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Johnson & Johnson today announced that its Janssen Pharmaceutical Companies received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for its investigational Ebola vaccine regimen for the prevention of the Ebola Virus Disease caused by the *Zaire ebolavirus* species. Two Marketing Authorisation Applications (MAAs) were submitted to the EMA in support of the vaccines in the two-dose regimen (Ad26.ZEBOV, MVA-BN-Filo).

Janssen's investigational Ebola vaccine regimen is specifically designed to support preventive vaccination in countries that are at risk of Ebola outbreaks, as well as for other at-risk groups such as healthcare workers, Biosafety Level 4 (BSL-4) lab workers, military deployed from other countries, airport staff and visitors to high-risk countries. Janssen is collaborating with the World Health Organization (WHO) on vaccine pre-qualification to broaden access of its investigational Ebola vaccine regimen to those most in need and enable registration in African countries; European Commission (EC) approval of this regimen may help accelerate this process.

The most recent Ebola outbreak, which started in the Democratic Republic of the Congo (DRC) in 2018 was the world's second worst on record.[1] It has caused more than 3,000 cases and over 2,000 deaths – a mortality rate of 65 percent.[2]

"This outbreak in the DRC saw the first large-scale deployment of vaccines coordinated via a comprehensive public health response, which included Janssen's novel investigational two-dose vaccine regimen," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson. "We are pleased with the Committee's positive opinion as it brings us one step closer to achieving our ultimate vision at Johnson & Johnson to go further and prevent future Ebola outbreaks before they start and to help communities most at risk."

To date, approximately 60,000 people have been vaccinated with Janssen's investigational preventive Ebola vaccine regimen in clinical studies and vaccination initiatives.[3-12] Janssen-sponsored Phase 1 studies have been reported in peer-reviewed journals including *JAMA* [3,4] and the *Journal of Infectious Diseases,*[5,6] and Phase 1, 2 and 3 data were recently presented at the 2019 European Congress of Clinical Microbiology & Infectious Disease (ECCMID).[7-9] These studies indicate that the vaccine regimen is well tolerated, inducing robust and durable immune responses to the *Zaire ebolavirus* strain. In May 2019, the WHO's Strategic Advisory Group of Experts (SAGE) on immunization recommended the use of the Janssen investigational Ebola vaccine regimen as part of efforts to contain the DRC outbreak[10] and more than 50,000 people in the DRC[11] and Rwanda[12] were vaccinated.

The regimen includes Ad26.ZEBOV as the first dose, based on Janssen's proprietary AdVac® viral vector technology,[13] and MVA-BN-Filo as the second dose, based on Bavarian Nordic's MVA-BN® technology, administered approximately eight weeks later.[5] The goal of this two-dose approach is to induce long-term immunity against Ebola Virus Disease. The AdVac® technology, alongside the company's PER.C6®

production cell line,[13] is also being used in Johnson & Johnson's efforts to develop a preventive vaccine against COVID-19 disease,[14] and is the basis of the company's investigational HIV,[15] RSV[16] and Zika vaccine candidates.

"Today's CHMP opinion confirms the potential of Janssen's vaccine technology, which we hope to apply against a range of established and emerging epidemic threats, including the COVID-19 pandemic," said Johan Van Hoof, M.D., Global Therapeutic Area Head, Vaccines, and Managing Director, Janssen Pharmaceutica N.V. "If our investigational Ebola vaccine regimen is approved by the European Commission, this would be Janssen's first vaccine approval and an important step forward in our efforts to help protect people at risk of Ebola Virus Disease. Our progress of accelerating the development and delivery of an Ebola vaccine would not have been possible without the expertise and dedication of our multiple partners around the world, for whom we are extremely grateful."

Johnson & Johnson has made a significant investment in the investigational Ebola vaccine regimen since its decision to accelerate the development program in 2014 in response to the Ebola crisis in West Africa. The Company is grateful to its global partners who have helped to support and co-fund these efforts, including Bavarian Nordic A/S, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS), the Innovative Medicines Initiative (IMI) funded through the EU Horizon 2020 program, and the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

Regulatory Submissions & Status

Today's positive opinion follows the granting of an Accelerated Assessment for Janssen's investigational preventive Ebola vaccine regimen MAAs by the CHMP in September 2019. The MAAs are supported by data from more than ten Phase 1, 2 and 3 clinical studies evaluating the safety and immunogenicity (ability to induce an immune response) of the vaccine regimen in more than 6,500 adults and children across the U.S., Europe and Africa,[3-9] preclinical studies, and immunobridging analyses comparing the results of clinical and preclinical studies.

Discussions with the FDA are ongoing to define the required data set for filing Janssen's Ebola vaccine regimen under the FDA's Animal Rule licensure pathway.

About Janssen's Ebola Vaccine Regimen

The Janssen investigational preventive Ebola vaccine regimen (Ad26.ZEBOV, MVA-BN-Filo) utilizes a viral vector strategy in which viruses – in this case adenovirus serotype 26 (Ad26) and Modified Vaccinia Virus Ankara (MVA) – are genetically modified so that they cannot replicate in human cells. In addition, these vectors are modified to safely carry the genetic code of an Ebola virus protein in order to trigger an immune response.[4]

Janssen's investigational vaccine regimen originates from a collaborative research program with the NIH and received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases, part of NIH, under Contract Number HHSN272200800056C. Further funding for the Ebola

vaccine regimen has been provided in part with federal funds from the Office of the Assistant Secretary for Preparedness and Response, BARDA under Contract Numbers HHSO100201700013C and HHSO100201500008C.

The Innovative Medicines Initiative (IMI) provided funding through the IMI Ebola+ Programme to support a number of consortia that initiated multiple clinical trials and other vaccine development activities. The consortia funded by the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking are EBOVAC1 (grant nr. 115854), EBOVAC2 (grant nr. 115861), EBOVAC3 (grant nr. 800176), EBOMAN (grant nr. 115850) and EBODAC (grant nr. 115847). This Joint Undertaking receives support from the EU's Horizon 2020 Framework Programme for Research and Innovation and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Johnson & Johnson also acknowledges its many partners in the ongoing global clinical program for the vaccine regimen, including Bavarian Nordic A/S, Centre Muraz, College of Medicine and Allied Health Sciences (COMAHS, University of Sierra Leone), Grameen Foundation, Inserm, Inserm Transfert, London School of Hygiene & Tropical Medicine (LSHTM), Wellcome Trust, Coalition for Epidemic Preparedness Innovations (CEPI), Uganda Virus Research Institute (UVRI), University of Antwerp, University of Oxford, Université de Kinshasa (UNIKIN), Vibalogics GmbH, Walter Reed Army Institute of Research (WRAIR), World Vision Ireland, The Ministry of Health and Sanitation Sierra Leone, Republic of Rwanda Ministry of Health and the Democratic Republic of the Congo Ministry of Public Health and all the people who participated in clinical trials during the Ebola epidemic.

About the Janssen Pharmaceutical Companies

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com . Follow us at @JanssenGlobal

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.jnj.com . Follow us at @JNJNews .

Notice to Investors Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding a collaboration to advance development of an investigational Ebola vaccine regimen. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or

unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov , www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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