MEDIA ADVISORY

UPDATE ON INVESTIGATIONAL PRIME BOOST HIV-1 VACCINE REGIMEN
IN DEVELOPMENT AT THE JANSSEN PHARMACEUTICAL COMPANIES OF JOHNSON & JOHNSON

Durban, South Africa — On Tuesday, July 19th Johnson & Johnson and several of its partners provided an update on the investigational heterologous prime-boost HIV-1 vaccine regimen in development at its Janssen Pharmaceutical Companies, including progress from a fully enrolled Phase I/IIa clinical study (HIV-V-A004) in five countries, which was initiated based on positive results from pre-clinical studies in non-human primates published in *Science* last year.

Despite great progress in HIV treatments, HIV remains one of the greatest global health threats of our time with millions continuing to be infected each year. Developing a safe and effective global HIV vaccine, to protect against all clades of the virus, remains a top health priority globally and is deemed essential to conclusively ending the epidemic as part of a comprehensive HIV/AIDS response.

Uniting for an HIV-Free World

Janssen Vaccines & Prevention B.V., one of the Janssen Pharmaceutical Companies, is collaborating with multiple partners on a next generation approach which, based on very encouraging preclinical results, may ultimately prove to be a strategy for protecting against global human immunodeficiency virus (HIV-1) infection. Janssen collaborators include:

- Beth Israel Deaconess Medical Center (BIDMC)/Harvard
- HIV Vaccine Trial Network (HVTN)
- International AIDS Vaccine Initiative (IAVI)
- National Institute of Allergy and Infectious Diseases (NIH)
- Ragon Institute of Massachusetts General Hospital
- United States Military HIV Research Program (MHRP)

First Phase I/IIa study fully enrolled and second Phase I/IIa study initiated

Reporting on progress with its in-human studies Janssen confirmed that the first phase I/IIa study (*NCT02315703*) involving approximately 400 healthy volunteers with sites in South Africa, Rwanda, Uganda, Thailand and the United States has been fully enrolled. The study is evaluating the safety/tolerability and immunogenicity of a “prime-boost” vaccine approach, which leverages AdVac® Technology from Janssen and a number of different boosters including a trimERIC envelope protein and MVA vectors.

Volunteers are first given an adenovirus serotype 26 (Ad26) vectored vaccine to prime the immune system, and then one of several boosters intended to enhance the immune system over time. This approach is intended to increase both the magnitude of the immune response and the overall protection against subsequent viral infection.
A heterologous prime-boost vaccine regimen using a similar AdVac® vector, along with an MVA-based vector, is being used in Janssen’s preventative Ebola candidate vaccine regimen that is currently in Phase 3 human clinical studies.

It was also announced that a second Phase I/IIa trial (NCT02788045) has also just commenced. The clinical study will enroll 198 healthy volunteers to assess safety/tolerability and immunogenicity of regimens using a newly developed tetravalent Ad26 product prime compared with regimens using the trivalent Ad26 being evaluated in the first Phase I/IIa.

Ongoing phase 1 clinical studies have been evaluating the safety and immunogenicity of the different components which are included in the regimens to be used in these in-human studies.

Pre-clinical results formed basis for in-human studies
Results from the pre-clinical studies in non-human primates, published in *Science*, showed superiority of heterologous prime-boost vaccine regimens—which first prime the immune system, then boost the immune system to increase the response.

The study results showed that the investigational prime-boost vaccine regimen provided complete protection from becoming infected with simian immunodeficiency virus (SIV), a virus similar to HIV that infects NHPs, in half of the vaccinated NHPs (n=12) against a series of six repeated challenges. This work also demonstrates that there is a strong link between the protective ability of the vaccine regimen and the number of antibody functions to fight the virus, so called polyfunctionality, which supports the continued development of the vaccine regimen for human use. These results have previously been presented at several international congresses.

Since 2005, Janssen Vaccines & Prevention B.V. has been participating in the National Institutes of Health (NIH) supported Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) program under grants AI066305, AI078526, AI096040 to evaluate HIV-1 vaccine candidates to address the epidemic. The pre-clinical study was supported by grants from the NIH: AI060354; AI078526; AI0080280; AI084794; AI095985; AI096040; AI102660; AI102691; OD011170; HHSN261200300001E, as well as funding from the Bill & Melinda Gates Foundation, and the Ragon Institute of Massachusetts General Hospital, MIT, and Harvard.

There is an opportunity for one-on-one interviews with Janssen researchers and partners from MHRP and BIDMC/Harvard during the International AIDS Conference. If you’d like to schedule an interview with a speaker in advance, please contact Ronan Collins who is on site in Durban. Contact details are included below.

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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.

Our Global Public Health Strategy
We have a robust portfolio of innovative products, expertise and experience focused on maternal, newborn and child health, HIV/AIDS and tuberculosis (TB). We use holistic approaches to deliver better health outcomes in addition to quality outputs. And we bring to bear our deep expertise, talent, operational excellence, community engagement and partnerships to build a healthy world free of disease. We work in partnership with governments, donors, non-profits and multilateral institutions to develop and deliver integrated, evidence-based solutions for public health. Learn more at www.jnj.com/global-public-health and follow us @JNJGlobalHealth

About Janssen
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 and 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 regarding product development. 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. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. 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 December 28, 2014, 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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