NewLink Genetics Announces Merck Has Begun Rolling Submission of Licensure Application for Ebola vaccine V920 (rVSVΔG-ZEBOV-GP) to U.S. Food and Drug Administration

November 15, 2018

In 2014 the Company entered into a license agreement with Merck to develop, manufacture and commercialize NewLink Genetics' Ebola vaccine candidate

AMES, Iowa, Nov. 15, 2018 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) reported today that Merck has begun the submission of a rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for V920 (rVSVΔG-ZEBOV-GP, live attenuated). This rolling submission is made pursuant to the FDA's Breakthrough Therapy Designation for V920, which was announced by Merck in July 2016 and is anticipated to be completed in 2019.

The FDA's approval of this Ebola vaccine would trigger the issuance of a priority review voucher owned by Merck and in which NewLink Genetics has a substantial economic interest. Thereafter, NewLink would have the right to monetize its share of interest in the voucher. This Ebola vaccine candidate was originally developed by the Public Health Agency of Canada (PHAC) and thereafter licensed to NewLink Genetics. Additional information related to this Ebola vaccine candidate may be found in the most recent 10Q and other filings under the "Investors & Media" section on the Company's website.

"We are pleased that Merck has begun the submission process for Ebola candidate V920," said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. "Given the recent outbreaks and recurrent risk Ebola poses to global public health, we are encouraged by the potential for this vaccine to address this deadly disease."

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focused on developing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' immunotherapeutic candidates, indoximod and NLG802, a prodrug of indoximod, are investigational, orally available small molecules targeting the IDO pathway and are designed to harness multiple components of the immune system to combat cancer. Indoximod reverses the immunosuppressive effects of low tryptophan and high kynurenine through mechanisms that include modulation of the AhR-driven transcription of genes that control immune function. This results in increased proliferation of effector T cells, increased differentiation into helper T cells rather than regulatory T cells, and downregulation of IDO expression in dendritic cells. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications including recurrent pediatric brain tumors, DIPG, and AML. For more information, please visit www.newlinkgenetics.com and follow us on Twitter @NLNKGenetics.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink Genetics 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 "may," "appear to," "has potential to," "look forward to," 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 NewLink's clinical trials for product candidates, future financial events, actions of our third party partners, 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, 2017 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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