



NEWS RELEASE

Merck Receives EU CHMP Positive Opinion for Investigational V920 Ebola Zaire Vaccine for Protection Against Ebola Virus Disease

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Opinion Supports Use of KEYTRUDA, as Monotherapy or in Combination with Platinum and 5-Fluorouracil Chemotherapy, in Patients Whose Tumors Express PD-L1 (CPS ≥ 1)

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending a conditional marketing authorization for V920 Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live). If affirmed by the European Commission, the vaccine will be authorized under the brand name ERVEBO® (pronounced UR-VEE-BOH) and indicated for active immunization of individuals 18 years of age or older to protect against Ebola Virus Disease (EVD) caused by Zaire Ebola virus. The use of ERVEBO should be in accordance with official recommendations. The CHMP's recommendation, completed under accelerated assessment, will now be considered by the European Commission. If the European Commission affirms the CHMP opinion, it will grant a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the European Union, as well as European Economic Area members, Iceland, Liechtenstein and Norway. ERVEBO is currently under review in the United States.

"This positive opinion from CHMP represents important progress towards licensure of a vaccine to provide protection from Ebola virus disease to people in areas affected by the Ebola Zaire virus," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "Our work would not have been possible without the efforts of countless numbers of people, especially those from the World Health Organization and many other government and non-governmental organizations, who have worked tirelessly on the development of this important vaccine."

Our top priority is the achievement of registration of our German ERVEBO manufacturing site, so that licensed supply can be used to support global public health preparedness."

Status of International Regulatory Filings for V920

In September 2019, the U.S. Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) and granted priority review for V920. The Prescription Drug User Fee Act (PDUFA), or target action date, is set for March 14, 2020. In parallel, and in close collaboration with FDA and EMA, submissions have also been made to the World Health Organization (WHO) to achieve prequalification status and to African health authorities in collaboration with the African Vaccine Regulatory Forum (AVAREF).

On July 25, 2016, Merck announced that the U.S. Food and Drug Administration (FDA) had granted the vaccine candidate Breakthrough Therapy Designation, and that the European Medicines Agency (EMA) had granted PRIME (PRIority MEdicines) status.

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

PRIME is a process from the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. PRIME is intended to optimize development plans and speed up assessment of the medicine's application so these medicines may potentially reach patients earlier. PRIME focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by EMA. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data.

About V920

V920 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.

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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