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## **Merck and NewLink Genetics Enter Into Licensing and Collaboration Agreement for Investigational Ebola Vaccine**

### **Clinical Development, Manufacturing Expertise, and Scale Critical to Success**

WHITEHOUSE STATION, N.J. & AMES, IA--(BUSINESS WIRE)-- Merck (NYSE:MRK), known as MSD outside the United States and Canada, and NewLink Genetics Corporation (NASDAQ:NLNK), announced today that they have entered into an exclusive worldwide license agreement to research, develop, manufacture, and distribute NewLink's investigational rVSV-EBOV (Ebola) vaccine candidate.

The vaccine candidate, originally developed by the Public Health Agency of Canada (PHAC), is currently being evaluated in Phase I clinical trials. Pending the results of ongoing Phase I trials the U.S. National Institutes of Health (NIH) has announced plans to initiate, in early 2015, a large randomized, controlled Phase III study to evaluate the safety and efficacy of the rVSV-EBOV vaccine and another investigational Ebola vaccine co-developed by the National Institute of Allergy and Infectious Diseases (NIAID) and GlaxoSmithKline.

"Effective Ebola vaccines will be a critical component of comprehensive prevention and control measures for people at risk of Ebola virus infection and to stem future outbreaks globally," said Dr. Julie Gerberding, president of Merck Vaccines. "Merck is committed to applying our vaccine expertise to address important global health needs and, through our collaboration with NewLink, we hope to advance the public health response to this urgent international health priority."

According to Dr. Charles Link, chairman and chief executive officer of NewLink Genetics, "Merck's vaccine development expertise, commercial leadership and history of successful strategic alliances make it an ideal partner to expedite the development of rVSV-EBOV and, if demonstrated to be efficacious and well-tolerated, to make it available to individuals and communities at risk of Ebola virus infection around the world."

Under the terms of the agreement, Merck will be granted the exclusive rights to the rVSV-EBOV vaccine candidate as well as any follow-on products. The vaccine candidate is under an exclusive licensing arrangement with a wholly-owned subsidiary of NewLink Genetics. Under these license arrangements, the PHAC retains non-commercial rights pertaining to the vaccine candidate.

Phase I clinical trials of the rVSV-EBOV vaccine are now underway at the Walter Reed Army Institute of Research and the NIAID at the NIH. Additional Phase I studies are underway or planned to begin in the near future at clinical research centers in Switzerland, Germany, Kenya, and Gabon in a World Health Organization-coordinated effort, and in Canada by the Canadian Immunization Research Network.

"This vaccine is the result of years of hard work and innovation by Canadian scientists. We are pleased that this new alliance coupled with the clinical trials currently underway will further strengthen the possibility that the vaccine will make a difference in the global response to the Ebola outbreak," said Canada's Minister of Health, Rona Ambrose.

### **About rVSV Vaccine Platform**

This vaccine platform is based on an attenuated strain of vesicular stomatitis virus that has been modified to express an Ebola virus protein that plays an essential role in establishing virus infection. The rVSV-EBOV vaccine was created by scientists at the Public Health Agency of Canada's National Microbiology Laboratory. A significant portion of the funding for the further development of the vaccine came from the CBRN Research and Technology Initiative, a federal program led by Defence Research and Development Canada. In 2010, the PHAC signed a licensing arrangement with BioProtection Systems (BPS), a wholly-owned subsidiary of NewLink Genetics, as the sole licensee for these vaccines and the underlying technology. BPS has worked with the PHAC to produce clinical trial materials and to move this vaccine candidate into Phase I studies.

### **About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United

States and Canada. Through our prescription medicines, vaccines, biologic therapies, and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](#), [Facebook](#) and [YouTube](#).

## **About NewLink Genetics Corporation**

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immuno-oncology products to improve treatment options for patients with cancer. NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. BioProtection Systems, a wholly-owned subsidiary of NewLink Genetics Corporation, is focused on the research, development and commercialization of vaccines. BPS is focused on control of emerging infectious diseases, including improvement of existing vaccines and providing rapid-response prophylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics or acts of bioterrorism. For more information please visit <http://www.linkp.com>.

## **Merck Forward-Looking Statement**

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2013 Annual Report on Form 10-K and the company's other filings with the SEC available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

## **NewLink Genetics Corporation Forward-Looking Statement**

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," 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 regarding plans to develop and commercialize our 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 makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2013, and subsequent filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink 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's views as of any date subsequent to the date of this press release.

Photos/Multimedia Gallery Available: <http://www.businesswire.com/multimedia/home/20141124005161/en/>

**Merck Media Contacts:**  
Pam Eisele, 267-305-3558

Imraan Munshi, 215-652-0059

or

**Investor Contacts:**

NewLink Genetics

Jack Henneman, 515-598-2561

or

Merck

Justin Holko, 908-423-5088

Source: Merck

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