NewLink Genetics Announces FDA Accepts Partnered Biologics License Application (BLA) and Grants Priority Review for Ebola Vaccine V920 (rVSV∆G-ZEBOV-GP)

September 17, 2019

AMES, Iowa, Sept. 17, 2019 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced that the U.S. Food and Drug Administration (FDA) has accepted Merck's Biologics License Application (BLA) and granted priority review for the investigational Ebola vaccine (V920), for the prevention of disease caused by the Ebola Zaire virus. Merck's rolling submission was made pursuant to the FDA's Breakthrough Therapy Designation for V920, a designation awarded to our partner, Merck, in July 2016. The Prescription Drug User Fee Act (PDUFA), or target action date, is set for March 14, 2020. As NewLink has previously stated, 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.

"We are pleased with this morning's announcement from our partner, Merck. The global community, Merck and government partners have worked relentlessly to further the development of the investigational V920 Ebola vaccine," said Brad Powers, a member of the Office of the CEO. "We are thankful to those frontline responders who work tirelessly to help fight this devastating disease, and we believe this vaccine has the potential to impact many lives."

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focused on developing novel oncology product candidates to improve the lives of patients with cancer where treatment options are limited. NewLink Genetics' IDO pathway inhibitors, indoximod and its prodrug, NLG802, are immuno-oncology drug candidates designed to harness multiple components of the immune system to combat cancer. For more information, please visit 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 contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "will be," "may," "appear to," "has potential to," "look forward to," "are designed 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 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' Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 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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