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Up to 200,000 Regimens of Janssen's Investigational Ebola Vaccine to be Supplied to Rwanda for Use in Border Region near Democratic Republic of the Congo (DRC)

NEW BRUNSWICK, N.J., December 8, 2019 – Johnson & Johnson today announced that its Janssen Pharmaceutical Companies will provide up to 200,000 Ebola vaccine regimens to the Republic of Rwanda. This commitment will support a new immunization program led by the Rwanda Government that aims to help protect the country's citizens from the Ebola outbreak in neighboring Democratic Republic of the Congo (DRC). The first batches of Janssen vaccine have been delivered to the country, and further shipments are being organized.

On July 17, 2019, the World Health Organization (WHO) declared the DRC Ebola outbreak a Public Health Emergency of International Concern (PHEIC). More than 3,300 cases, including more than 2,200 deaths, have been reported to date, making the outbreak second only to the 2014-2016 West Africa epidemic, and raising concerns about its potential to cross international borders. In October, the Johnson & Johnson announced that the DRC would begin using the Janssen investigational vaccine as part of an expanded response to the outbreak.

"Johnson & Johnson recognizes the Rwandan Government's decision to proactively deploy Janssen's investigational Ebola vaccine to help prevent the spread of the disease into the country," said **Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson**. "We stand ready to support Rwanda's initiative on epidemic preparedness."

WHO's Strategic Advisory Group of Experts (SAGE) on Immunization recommended in May 2019 that Janssen's investigational Ebola vaccine regimen be evaluated as part of expanded efforts to contain the DRC outbreak. Additionally, WHO's Emergency Committee stated, "At-risk countries should put in place approvals for investigational medicines and vaccines as an immediate priority for preparedness."

Dr. Diane Gashumba, Rwanda Minister of Health, said, "Following various trials of the Ebola vaccine in different countries, and the World Health Organization's Strategic Advisory Group of Experts' recommendations, the Rwanda Food and Drug Authority have reviewed the trials made about this vaccine around the world and it has been approved that the Janssen vaccine is safe and that it can be given as a preventive measure. Therefore, Rwanda FDA granted conditional approval under exceptional emergency for Janssen's Ebola vaccine regimen."

Dr. Gashumba continued, "We are thankful to Johnson & Johnson who demonstrated commitment as a global partner to improve the health of our people by providing the Ebola vaccine that we are going to use during this voluntary Ebola vaccination campaign, and we acknowledge Wellcome Trust and the UK

Department for International Development (DFID) for participating in the funding of the Umurinzi Program."

To date, nearly 8,000 volunteers across the U.S., Europe and Africa have participated in multiple clinical studies of the Janssen vaccine. This includes approximately 1,300 individuals who have received the Janssen vaccine in the DRC according to the country's Ebola response committee. The two-dose regimen includes Ad26.ZEBOV as the first dose, which is based on Janssen's AdVac® technology, and MVA-BN-Filo as the second dose, which is based on Bavarian Nordic's MVA-BN® technology and is administered approximately eight weeks later. Study results indicate that the vaccine is well tolerated and induces robust and durable immune responses to the Ebola virus Zaire strain – the cause of the DRC outbreak.

Johnson & Johnson has made a significant investment in Janssen's Ebola vaccine regimen since its decision to accelerate the development program in 2014 in response to the widespread outbreak that occurred in West Africa that year. The vaccine regimen was developed in collaboration with global partners, 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 programme, and the National Institutes of Health (NIH) at HHS.

About the Rwandan Initiative
Fears for further spread of Ebola heightened when a case of the disease was reported in July 2019 in the DRC City of Goma, which is home to two million people and is a major trading hub located near the Rwandan border. A significant number of Rwandan citizens cross the border with the DRC on a regular basis as part of work, school or family commitments. Following an evaluation of the situation, the Rwanda Ministry of Health has decided to use Janssen's vaccine regimen in the border zones, with the objective of creating a protective barrier to prevent Ebola from impacting its citizens and from spreading further.

The new vaccination program is called Umurinzi, which locally refers to the Umurinzi tree which means "guardian" in Kinyarwanda, an official language of Rwanda. The program will include a large-scale vaccination campaign involving approximately 200,000 Rwandans ages two years and older in regions bordering the DRC judged to be at-risk. In parallel, an immunogenicity study and a clinical study in pregnant women are being discussed.

"This is a crucial step forward. Trials to date suggest that the Janssen vaccine produces a good immune response against Ebola," said **Dr Jeremy Farrar, Director of Wellcome**. "The new Rwanda initiative aims to leverage this potential new prevention tool with the goal of preventing Ebola and building our knowledge on how best the vaccine can be used to complement wider public health responses."

The Umurinzi Ebola Vaccine Program immunization campaign is being planned by the Rwanda Ministry of Health and its Rwanda Biomedical Center, who will work with local partners such as Emory University's Project San Francisco in Kigali to implement the program together with Rinda Ubuzima. Johnson & Johnson's Global Public Health division is helping to support community engagement and health system capacity for Umurinzi through its work in the EBODAC (Ebola Vaccine Deployment, Acceptance and Compliance) consortium, which is funded by the Innovative Medicines Initiative (IMI) and also includes the London School of Hygiene & Tropical Medicine (LSHTM), World Vision and Grameen Foundation.

Innovative iris scanning technology and automated phone reminders will help track the uptake and impact of the Janssen vaccine while a mobile training platform will reinforce key Ebola messages for the community health worker population.

