September 25, 2017

NewLink Genetics Announces Clinical Collaboration to Evaluate IO-Based Combination Therapies in Pancreatic Cancer

Phase 2, randomized, double-blind, placebo-controlled trial of indoximod in combination with durvalumab, an immune checkpoint inhibitor, along with gemcitabine/ABRAXANE® (nab-paclitaxel) and durvalumab with gemcitabine/ABRAXANE® versus gemcitabine/ABRAXANE®

AMES, Iowa--(BUSINESS WIRE)-- NewLink Genetics Corporation (Nasdaq: NLNK) today announced that it has entered into a clinical collaboration agreement with AstraZeneca to evaluate the combination of indoximod, NewLink Genetics' small molecule IDO pathway inhibitor, and durvalumab, AstraZeneca's anti-PD-L1 monoclonal antibody, along with standard of care chemotherapy for patients with metastatic pancreatic cancer.

The primary objective for this randomized placebo-controlled, Phase 2 study is to evaluate the efficacy and safety of the immuno-oncology-based combination compared to gemcitabine/ABRAXANE alone. Patients will also be enrolled into a smaller cohort evaluating the combination of durvalumab with gemcitabine/ABRAXANE.

The Phase 2 trial will be funded equally by both companies, with NewLink Genetics serving as the study sponsor. NewLink Genetics' share of the aggregate expense of the trial is not expected to have a material effect on its financial position.

"We are pleased to initiate a joint immuno-oncology clinical collaboration with AstraZeneca," said Dr. Charles J. Link, Jr., Chairman, Chief Executive Officer and Chief Scientific Officer of NewLink Genetics. "As recent data have indicated, indoximod combinations with immunotherapy and chemotherapy show promise of improving outcomes for patients with multiple tumor types."

About Durvalumab

Durvalumab (*Imfinzi*™), a human monoclonal antibody directed against PD-L1, blocks PD-L1 interaction with PD-1 and CD80 on T cells, countering the tumour's immune-evading tactics and inducing an immune response.

Durvalumab is being assessed in Phase III trials as a monotherapy in various stages of NSCLC, in small-cell lung cancer (SCLC), in metastatic urothelial cancer (mUC) and in head and neck squamous cell carcinoma (HNSCC). The combination of durvalumab and tremelimumab is being assessed in Phase III trials in NSCLC, SCLC, mUC and HNSCC and in Phase I/II trials in hepatocellular carcinoma and haematological malignancies.

Imfinzi received accelerated approval from the US Food and Drug Administration for previously treated patients with advanced bladder cancer and is under review in Canada and Australia for similar use.

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, acute myeloid leukemia, pancreatic cancer and prostate cancer.

About Metastatic (Stage IV) Pancreatic Cancer[1]

Approximately 53,670 new cases of pancreatic cancer in the US will be diagnosed in 2017 according to the National Cancer Institute (NCI), and a little over 43,000 people will die of the disease this year. Pancreatic cancer is difficult to detect in its early stages. Because of this, approximately 52% of all pancreatic cancers are metastatic, or advanced, in nature and are associated with a poor prognosis. The 5-year survival rate for pancreatic cancer overall is only 8.2%, and drops to a low of 2.7% for individuals whose pancreatic cancer has metastasized to farther regions of the body.

[1] National Cancer Institute: Pancreas Cancer

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, prostate cancer, acute myeloid leukemia, and pancreatic cancer. For more information, please visit www.newlinkgenetics.com and follow us on Twitter @NLNKGenetics.

IMFINZI™ is a registered trademark of AstraZeneca.

ABRAXANE® is a registered trademark of Celgene Corporation.

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 any 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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Investors:
NewLink Genetics
Lisa Miller, 515-598-2555
Director of Investor Relations
lmiller@linkp.com
or
Media:
LaVoieHealthScience
Andrew Mastrangelo, 617-374-8800, ext. 108
AVP, Public & Media Relations
amastrangelo@lavoiehealthscience.com

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