca collaboration in pancreatic cancer to initiate 1H 2018

Financial Guidance and Outlook

"Entering 2018, we have aligned our business and investments to drive Indigo301 and other high-potential development programs," said Jack Henneman, Executive Vice President and Chief Financial Officer for NewLink Genetics. "As we continue to progress, we remain committed to maintaining the strength of our balance sheet in support of our most promising clinical programs."

NewLink Genetics ended 2017 with approximately $158 million in cash and cash equivalents. Updated guidance for use of cash is provided in the slide presentation available on the company's website.

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, 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. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1/PD-L1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies. For more information, please visit www.newlinkgenetics.com and follow us on Twitter @NLNKGenetics.

KEYTRUDA® is a registered trademark of Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink 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 "guidance," "upcoming," "will," "plan," "anticipate," "approximate," "expect," 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 NewLink Genetics' financial guidance for 2018; 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; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; 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, 2016 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink 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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