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FDA grants priority review for Merck’s Ebola Vaccine

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

Merck, known as MSD outside the United States and Canada, has 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.