Press Contacts:
Ernie Knewitz
eknewitz@its.jnj.com
+1 732-524-1090

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

Johnson & Johnson Announces Donation of up to 500,000 Regimens of Janssen's Investigational Ebola Vaccine to Support Outbreak Response in Democratic Republic of the Congo (DRC)

The government of the DRC supports use of Janssen's vaccine regimen as part of expanded public health response to country's Ebola outbreak – the second-worst on record

NEW BRUNSWICK, N.J., October 31, 2019 – The government of the Democratic Republic of the Congo (DRC) has decided to use the investigational Ebola vaccine regimen currently being developed by the Janssen Pharmaceutical Companies of Johnson & Johnson as part of an expanded public health initiative to help contain the country's Ebola outbreak. More than 3,000 cases, including more than 2,000 deaths, have been reported in the DRC outbreak to date, making it second only to the 2014-2016 West Africa epidemic. To help protect people at risk of Ebola, Janssen has committed to donate up to 500,000 vaccine regimens in support of a new clinical study in the DRC. The first batches of vaccine have been shipped to the country.

"Johnson & Johnson has been working to provide solutions to the world's unmet healthcare needs for over a century—and the threat of Ebola is one of the most urgent challenges we've ever encountered," said **Alex Gorsky, Chairman and Chief Executive Officer, Johnson & Johnson.** "The fact that we're in a position to help the people of the DRC protect their communities from such a serious threat—just a few years after we pledged to accelerate vaccine development efforts—is a testament to both the ingenuity of Janssen's scientists, and the power of close collaboration between partners committed to working for the greater good of all."

The DRC Minister of Public Health, Dr. Eteni Longondo, recently announced the country's decision to introduce Janssen's investigational vaccine alongside other tools as part of an expanded public health response to fight the Ebola outbreak. Additionally, the DRC's Ebola response coordinator, Dr. Jean-Jacques Muyembe, has shared that the country plans to begin using the vaccine in the border city of Goma, which is a trading hub for the DRC and neighboring Rwanda. A number of global health organizations, in collaboration with DRC stakeholders, will work closely to provide the vaccine beginning in November.

New Initiative Reflects Recent Guidance
On July 17, 2019, the World Health Organization (WHO) declared the Ebola outbreak in DRC a Public Health Emergency of International Concern (PHEIC), stating that "optimal vaccine strategies that have maximum impact on curtailing the outbreak, as recommended by WHO's Strategic Advisory Group of Experts (SAGE), should be implemented rapidly." In line with recent recommendations from SAGE, the new vaccination initiative in the DRC will offer the Janssen investigational vaccine regimen to individuals at some risk of Ebola infection who live in areas close to the current outbreak zone, with the goal of preventing the further geographic spread of the virus.

In response to the Ebola outbreak in West Africa in 2014-2016, Johnson & Johnson accelerated the development of Janssen's Ebola vaccine regimen. To date, more than 6,500 volunteers across the U.S., Europe and Africa have participated in multiple clinical studies of the vaccine. 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.

"No single entity can solve this outbreak which has continued for more than a year," said **Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson.** "The global health community has come together in support of this initiative using Janssen's investigational Ebola vaccine regimen to help prevent its further spread. This collaboration is essential, and a great demonstration of how the public and private sectors can work together to help tackle a public health crisis."

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.

As part of the DRC's expanded public health response, a new clinical study of the vaccine regimen will be implemented by the Institut National de Recherche Biomédicale (INRB) and the DRC Ministry of Health, supported by Médecins Sans Frontières (MSF), Epicentre and the London School of Hygiene & Tropical Medicine (LSHTM), under the leadership of the Principal Investigator Professor Jean-Jacques Muyembe, INRB Director and head of the DRC multisector Ebola response committee. The trial will be sponsored by LSHTM, and funded by the Coalition for Epidemic Preparedness Innovations (CEPI), the European Union, the UK Department for International Development (DFID), Wellcome and the Paul G. Allen Family Foundation. Janssen is donating supplies of its investigational vaccine regimen for the study.

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].

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 company is grateful to its global partners who have helped to support and co-fund these efforts. 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, which is supported by the European Commission, 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 research and innovation programme 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.

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