Merck Remains Steadfast in its Commitment to Supporting International Response Efforts to the Ebola Outbreak in the Democratic Republic of the Congo (DRC)

Terms:
Company Statements

Subtitle:
Merck Continues to Maintain a Pre-licensure Stockpile of Investigational V920 Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live attenuated) Being Used to Support International Outbreak Response

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KENILWORTH, N.J. April 9, 2019 -- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today re-affirmed its commitment to continue to work with the World Health Organization (WHO), Gavi (the Vaccine Alliance), the United States Government and other key stakeholders to provide supply of the investigational V920 Ebola Zaire vaccine as part of international response efforts to the current Ebola outbreak in the Democratic Republic of the Congo (DRC).

Merck recognizes the unique challenges this current outbreak presents, and we commend the Government of the DRC, the WHO and its Regional Office for Africa, Médecins Sans Frontières (MSF) and all involved for their leadership and courage in working tirelessly to stop this dangerous outbreak.

As this outbreak remains a challenge to all concerned, Merck continues to work urgently with our collaborators in three key areas:

1. Pre-licensure preparedness: supporting outbreak response efforts prior to regulatory licensures by providing the investigational vaccine for use;
2. Registrations: working rapidly to obtain regulatory licensures and WHO prequalification, including accelerated registrations in African countries at risk for Ebola outbreaks; and
3. Post-licensure preparedness: if approved, supplying vaccine to support future, more permanent, stockpiles comprised of licensed vaccine.

As of April 8, 2019, Merck has donated and shipped nearly 145,000 doses of investigational vaccine to the WHO, based on requests by the WHO, in support of international response efforts to the outbreaks. At the time of this posting, according to the DRC Ministry of Health, it is estimated that more than 96,000 individuals have now been vaccinated as part of the ongoing response. Merck is working to maintain a stockpile of 300,000 dose-equivalents of investigational vaccine, as we have previously communicated. This stockpile consists of a mixture of the vaccine in bulk form not filled in vials and filled vaccine doses in vials. This stockpile, as with any vaccine stockpile, is inherently dynamic -- numbers can change due to shipments, expiry and replenishment. Recognizing that the situation in the DRC is dynamic and that vaccine demand might increase, we are actively working with our collaborators to meet potentially evolving needs, including ongoing replenishment and potential expansion of the current stockpile beyond the doses already made available. Beyond doses already sent, there are approximately 195,000 doses available and ready to be shipped as needed, and Merck is expecting an estimated 100,000 additional doses to be available for shipment within the next three months. We are also working with collaborators to consider and pursue options that might allow for even more investigational doses to be available prior to licensure.

Merck is simultaneously making progress with regulatory submissions for V920. As previously announced in November 2018, the submission of a rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for V920 is underway. The European Medicines Agency (EMA) recently accepted the Marketing Authorization Application (MAA) for V920 and will begin review of the application. In parallel, and in close collaboration with FDA and EMA, submissions have also been made to the WHO to achieve prequalification status and to health authority representatives of the African Vaccine Regulatory Forum (AVAREF). Thanks to strong collaborations across multiple partners, reviews are being pursued in as concurrent and accelerated a manner as possible. These regulatory submission milestones represent important progress toward registration, and if approved, helping enable more
sustainable access of an Ebola vaccine to those who need it most, including communities in countries at risk for Ebola outbreaks in Africa.

About Merck’s Investigational V920 Ebola Zaire Vaccine

V920, Merck's investigational Ebola Zaire vaccine, was initially engineered by scientists from the Public Health Agency of Canada’s National Microbiology Laboratory and subsequently licensed to a subsidiary of NewLink Genetics Corporation. In late 2014, when the Ebola outbreak in western Africa was at its peak, Merck licensed V920 from NewLink Genetics. Since that time, the company has worked closely with a number of external collaborators to enable a broad clinical development program with partial funding from the U.S. Government, including the Department of Health and Human Service’s Biomedical Advanced Research Development Authority (BARDA) under Contract No. HHSO100201700012C and other contracts, as well as the Department of Defense’s Defense Threat Reduction Program (DTRA) and Joint Vaccination Acquisition Program (JVAP), among others. Merck is responsible for the research, development, manufacturing and regulatory efforts in support of V920. The company has committed to working closely with other stakeholders to accelerate the continued development, production and, if licensed, distribution of the vaccine.

Merck’s Commitment to Infectious Diseases

For more than 100 years, Merck has contributed to the discovery and development of novel medicines and vaccines to combat infectious diseases. In addition to a combined portfolio of vaccines and antibacterial, antiviral and antifungal medicines, Merck has multiple programs that span discovery through late-stage development. To learn more about Merck's infectious diseases pipeline, visit www.merck.com.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. 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 health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. 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 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; 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 2018 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).

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