



NEWS RELEASE

# In Interim Results from Phase 3 Study, Merck's Investigational Ebola Vaccine Efficacious; Study is Continuing

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Global Collaboration Enabled Vaccine to Move from First-in-Human Studies to Initial Phase 3 Results Within One Year

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (known as MSD outside the US and Canada) said today that its investigational Ebola vaccine candidate, rVSV-ZEBOV, was found to have 100 percent efficacy in an analysis of interim data from a Phase 3 ring vaccination trial in Guinea. Preliminary conclusions from this study, which is continuing, were published on-line today in *The Lancet*. The authors report that vaccine efficacy was 100 percent (95% confidence interval: 74.7 - 100%;  $p=0.0036$ ) following vaccination with a single dose of the rVSV-ZEBOV vaccine. It appeared that all vaccinated individuals were protected against Ebola virus infection within 6 to 10 days of vaccination.

To date, more than 4,000 participants have received the vaccine in this innovative trial, called "Ebola ça suffit" or "Ebola, that's enough." The trial was conducted by a team that included researchers from the World Health Organization (WHO), the Norwegian Institute of Public Health, the Health Ministry of Guinea and Médecins sans Frontières, among others. The results from this continuing study, as well as other studies already underway (see below) and additional studies to be conducted, will be used to support worldwide regulatory submissions.

"Merck has an enduring commitment to develop vaccines and medicines that address the world's most devastating infectious diseases," said Dr. Roger M. Perlmutter, president of Merck Research Laboratories. "Building on pioneering early work by the Public Health Agency of Canada and NewLink Genetics Corporation, the extraordinary

efforts of the team in Guinea and other experts have yielded interim results that suggest a potential role for our rVSV-ZEBOV vaccine in the fight against Ebola disease.”

## About the development of the rVSV-ZEBOV vaccine

The rVSV-ZEBOV vaccine was initially engineered with support from the Public Health Agency of Canada and was licensed to NewLink Genetics Corporation. To make the vaccine, the vesicular stomatitis virus was weakened by removing one of its genes, which was then replaced with a single Ebola virus gene that cannot cause disease by itself. Vaccinated individuals have been shown to develop antibodies against the Ebola virus, which could help protect against future infection. The significance and durability of this immune response have not been determined.

In late 2014, when the current Ebola outbreak was at its most severe, Merck licensed rVSV-ZEBOV from NewLink Genetics, with the goal of accelerating the assessment of this candidate vaccine. Since that time, Merck has helped to enable a broad development program, including the interim phase 3 efficacy results released today. To date, the rVSV-ZEBOV vaccine has been administered to more than 9,000 people in phase 1, 2 and 3 clinical trials.

In addition to NewLink and the Public Health Agency of Canada, leading global and national health organizations including the National Institute of Allergy and Infectious Diseases (NIAID), the Walter Reed Army Institute of Research (WRAIR), the Canadian Immunization Research Network (CIRN) and the US Army Medical Research Institute of Infectious Diseases (USAMRIID) have helped to conduct studies of the rVSV-ZEBOV vaccine. Major funders for these studies included the US Department of Defense’s (DoD) Defense Threat Reduction Agency (DTRA) and Joint Vaccine Acquisition Program (JVAP), the US Department of Health and Human Service’s Biomedical Advanced Research Development Authority (BARDA), the National Institutes of Health (NIH) and the Wellcome Trust.

In addition to the phase 3 trial in Guinea described above, other studies evaluating the rVSV-ZEBOV vaccine include the STRIVE (Sierra Leone Trial to Introduce a Vaccine against Ebola) phase 3 study currently being conducted by the Sierra Leone College of Medicine and Allied Health Sciences (COMAHS), Sierra Leone Ministry of Health and Sanitation and the US Centers for Disease Control and Prevention (CDC); and the PREVAIL (Partnership for Research on Ebola Vaccines in Liberia) phase 2 study being conducted by a Liberia-NIH partnership in Liberia.

Merck is responsible for research, development and manufacturing efforts in support of the rVSV-ZEBOV vaccine. Merck has committed to work closely with other stakeholders to accelerate the continued development, production and, if licensed, distribution of the vaccine.

## 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**.

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This news release of Merck & Co., Inc., Kenilworth, NJ, USA (the "company") 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 the company'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 healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company'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 the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company 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 the company's 2014 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

Merck

Media Contacts:

Pam Eisele, 267-305-3558

or

Investor Contacts:  
Justin Holko, 908-740-1879

