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NewLink Genetics Receives Notice of Allowance from USPTO Covering Indoximod Salts and Prodrugs

AMES, Iowa, July 10, 2017 (GLOBE NEWSWIRE) -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today announced that it has received a Notice of Allowance for U.S. patent application number 15/171,031 from the United States Patent and Trademark Office (USPTO) covering claims to the salts and prodrugs of indoximod (1-methyl-D-tryptophan). Indoximod is NewLink's orally bioavailable, small molecule targeting the IDO pathway with a distinct mechanism of action.

"We are delighted to hear this positive news from the U.S. patent office," said Charles J. Link, Jr., M.D., Chief Executive Officer of NewLink Genetics. "Indoximod continues to make significant progress in the clinic with promising data across multiple indications. This decision by the U.S. patent office represents a key milestone in the alignment of indoximod's global patent strategy with our clinical development path."

Upon issuance, the new patent will provide NewLink with intellectual property protection covering the compounds and pharmaceutical compositions comprised of salts and prodrugs of indoximod.

"We believe indoximod's promising clinical activity and favorable safety profile, coupled with its differentiated mechanism of action, position indoximod as a key molecule to be considered in IO combinations," said Nicholas Vahanian, M.D., Chief Medical Officer of NewLink Genetics. "We are excited in our upcoming pivotal trial in metastatic melanoma and allowances of these patents align well with our strategy. Additionally, the preclinical data we presented in April at the AACR Annual Meeting illustrated how [NLG802](#), which is our prodrug of indoximod and a new chemical entity, increased the plasma concentrations of indoximod."

This Notice of Allowance concludes the substantive examination of our patent application and will result in the issuance of a U.S. patent after administrative processes are completed. The U.S. patent scheduled to issue from this application will expire in 2036.

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 NLG802

NLG802 is an investigational, orally available prodrug of indoximod, a 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 will evaluate NLG802 in a Phase 1 dose-escalation clinical trial in cancer patients to assess the safety and pharmacokinetics of NLG802.

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 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, prostate cancer, acute myeloid leukemia, and pancreatic 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 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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