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Johnson & Johnson Announces World Health Organization will Review Ebola Vaccine Regimen for Emergency Use Assessment and Listing (EUAL)

Preparations also underway to initiate first-in-human study for multivalent vaccine regimen to combat Ebola, Sudan and Marburg viruses

ANTWERP, BELGIUM – September 12, 2016 – Johnson & Johnson announced today that Janssen Vaccines & Prevention B.V. (Janssen) has completed a submission to the World Health Organization (WHO) for Emergency Use Assessment and Listing (EUAL) for its investigational preventive Ebola prime-boost vaccine regimen. The EUAL is a special procedure that can be implemented when there is an outbreak of a disease with high rates of morbidity or mortality and a lack of treatment or prevention options.

"Over the past four decades, we have seen 25 Ebola outbreaks, with the most recent in West Africa killing seven times more people than all previous outbreaks combined," said Paul Stoffels, M.D., Chief Scientific Officer, Johnson & Johnson. "We must take action now so that a tragedy on the scale of West Africa never happens again. Having an Ebola vaccine available is critical for global preparedness. If the WHO grants an emergency use listing, this will accelerate the availability of Janssen's investigational vaccine regimen to the international community in the event another Ebola crisis occurs."

EUAL assists UN Member States and procurement agencies determine the acceptability for use of a specific vaccine in a public health emergency. The decision to grant EUAL to the investigational preventative vaccine regimen will be based on an evaluation of available data including quality, safety, and immunogenicity, as well as a risk/benefit analysis. While EUAL potentially allows for deployment of a vaccine in an emergency, the vaccine remains investigational pending formal regulatory agency review and approval.

The news coincides with the opening of the 8th International Symposium on Filoviruses in Antwerp, Belgium, hosted by the Antwerp Institute of Tropical Medicine, which is reviewing

global progress against Ebola. The first outbreak of the disease was reported exactly 40 years ago, in September 1976 in Zaire (now the Democratic Republic of the Congo).

“Forty years after Ebola’s discovery, the potential availability of a durable prime-boost vaccine would be a tremendous achievement in global health,” said Johan Van Hoof, M.D., Global Therapeutic Area Head, Infectious Diseases and Vaccines, Janssen Pharmaceutical Companies, and a keynote speaker at the 8th International Symposium on Filoviruses. “If listed for emergency use, the investigational Janssen vaccine regimen could be a vital prevention tool for rapid outbreak response, particularly for health workers and vulnerable communities on the frontlines.”

Prime-boost vaccination is an established prevention approach for several infectious diseases. It involves giving an initial dose to prime the immune system, followed by a booster dose at a later date with the goal of potentially strengthening and optimizing the duration of immunity. Janssen’s heterologous prime-boost vaccine regimen contains two components based on AdVac® technology from Janssen, and MVA-BN® technology from Bavarian Nordic A/S.

The first clinical data for the investigational Janssen vaccine regimen among healthy volunteers were published in *JAMA: The Journal of the American Medical Association* in April 2016. The Phase 1 results from a UK study suggested that the regimen was well-tolerated and immunogenic (produced an immune response). The study found that 100 percent of study participants achieved an initial antibody response to Ebola, and that this was sustained eight months following vaccination among all volunteers.

The UK study provided the first set of data from a total of 10 clinical studies that are being conducted on a parallel track across the U.S., Europe and Africa in support of potential full licensure for a Janssen Ebola vaccine regimen. The first study of the vaccine regimen in a West African country affected by the Ebola epidemic began in Sierra Leone in October 2015.

Janssen is also preparing to initiate a first-in-human Phase 1 clinical study to test a second-generation, multivalent version of the AdVac/MVA-BN vaccine regimen. The multivalent heterologous prime-boost regimen is intended to protect against multiple filoviruses that cause disease in humans, including the Ebola, Sudan and Marburg viruses. The U.S. study will test the safety, tolerability and immunogenicity of this vaccine regimen in varying dosing schedules among healthy volunteers. The National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH), is funding this study. More information can be found at ClinicalTrials.gov.

About Janssen’s Ebola Vaccine Regimens

Janssen has made a substantial investment to support the development of its investigational monovalent Ebola vaccine regimen and multivalent Ebola, Sudan and Marburg vaccine regimen. We are also grateful for the significant support and funding contributed by our global partners to help accelerate the development of these vaccine regimens.

The monovalent and multivalent vaccine regimens originate from a collaborative research program with the National Institutes of Health (NIH) that commenced in 2008. The program has been funded in part with Federal funds and preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, under Contract Numbers HHSN272200800056C, and HHSN272201000006I and HHSN272201200003I, respectively. The MVA-BN-Filo material used in Phase 1 studies was produced under NIAID/Fisher BioServices contract #FBS-004-009 and NIH contract HHSN272200800044C.

In January 2015, Europe's Innovative Medicines Initiative (IMI) awarded consortia of leading global research institutions and non-government organizations working in conjunction with the Janssen Pharmaceutical Companies grants totaling more than €100 million from the Ebola+ programme to support the development, manufacturing and deployment of the monovalent Ebola vaccine regimen. The IMI2 Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and European Federation of Pharmaceutical Industries and Associations (EFPIA).

In September 2015, Janssen Vaccines & Prevention B.V. was awarded $28.5 million from The Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services, to help accelerate the development of the monovalent Ebola vaccine regimen under Contract Number HHSO100201500008C.

Janssen in partnership with Bavarian Nordic rapidly scaled up production of the monovalent Ebola vaccine regimen and now has approximately 2,000,000 regimens available, with the capacity to produce several million regimens if needed.

About Johnson & Johnson
Caring for the world, one person at a time, inspires and unites the people of Johnson & Johnson. We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people. Our approximately 127,100 employees at more than 250 Johnson & Johnson operating companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

Our Commitment to Global Public Health
For 130 years, Johnson & Johnson has been committed to improving the health of individuals, families and communities around the world, including the most vulnerable populations. Today, our vibrant, entrepreneurial and committed employees bring business acumen and their collaborative spirit to help solve some of the most complex global health problems. By harnessing our collective breadth and scale, and our employees' passion and purpose, we strive to advance health care and positively impact the lives of all people.

About the Janssen Pharmaceutical Companies
At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at @JanssenGlobal.

Cautions Concerning Forward Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, including regarding development and production capacity of an 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 development, including the uncertainties of clinical success and regulatory approvals; technological advances and new products attained by

competitors; the challenges and risks involved in large-scale production of a vaccine; and the uncertainty of the level of demand for a vaccine against Ebola. A further list and description 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 January 3, 2016, including in Exhibit 99 thereto, 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 or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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