

## Phase III Trial of the MSD and NewLink Genetics Investigational Ebola Vaccine Initiated in Sierra Leone

### **rVSV-ZEBOV-GP (V920) Now Being Studied in Three Key Safety and Efficacy Clinical Trials**

*KENILWORTH, N.J. and AMES, IA, April 14, 2015 – MSD, known as MERCK in the United States and Canada, and NewLink Genetics Corporation, confirmed today that the third, late-stage, clinical trial of their Ebola vaccine candidate rVSV-ZEBOV-GP (V920) has been initiated in Sierra Leone. The vaccine candidate was originally developed by the Public Health Agency of Canada's National Microbiology Laboratory and licensed to NewLink Genetics in 2010. On Nov. 24, 2014, MSD and NewLink Genetics announced an exclusive licensing and collaboration agreement for the investigational Ebola vaccine.*

The Phase II/ III safety and effectiveness study, called STRIVE (**S**ierra Leone **T**rial to **I**ntroduce a **V**accine against **E**bola) taking place in Sierra Leone will involve 6,000 health and other frontline workers and is being led by the Sierra Leone College of Medicine and Allied Health Sciences, Sierra Leone Ministry of Health and Sanitation, and the U.S. Centers for Disease Control and Prevention (CDC).

“Fighting Ebola remains a global health priority, and MSD is committed to advancing the development of our and NewLink’s vaccine candidate as part of our overall response to the crisis,” said Mark Feinberg, M.D., Ph.D., chief public health and science officer, MSD Vaccines.

The MSD and NewLink rVSV-ZEBOV-GP vaccine candidate is now included in three large-scale clinical trials currently underway in West Africa. In addition to the trial in Sierra Leone, these trials are:

- **The Partnership for Research on Ebola Vaccines in Liberia (PREVAIL):** Led by a Liberia-U.S. clinical research partnership and sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), PREVAIL was designed to enroll approximately 27,000 healthy men and women aged 18 years and older. This randomized, controlled Phase II/III study to evaluate safety and efficacy, involves rVSV-ZEBOV-GP and another experimental Ebola vaccine. Based on declining Ebola virus incidence in Liberia, the trial leaders have determined that it is scientifically appropriate to expand the trial to additional sites in other West African countries. Discussions are underway to explore that possibility, but the trial has not yet expanded outside of Liberia.
- **Phase III study in Guinea:** The World Health Organization (WHO), the Health Ministry of Guinea, Médecins sans Frontières (MSF), Epicentre and The Norwegian Institute of Public Health have initiated a safety and effectiveness study investigating Merck's and NewLink's rVSV-ZEBOV-GP, the vaccine candidate that was selected by the WHO and study partners to be assessed first in this study.

### **About MSD**

MSD belongs to Merck & Co., Inc., located in Kenilworth, NJ, USA, a global healthcare leader working to help the world be well. 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.msd.de](http://www.msd.de)

**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 [www.linkp.com](http://www.linkp.com).

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