



NEWS RELEASE

# FDA Accepts Merck's Biologics License Application (BLA) and Grants Priority Review for V920, the Company's Investigational Vaccine for Ebola Zaire Virus

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Merck Continues to Expand Investigational Supply to Support International Ebola Outbreak Response

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck, known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) and granted priority review for Merck's investigational Ebola vaccine (V920), under review for the prevention of disease caused by the Ebola Zaire virus. The Prescription Drug User Fee Act (PDUFA), or target action date, is set for March 14, 2020. In July 2016, the FDA granted Breakthrough Therapy Designation to V920.

"Merck has worked with government partners and the global health community to accelerate development of our investigational V920 Ebola vaccine. FDA's priority review designation underscores our long-standing partnership with the U.S. government toward its development and licensure," said Dr. Paula Annunziato, vice president, Merck Research Laboratories. "A top priority for us remains achieving registration of V920 and regulatory approval of our German manufacturing site, so that licensed supply can be produced over time to support global public health preparedness and health security objectives. We look forward to continuing to work with the FDA throughout the review process."

In parallel to its regulatory efforts, Merck has remained steadfast in its commitment to scale-up the number of investigational V920 Ebola vaccine doses being produced to help international public health officials and government authorities meet ongoing, unpredictable, and evolving outbreak response needs in the Democratic

Republic of the Congo (DRC) and neighboring countries. Since May 2018, Merck has donated and shipped more than 245,000 1.0mL investigational V920 Ebola vaccine doses to the World Health Organization (WHO) in response to requests by the WHO. Beyond doses already delivered, more than 190,000 additional 1.0mL investigational doses are currently available and ready to ship to the outbreak region at WHO's request.

In addition, in June 2019, Merck started executing an updated replenishment strategy to increase investigational V920 Ebola vaccine supply, based on ongoing consultations with the U.S. Department of Health and Human Services, WHO and Gavi (the Vaccine Alliance). The strategy targets production of an additional estimated 650,000 1.0mL investigational doses, to be released and made available in a phased manner over the next 6-to-18 months. In total, past, current and upcoming production will amount to more than 900,000 1.0mL investigational doses of V920. Stockpiles are inherently dynamic, and therefore all estimates included here are as of the time of this statement and subject to change.

New investigational supply will be based on a combination of leveraging material from ongoing production activities at the planned commercial manufacturing site in Germany and new production at a clinical manufacturing site in the U.S. While the company continues to explore opportunities to accelerate production, our timing estimates are based on the need to meet manufacturing and quality-control requirements.

"We continue to be proud and humbled to provide our investigational V920 Ebola vaccine as an additional tool in support of the comprehensive public health response efforts against the current Ebola outbreak. Merck appreciates and continues to work closely with our collaborators and is inspired by the relentless determination of everyone involved, especially frontline responders, working to contain this unique and dangerous outbreak," Dr. Annunziato added.

## Status of International Regulatory Filings for Merck's Investigational V920 Ebola Zaire Vaccine

In March 2019, the European Medicines Agency (EMA) accepted the Marketing Authorization Application (MAA) for V920 for review. 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).

## 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) and the Department of Defense's Defense Threat Reduction Program (DTRA) and Joint Vaccination Acquisition Program (JVAP), among others. Merck's V920 investigational supply replenishment activities are supported by partial Federal funding from BARDA under Contract No. HHSO100201700012C. 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](http://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](http://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](http://www.sec.gov)).

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