



News Release

FOR IMMEDIATE RELEASE

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MSD's ERVEBO® [Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP) live] Granted Conditional Approval in the European Union

Authorisation Represents Significant Advancement in the Global Response to Ebola

MSD Remains Committed to Working with International Partners in Ebola Outbreak Response

Hoddesdon, November 12, 2019 -- MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA (NYSE: MRK)) has announced that the European Commission has granted a conditional marketing authorisation to ERVEBO for active immunisation 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 approval is based on data submitted to the European Medicines Agency for accelerated assessment in March 2019. With this approval, the European Commission will grant a centralised marketing authorisation 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 Priority Review with the U.S. Food and Drug Administration (FDA) with a target action date of March 14, 2020.

“The European Commission’s marketing authorisation of ERVEBO is the result of an unprecedented collaboration for which the entire world should be proud. It is a historic milestone and a testament to the power of science, innovation, and public-

private partnership,” said Kenneth C. Frazier, chairman, and chief executive officer, MSD. “After recognising the need and urgency for an Ebola Zaire vaccine, many came together across sectors to answer the global call for outbreak preparedness. We at MSD are honoured to play a part in Ebola outbreak response efforts and we remain committed to our partners and the people we serve. We also look forward to continuing to work with the FDA and the African countries on their regulatory reviews over the coming months and with the World Health Organisation on vaccine prequalification, which will help broaden access to this important vaccine for those who need it most.”

Given the unique manufacturing requirements for ERVEBO, this approval allows MSD to initiate manufacturing of licensed doses in Germany, which are expected to start becoming available in the third quarter of 2020. MSD is also working closely with the World Health Organisation (WHO), the United States Government, and Gavi, the Vaccine Alliance, to ensure uninterrupted access of its investigational Ebola Zaire vaccine (V920) in support of ongoing international response efforts in the Democratic Republic of Congo (DRC). As previously announced, MSD has committed to manufacture additional doses of investigational V920 over the coming year.

As part of its clinical development, and in response to requests from the WHO, MSD has, to date, donated more than 250,000 1.0mL doses of V920 to the WHO for use in outbreak response efforts occurring in the DRC since May 2018.

MSD has made a submission to the WHO seeking prequalification status for the vaccine, as well as submissions to selected African country National Regulatory Authorities in collaboration with the African Vaccine Regulatory Forum (AVAREF), which, if approved, will allow the vaccine to be registered in several African countries.

More About the Development of Investigational V920

V920 was initially engineered by scientists from the Public Health Agency of Canada’s National Microbiology Laboratory and the technology was subsequently obtained by a subsidiary of NewLink Genetics Corporation. In late 2014, when the Ebola outbreak in western Africa was at its peak, and with the goal of applying its capabilities in process research, clinical development, and manufacturing to an important global effort, MSD acquired the rights to develop 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. MSD's V920 vaccine supply replenishment activities are supported by partial Federal funding from BARDA under Contract No. HHSO100201700012C. MSD has been 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 distribution of the vaccine.

About MSD

For more than a century, MSD, a leading global biopharmaceutical company, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. 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, programmes and partnerships. Today, MSD 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.msd-uk.com and connect with us @MSDintheUK on [Twitter](#), [Instagram](#), [LinkedIn](#), [YouTube](#) and [Facebook](#).

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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