NewLink Genetics Announces European Commission Grant of Conditional Marketing Approval for Ebola Vaccine V920 (ERVEBO®)

November 12, 2019

AMES, Iowa, Nov. 12, 2019 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) announced that Monday, November 11th, the European Commission (EC) granted a conditional marketing authorization to ERVEBO®, investigational V920 Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP), as confirmed by our partner, Merck (NYSE:MRK), known as MSD outside the US and Canada. With this approval, the EC will grant a centralized marketing authorization for the vaccine with unified labeling that is valid in 31 European countries.

The granting of this approval by the EC follows the September 17th announcement by the FDA that it has accepted the Biologics License Application (BLA) and granted priority review for the investigational Ebola vaccine (V920). The Prescription Drug User Fee Act (PDUFA), or target FDA 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.

"We are thrilled by the EC's decision to approve this Ebola vaccine, offering the potential for protection from this devastating disease," noted Eugene Kennedy, MD, Chief Medical Officer and member of NewLink Genetics' Office of the CEO. "We are also grateful to our partner Merck, and to the regulatory bodies involved for their diligent efforts to advance solutions to combat this deadly illness."

About NewLink Genetics Corporation

NewLink Genetics is a clinical-stage biopharmaceutical company that has historically focused on developing novel immunotherapeutic products for the treatment of patients with cancer. On September 30, 2019, NewLink announced its intent to merge with Lumos Pharma, a private clinical-stage biopharmaceutical company targeting rare and neglected diseases. At the close of the proposed merger, the combined company will operate as Lumos Pharma focused on Lumos' sole product candidate, LUM-201 (ibutamoren), an oral growth hormone (GH) secretagogue targeting pediatric growth hormone deficiency (PGHD) and other rare endocrine disorders. If approved, LUM-201 has the potential to represent the first orally administered growth hormone stimulating therapy for a subset of PGHD patients, an established market where daily recombinant human growth hormone injections represent the current standard-of-care treatment regimen. 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 "forecast," "projected," "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," "potential," 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 expectation regarding the centralized marketing authorization to be granted by the EC; the PDUFA date; NewLink's right to monetize its share of the priority review voucher owned by Merck; 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 the risks related to the ability to monetize and realize the anticipated benefits of the priority review voucher and risks that the conditional authorization does not covert into a standard marketing authorization. Further risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements are discussed in "Risk Factors" and elsewhere in NewLink Genetics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 and other reports filed with the 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

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