NewLink Genetics Announces EU Regulatory Committee (CHMP) Recommendation for Conditional Marketing Authorization for Ebola Vaccine V920 (ERVEBO®)

October 21, 2019

AMES, Iowa, Oct. 21, 2019 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) announced today that Friday, October 18th, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a conditional marketing authorization for investigational V920 Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP), as confirmed by our partner, Merck & Co., Inc. (NYSE:MRK). This Committee recommendation will now be reviewed by the European Commission (EC) which, if it chooses to affirm the CHMP's recommendation, will grant a centralized marketing authorization of the vaccine (brand name ERVEBO®) under a unified label valid in 31 European countries.

This opinion issued by the CHMP follows the recent announcement by the FDA that it has accepted the Biologics License Application (BLA) and granted priority review for the investigational Ebola vaccine (V920). As previously reported, the Prescription Drug User Fee Act (PDUFA), or target FDA action date, is set for March 14, 2020. Should this vaccine be approved by the FDA, a monetizable Priority Review Voucher (PRV) would be issued, in which NewLink Genetics owns a substantial financial interest.

"We are delighted by this EMA Committee opinion supporting the conditional marketing authorization of our partnered Ebola virus vaccine," commented Carl Langren, Chief Financial Officer and member of NewLink Genetics' Office of the CEO. "We believe the Committee's positive opinion represents further recognition of the critical nature of this Ebola outbreak and signifies the urgency with which regulatory bodies are addressing the severe risk this disease poses to a worldwide population."

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," "if," "should," "would," "set for," 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.

Investor & Media Contact:

Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
lmiller@linkp.com

Source: NewLink Genetics Corporation

Source: NewLink Genetics Corporation