About Janssen's Ebola Vaccine Regimen

The Janssen vaccine regimen (Ad26.ZEBOV, MVA-BN-Filo) consists of two doses leveraging different vaccines. The goal of this approach is to induce robust and long-lasting immunity. The regimen utilizes a viral vector strategy in which viruses – in this case adenovirus serotype 26 (Ad26) and Modified Vaccinia Ankara (MVA) – are genetically modified so that they cannot replicate in human cells, while safely inducing the production of Ebola virus proteins in order to trigger an immune response. Janssen-sponsored Phase 1 studies of the Ebola vaccine regimen have been reported in peer-reviewed journals including *JAMA: The Journal of the American Medical Association*[1,2] and the *Journal of Infectious Diseases*[3,4], and Phase 1, 2 and 3 data were recently presented at the 2019 European Congress of Clinical Microbiology & Infectious Disease (ECCMID)[5–7].

Janssen's investigational Ebola vaccine regimen was developed in a collaborative research program with the NIH and received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, under Contract Numbers HHSN272200800056C and HHSN272201200003I, respectively. 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 IMI provided funding through the IMI Ebola+ Program 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), Uganda Virus Research Institute (UVRI), University of Antwerp, University of Oxford, Vibalogics GmbH, Walter Reed Army Institute of Research (WRAIR) and World Vision Ireland.

Our Commitment to Pandemic Preparedness & Response

Today's announcement further demonstrates Johnson & Johnson's ongoing commitment to global pandemic preparedness efforts. We are one of the few innovative healthcare companies in the world today that is actively engaged across multiple disease areas that are central to this challenge. Through our Janssen Pharmaceutical Companies, we are actively engaged in developing new vaccines and/or treatments to combat a wide range of infectious diseases that are already pandemics, such as HIV, tuberculosis and hepatitis B, or that have pandemic potential, including Ebola, Zika, and influenza.

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.

Cautions 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: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges inherent in new product development, including the uncertainty of clinical success, obtaining regulatory approvals and of the overall timeline for the availability of a potential vaccine against Ebola; competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations; manufacturing difficulties and delays; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; trends toward health care cost containment and the uncertainty of the level of demand for a vaccine against Ebola. 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 30, 2018, 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. Neither 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.

References:

1. Winslow RL, Milligan ID, Voysey M, et al. Immune Responses to Novel Adenovirus Type 26 and Modified Vaccinia Virus Ankara–Vectored Ebola Vaccines at 1 Year. *JAMA*. 2017;317(10):1075. doi:10.1001/jama.2016.20644.
2. Milligan ID, Gibani MM, Sewell R, et al. Safety and Immunogenicity of Novel Adenovirus Type 26– and Modified Vaccinia Ankara–Vectored Ebola Vaccines. *JAMA*. 2016;315(15):1610. doi:10.1001/jama.2016.4218.
3. Anywaine Z, Whitworth H, Kaleebu P, et al. Safety and Immunogenicity of a 2-Dose Heterologous Vaccination Regimen With Ad26.ZEBOV and MVA-BN-Filo Ebola Vaccines: 12-Month Data From a Phase 1 Randomized Clinical Trial in Uganda and Tanzania. *J Infect Dis*. February 2019. doi:10.1093/infdis/jiz070.
4. Mutua G, Anzala O, Luhn K, et al. Safety and Immunogenicity of a 2-Dose Heterologous Vaccine Regimen With Ad26.ZEBOV and MVA-BN-Filo Ebola Vaccines: 12-Month Data From a Phase 1 Randomized Clinical Trial in Nairobi, Kenya. *J Infect Dis*. February 2019. doi:10.1093/infdis/jiz071
5. Rodolphe Thiebaut, Matthew D Snape, Neil Goldstein, Cynthia Robinson, Auguste Gaddah, Viki Bockstal, Odile Launay, Jean-Daniel Lelievre, Laura Richert, Christine Betard, Andrew Pollard, Malick Gibani, Elizabeth Clutterbuck, Maarten Leyssen, Kerstin Luhn, Macaya Douoguih. Safety and immunogenicity of 2-dose Ebola vaccine regimen with Ad26.ZEBOV and MVA-BN-Filo in a phase II clinical trial in Europe (EBOVAC2) - ECCMID Live. https://www.eccmidlive.org/#!resources/safety-and-immunogenicity-of-2-dose-ebola-vaccine-regimen-with-ad26-zebov-and-mva-bn-filo-in-a-phase-ii-clinical-trial-in-europe-ebovac2-462543af-682f-4031-ae04-4fb46580f2c2.
6. Bailah Leigh, David Ishola, Daniela Manno, Kwanbena Owusi-Kyei, Muhammed Afolabi, Frank Baiden, Neil Goldstein, Cynthia Robinson, Mohamed Samai, Auguste Gaddah, Viki Bockstal, Ken Awuondo, Brett Lowe, Brian Greenwood, Maarten Leyssen, Deborah Watson-Jones, Macaya Douoguih. Safety and immunogenicity of a 2-dose Ebola vaccine regimen with Ad26.ZEBOV and MVA-BN-Filo in a Phase III clinical trial in Sierra Leone - ECCMID Live. https://www.eccmidlive.org/#!resources/safety-and-immunogenicity-of-a-2-dose-ebola-vaccine-regimen-with-ad26-zebov-and-mva-bn-filo-in-a-phase-iii-clinical-trial-in-sierra-leone-99d83beb-79d2-423a-8e16-b648d9fdb059.
7. Neil Goldstein, Viki Bockstal, Cynthia Robinson, Auguste Gaddah, Ramon Roozendaal, Kerstin Luhn, Stephan Bart, Macaya Douoguih. Anamnestic response after antigen re-exposure following Ebola vaccine regimen with Ad26.ZEBOV and MVA-BN-Filo in a phase I study - ECCMID Live. https://www.eccmidlive.org/#!resources/anamnestic-response-after-antigen-re-exposure-following-ebola-vaccine-regimen-with-ad26-zebov-and-mva-bn-filo-in-a-phase-i-study.

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