

NewLink Genetics Announces FDA Approval of Ebola Vaccine V920 (ERVEBO®)

December 20, 2019

AMES, Iowa, Dec. 20, 2019 (GLOBE NEWSWIRE) -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) announced today that, after priority review, the [FDA has granted approval of ERVEBO®](#), or Zaire Ebola virus vaccine V920 (rVSVΔG-ZEBOV-GP), as confirmed by our partner, [Merck](#) (NYSE:MRK), known as MSD outside the US and Canada. This represents the first vaccine approved by the FDA for the Ebola virus and follows the November 11th grant by the European Commission (EC) of a [marketing authorization for ERVEBO®](#) across 31 European countries.

Yesterday's approval comes almost three months prior to the Prescription Drug User Fee Act (PDUFA), or target FDA action date, originally set for March 14, 2020. As NewLink has previously stated, the FDA's approval of this Ebola vaccine will trigger the issuance of a priority review voucher (PRV) owned by Merck and in which NewLink Genetics has a substantial economic interest. Thereafter, NewLink will have the right to monetize its share of interest in the voucher.

"We are delighted by the FDA's decision to approve this Ebola vaccine and by the agency's recognition of the potential this vaccine may offer to protect individuals who may be exposed to Ebola from contracting this deadly disease," commented Eugene Kennedy, MD, Chief Medical Officer and member of NewLink Genetics' Office of the CEO. "We are grateful to our partner Merck, and to the regulatory bodies involved, for their dedication to advancing solutions to combat this deadly illness."

ERVEBO® is a registered trademark of Merck Sharp & Dohme Corp ("Merck")

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's 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.

Information Regarding the Proposed Merger with Lumos and Where to Find It

In connection with the proposed merger (the "Merger") among NewLink, Cyclone Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (the "Merger Sub"), and Lumos, pursuant to the terms of the Agreement and Plan of Merger dated September 30, 2019 (the "Lumos Merger Agreement") by and among NewLink, Merger Sub and Lumos, the Company intends to file relevant materials with the Securities and Exchange Commission (the "SEC"), including a proxy statement for its stockholders containing the information with respect to the Merger and the Lumos Merger Agreement specified in Schedule 14A promulgated under the Securities Exchange Act of 1934, as amended and describing the proposed Merger. The proxy statement and other relevant materials (when they become available), and any other documents filed by the Company with the SEC, may be obtained free of charge at the SEC website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by the Company by directing a written request to: NewLink Genetics Corporation, 2503 South Loop Drive, Ames, IA 50010. Investors and security holders are urged to read the proxy statement and the other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

Participants in the Solicitation

The Company and its directors and executive officers and Lumos and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of the Company in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger will be included in the proxy statement referred to above. Additional information regarding the directors and executive officers of the Company is also included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and the proxy statement for the Company's 2019 Annual Meeting of Stockholders. These documents are available free of charge at the SEC web site (www.sec.gov) and from the Company at the address described above.

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 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 convert 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.

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