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First Long-term Immune Response Data for Investigational HIV-1 Preventive Vaccine Announced by Johnson & Johnson

In early-stage APPROACH study, mosaic-based vaccine regimen maintained robust immune response one year after last vaccination

AMSTERDAM, THE NETHERLANDS, 24 July 2018 – Johnson & Johnson today announced the first long-term immune response data for an investigational mosaic-based preventive vaccine regimen against HIV-1 infection in development at its Janssen Pharmaceutical Companies. In the early-stage (Phase 1/2a) APPROACH study, a robust HIV antibody response was maintained in all healthy volunteers who received the lead vaccine regimen at 96 weeks, one year after the last vaccination. These data were shared in an oral presentation at the 22nd International AIDS Conference (AIDS 2018) in Amsterdam, The Netherlands.

The long-term results presented at AIDS 2018 build on initial data from the APPROACH study that were published in *The Lancet* on July 6, 2018.

"Our vision is to achieve a world without HIV, and this will require a preventative HIV vaccine," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "Johnson & Johnson is determined to work with partners to address this critical gap, and bring forward the best science to find an HIV vaccine in our lifetimes that will change the trajectory of health for populations at risk of HIV worldwide."

The search for an HIV vaccine began the moment the virus was discovered over 30 years ago. But due to the unique properties of the virus – including its global genetic diversity – developing an effective vaccine is highly challenging. Janssen's investigational mosaic-based vaccine regimen is designed as a 'global vaccine' with the aim to prevent infections due to a wide range of HIV-1 strains around the world that are responsible for the pandemic. The vaccine regimen contains mosaic immunogens (molecules capable of

inducing an immune response) that have been created using genes from a variety of viral subtypes.

Based on results from APPROACH and other early-stage studies, in November 2017 Janssen and its global partners initiated the first efficacy study for a mosaic-based vaccine regimen. The Phase 2b trial, HVTN 705/HPX2008 (also known as 'Imbokodo'), aims to enroll 2,600 young women aged 18-35 in five sub-Saharan African countries to determine whether the vaccine is safe and able to reduce HIV infection in this population that would benefit greatly from new HIV preventive measures. Participants are now enrolling at clinical research sites in South Africa, Malawi, Zambia and Zimbabwe. Regulatory approval for the study is pending in Mozambique.

Results from HVTN 705/HPX2008 are expected in 2021. Additional large-scale studies will be needed for licensure of the mosaic-based vaccine regimen against HIV-1.

"Although we are still at an early stage of the development process, we are making important progress," said Johan Van Hoof, M.D., Global Therapeutic Area Head, Infectious Diseases & Vaccines, and Managing Director, Janssen Vaccines and Prevention B.V. "These data demonstrate the durability of immune responses elicited by the mosaic-based vaccine regimen."

About the APPROACH Study
APPROACH (HIV-V-A004/NCT02315703) is a Phase 1/2a study in 393 healthy HIV-uninfected adults in the U.S., Rwanda, Uganda, South Africa and Thailand. It is evaluating the safety, tolerability and immunogenicity (ability to elicit an immune response) of various mosaic-based vaccine regimens for prevention of infection due to HIV-1.

These heterologous vaccine regimens contain two prime doses (weeks 0 and 12) of the trivalent viral vectored mosaic vaccine Ad26.Mos.HIV, utilizing Janssen's AdVac® technology based on adenovirus serotype 26 (Ad26). The prime doses are followed by two boosts (weeks 24 and 48) of either Ad26.Mos.HIV, MVA-Mosaic and/or different doses of a soluble protein Clade C gp140 adjuvanted with aluminum phosphate. By first priming and then boosting the immune system using different vaccine components, the goal is to produce a strong and long-lasting immune response to HIV.

At 96 weeks, one year after the last vaccine dose, all vaccine regimens evaluated in APPROACH had a favorable safety profile. No unexpected vaccine-related adverse events were reported. Additionally, all regimens maintained robust humoral and cellular HIV-1 immune responses elicited by vaccination. The most immunogenic regimen comprised mosaic Ad26 as the prime and Ad26+gp140 (high dose) as the boost. All study volunteers receiving this regimen achieved an HIV antibody response and sustained this response up to one year post-vaccination. Additionally, a high proportion of recipients achieved a cellular immune response. The mosaic vaccine concept has been selected for further evaluation in efficacy studies.

Janssen's partners on the APPROACH study included Beth Israel Deaconess Medical Center (BIDMC) at Harvard Medical School; the United States Military HIV Research

Program (MHRP) at the Walter Reed Army Institute of Research (WRAIR), with the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF); the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH); the Ragon Institute of Massachusetts General Hospital, MIT and Harvard; the International AIDS Vaccine Initiative (IAVI); and the HIV Vaccine Trials Network (HVTN).

Since 2005, Janssen Vaccines & Prevention B.V. has been participating in the NIH-supported Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) program under grants AI066305, AI078526 and AI096040.

Visit www.jnj.com/HIV to learn more about the breadth of HIV science being pursued by the Janssen Pharmaceutical Companies of Johnson & Johnson and its partners across prevention, treatment and cure research.

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 health care 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.

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.

Janssen Vaccines & Prevention B.V. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, regarding development of a potential preventive vaccine for HIV. 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 Vaccines & Prevention B.V., any of the other 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 31, 2017 including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's subsequent Quarterly Reports on Form 10-Q and other 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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