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Press Contacts:
Corina Ramers-Verhoeven
cramersv@its.jnj.com
+31 6 1530 0086

Ronan Collins
rcollin5@ITS.JNJ.com
+47 488 42 500

Seema Kumar
SKumar10@its.jnj.com
+1 908 405-1144

Investor Contact:
Lesley Fishman
LFishma@its.jnj.com
+1 732 524-3922

Johnson & Johnson Announces Submission of European Marketing Authorisation Applications for Janssen's Investigational Ebola Vaccine Regimen

Data from multiple preclinical, Phase 1, 2 and 3 studies support applications, which have been granted Accelerated Assessment by European Medicines Agency

NEW BRUNSWICK, N.J., November 7, 2019 – Johnson & Johnson today announced that its Janssen Pharmaceutical Companies have submitted Marketing Authorisation Applications (MAAs) to the European Medicines Agency (EMA) seeking licensure for an investigational Ebola vaccine regimen for the prevention of Ebola Virus Disease (EVD) caused by *Zaire ebolavirus* species. Two MAAs have been submitted in parallel supporting each vaccine in the two-dose regimen (Ad26.ZEBOV, MVA-BN-Filo). In September 2019, the EMA's Committee for Medicinal Products for Human Use (CHMP) granted an Accelerated Assessment for these applications.

"It is vital that we ensure global preparedness for Ebola given that the world's largest Ebola outbreaks have taken place in the last six years alone, with the latest currently underway in the Democratic Republic of the Congo (DRC)," said **Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson.** "With an understanding that vaccines have an important role to play in countering this epidemic threat, we look forward to the EMA's review of our applications for licensure."

The vaccine 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. The MAAs are supported by data from Phase 1, 2 and 3 clinical studies evaluating the safety and immunogenicity of the vaccine regimen in adults and children[1-7], preclinical studies, and immunobridging analyses. To date, more than 6,500 volunteers across the U.S., Europe and Africa have participated in over 10 clinical studies of the Janssen vaccine.

"Our goal is to deliver a vaccine that can be used both in response to Ebola outbreaks, and also more proactively as a prophylactic tool to help countries protect their populations," said **Johan Van Hoof, M.D., Global Therapeutic Area Head, Vaccines, and Managing Director, Janssen Vaccines & Prevention B.V., Janssen Pharmaceutica N.V.** "We are grateful to our many global partners who have helped us reach this important stage of development."

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 West Africa

epidemic. The company is grateful to its global partners who have helped to support and co-fund these efforts, including 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.

Discussions with the U.S. Food and Drug Administration (FDA) are ongoing to define the required data set for filing of the Janssen Ebola vaccine regimen under the FDA's Animal Rule licensure pathway. Janssen is also working in collaboration with the World Health Organization (WHO) to enable registration of the Ebola vaccine regimen in African countries.

On October 31, 2019, the company announced it will provide up to 500,000 regimens of its investigational vaccine for use in a new clinical trial organized by the DRC government and global health stakeholders in an effort to contain the country's Ebola outbreak.

About Janssen's Ebola Vaccine Regimen
The Janssen 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 produce one of the 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 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 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.

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.

Janssen-Cilag International N.V. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 Janssen-Cilag International N.V. and any of the other 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.

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