



News Release

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Janssen and Global Partners to Discontinue Phase 3 Mosaico HIV Vaccine Clinical Trial

Independent, scheduled review of Phase 3 Mosaico study finds investigational vaccine regimen lacks efficacy in preventing HIV¹

No vaccine-related safety issues identified

LEIDEN, THE NETHERLANDS (January 18, 2023) – The Janssen Pharmaceutical Companies of Johnson & Johnson, together with a consortium of global partners, today announced the results of an independent, scheduled data review of the Phase 3 Mosaico study (also known as HPX3002/HVTN706) of Janssen’s investigational HIV vaccine regimen.^{1,2} The study’s independent Data and Safety Monitoring Board (DSMB) determined during the review that the regimen was not effective in preventing HIV infection compared to placebo among study participants. No safety signals or concerns with the vaccine regimen were identified.¹

In light of the DSMB’s determination, the Mosaico trial will be discontinued. Participant notifications and further analyses of the data are underway. Throughout the trial, study investigators have ensured that any individuals who contracted HIV received prompt HIV treatment and care.³

“We are disappointed with this outcome and stand in solidarity with the people and communities vulnerable to and affected by HIV,” said Penny Heaton, M.D., Global Therapeutic Area Head, Vaccines, Janssen Research & Development, LLC. “We remain steadfast in our commitment to advancing innovation to help end the global HIV epidemic, 1.5 million people acquired HIV in 2021 alone, underscoring the high unmet need for new options and why we have long worked to tackle this global health challenge. We remain steadfast in our commitment to advancing innovation in HIV, and we hope the data from

Mosaico will provide insights for future efforts to develop a safe and effective vaccine. We are grateful to our Mosaico partners and the study investigators, staff, and participants.”

About the Phase 3 Mosaico Study

Mosaico, a Phase 3 study of Janssen’s investigational HIV vaccine regimen, began in 2019, and completed vaccinations in October 2022.² The study included approximately 3,900 cisgender men and transgender people who have sex with cisgender men and/or transgender people, who represent groups and populations vulnerable to HIV, at over 50 trial sites in Argentina, Brazil, Italy, Mexico, Peru, Poland, Puerto Rico, Spain and the United States.²

The study evaluated an investigational vaccine regimen containing a mosaic-based adenovirus serotype 26 vector (Ad26.Mos4.HIV) administered during four vaccination visits over one year.² A mix of soluble proteins (Clade C/Mosaic gp140, adjuvanted with aluminum phosphate) was also administered at visits three and four.²

The Mosaico DSMB analysis, based on the data available to date, indicated that the regimen does not protect against HIV and the study is not expected to meet its primary endpoint.¹ No safety issues with the vaccine regimen were identified.¹ In light of this, the study will be discontinued, and further analyses are underway.

The DSMB’s determination follows the primary analysis of the Phase 2b Imbokodo study, which was announced in August 2021 and found that a similar investigational HIV vaccine regimen did not provide sufficient protection against HIV in a population of young women in sub-Saharan Africa.⁴ The investigational vaccine regimen used in the Imbokodo study was found to have a favourable safety profile.

The Mosaico study was led by a global public-private partnership including the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), the HIV Vaccine Trials Network (HVTN), the U.S. Army Medical Research and Development Command (USAMRDC), and Janssen Vaccines & Prevention B.V. Since 2005, Janssen Vaccines & Prevention B.V. has been participating as a sub-grantee in the NIH-supported Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) program under grants AI066305, AI078526, AI096040 and AI128751 (Principal Investigator, Prof. Dan Barouch).

Johnson & Johnson’s Commitment to HIV

Johnson & Johnson has been committed to the fight against HIV for decades, playing a key role in bringing nine therapeutics to people living with HIV and continuing to drive innovation in HIV prevention and care.⁵

In January 2021, the dapivirine ring, a discreet long-acting HIV prevention method specifically developed for women by the International Partnership for Microbicides (IPM) and based on Janssen’s compound, was recommended by the World Health Organization as an additional prevention choice for women with a substantial chance of contracting HIV as part of combination prevention approaches.⁶ In July 2021, Zimbabwe became the first country to approve the use of the dapivirine ring among women ages 18 and older, with South Africa following suit in March 2022.⁷ Additional regulatory decisions are pending.

Johnson & Johnson also works with vulnerable communities on the frontlines of the HIV epidemic, and has supported collaborative initiatives like the DREAMS Partnership in sub-Saharan Africa⁸, the MenStar Coalition⁹, and the New Horizons Collaborative¹⁰.

To learn more about Johnson & Johnson's commitment to combatting HIV, please visit www.janssen.com/emea/our-focus/infectious-diseases-vaccines/hiv.

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 135 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest diversified healthcare products 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 of Johnson & Johnson

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension. Learn more at www.janssen.com/emea. Follow us at @JanssenEMEA

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding Janssen's investigational, mosaic-based HIV 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 Vaccines & Prevention, B.V., 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 of the agreement may not be realized or may take longer to realize than expected; 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 January 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Report 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 Janssen Vaccines & Prevention, B.V., 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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References

¹ Janssen Data on File. Mosaico PI DSMB. 2023

² ClinicalTrials.gov. A Study of Heterologous Vaccine Regimen of Adenovirus Serotype 26 Mosaic4 Human Immunodeficiency Virus(Ad26.Mos4.HIV), Adjuvanted Clade C gp140 and Mosaic gp140 to Prevent HIV-1 Infection Among Cis-gender Men and Transgender Individuals Who Have Sex With Cis-gender Men and/or Transgender Individuals (MOSAICO). Available at: <https://clinicaltrials.gov/ct2/show/NCT03964415>. Last accessed: January 2023.

³ Janssen Data on File, MOSAICO Study Protocol. 2020.

⁴ National Institute of Health. HIV Vaccine Candidate Does Not Sufficiently Protect Women Against HIV Infection. Available at: <https://www.nih.gov/news-events/news-releases/hiv-vaccine-candidate-does-not-sufficiently-protect-women-against-hiv-infection>. Last accessed: January 2023.

⁵ Johnson & Johnson. Our Mission to End HIV. HIV@40. Available at: <https://www.jnj.com/hiv>. Last accessed: January 2023.

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⁷ International Partnership for Microbicides. South Africa Approves Dapivirine Vaginal Ring for Use by Women. Available at: <https://www.ipmglobal.org/content/south-africa-approves-dapivirine-vaginal-ring-use-women>. Last accessed: January 2023.

⁸ U.S Department of State. DREAMS Partnership. Available at: <https://www.state.gov/pepfar-dreams-partnership/>. Last accessed: January 2023.

⁹ Men Star Coalition. Available at: <https://www.menstarcoalition.org/about-menstar/>. Last accessed: January 2023.

¹⁰ New Horizons. Available at: <https://www.newhorizonshiv.com/>. Last accessed: January 2023.