



**News Release**

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**Johnson & Johnson and Global Partners Announce Results from  
Phase 2b Imbokodo HIV Vaccine Clinical Trial in Young Women in  
Sub-Saharan Africa**

*Investigational vaccine candidate did not provide sufficient protection  
against HIV infection<sup>1</sup>*

*No vaccine-related safety signals identified<sup>1</sup>*

*J&J HIV vaccine programme continues with global Phase 3 Mosaico HIV study  
evaluating a different composition of the vaccine regimen in different populations<sup>2</sup>*

**NEW BRUNSWICK, N.J., 31 August, 2021** – Johnson & Johnson (NYSE: JNJ), together with a consortium of global partners, today announced results from the primary analysis of a Phase 2b HIV vaccine clinical trial known as the Imbokodo study (also known as HVTN 705/HPX2008).<sup>1,3</sup> Data showed the investigational HIV vaccine regimen did not provide sufficient protection against HIV infection in a population of young women in sub-Saharan Africa at high risk of acquiring HIV.<sup>1</sup> The investigational vaccine was found to have a favourable safety profile with no serious adverse events.<sup>1</sup>

Based on these results, the Imbokodo study will not continue. Study participants will be notified of the results, unblinded and informed whether they were in the study group who received the vaccine or the group who received placebo. Further analysis of the Imbokodo study is ongoing, and the study has provided enough data to progress with key immunological correlates research.

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In parallel to the Phase 2b Imbokodo HIV vaccine clinical trial, Janssen is sponsoring the ongoing Phase 3 Mosaico study (HVTN706/HPX3002) which is testing the safety and efficacy of a different composition of the HIV vaccine regimen among men who have sex with men (MSM) and transgender individuals.<sup>2</sup> This study is being conducted in the Americas and Europe where different strains of HIV are circulating.<sup>2,4</sup> Given these differentiating factors and following consultations with the Mosaico study independent Data and Safety Monitoring Board (DSMB), it was decided that the Phase 3 Mosaico study will continue at this time.

“We are extremely grateful to the women who volunteered for the Imbokodo study, and to our partners, including the people on the frontlines, all of whom are contributing every day to this enduring quest to make HIV history,” said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. “HIV is a unique and complex virus that has long posed unprecedented challenges for vaccine development because of its ability to attack, hijack and evade the human immune system. While we are disappointed that the vaccine candidate did not provide a sufficient level of protection against HIV infection in the Imbokodo trial, the study will give us important scientific findings in the ongoing pursuit for a vaccine to prevent HIV. We continue to stand in solidarity with people living with and vulnerable to HIV, and remain committed to furthering our research against this devastating virus.”

### **What the Imbokodo data tell us**

The Imbokodo vaccine regimen was administered to participants through four vaccination visits over one year.<sup>1</sup> The primary analysis was conducted 24 months after participants received their first vaccinations.<sup>1</sup> The study’s primary endpoint was based on the difference in number of new HIV infections between the placebo and vaccine groups from month seven (one month after the third vaccination timepoint) through month 24.<sup>1</sup> These data found that through 24 months of follow up, 63 of 1,109 participants who received placebo compared to 51 of 1,079 participants who received active vaccine acquired HIV.<sup>1</sup> This analysis demonstrated a vaccine efficacy point estimate of 25.2% (95% confidence interval of -10.5% to 49.3%). The vaccine regimen did not cause harm and was generally well-tolerated.<sup>1</sup>

“The high incidence of HIV among young women in sub-Saharan Africa remind us that, despite great progress made in treatment and prevention, HIV remains a major health challenge for the region,” said Professor Glenda Gray, President and Chief Executive Officer, South Africa Medical Research Council (SAMRC) and Imbokodo’s Protocol Chair. “This underscores the need to apply the knowledge that will be gained from this trial to continue to advance the pursuit of a global HIV vaccine.”

The Imbokodo study tested an investigational HIV regimen with an adenovirus vector containing four mosaic immunogens (Ad26.Mos4.HIV) at four vaccination visits over one year.<sup>3,5</sup> The Imbokodo regimen contains a soluble protein component (Clade C gp140, adjuvanted with aluminium phosphate), which is administered at vaccination visits three and four.<sup>1,3</sup> The ongoing Phase 3 Mosaico study is testing a different investigational vaccine regimen that involves the

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administration of a mosaic-based mixture of soluble proteins (Clade C/Mosaic gp140) at vaccination visits three and four.<sup>2</sup>

### **About the Phase 2b Imbokodo study**

Imbokodo, a Phase 2b study of Janssen's investigational HIV vaccine regimen, began in 2017.<sup>1,3</sup> The study enrolled approximately 2,600 young women across five countries in sub-Saharan Africa,<sup>3</sup> a region where women and girls accounted for 63 percent of all new HIV infections in 2020.<sup>6</sup> The study took place at 23 trial sites in Malawi, Mozambique, South Africa, Zambia and Zimbabwe.<sup>3</sup> Study investigators ensured that any HIV-infected participants in Imbokodo were referred to high-quality HIV treatment and care services.<sup>7</sup>

Imbokodo was supported by a public-private partnership led by Janssen Vaccines & Prevention B.V., part of the Janssen Pharmaceutical Companies of Johnson & Johnson; the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health; the Bill & Melinda Gates Foundation; and the HIV Vaccine Trials Network (HVTN). Additional partners providing support included the U.S. Army Medical Research and Development Command (USAMRDC) and the Ragon Institute of MGH, MIT and Harvard. The study was conducted at clinical sites coordinated by HVTN, and the South African Medical Research Council (SAMRC) helped to implement Imbokodo in South Africa.

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) programme 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 25 years, playing a central role in bringing nine therapeutics to people living with HIV, and continues to drive innovation in HIV prevention and care.<sup>8</sup>

Johnson & Johnson also supports communities affected by HIV through initiatives such as the DREAMS Partnership in sub-Saharan Africa,<sup>9</sup> the MenStar Coalition<sup>10</sup> and the New Horizons programme.<sup>11</sup>

### **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.janssen.com/emea](http://www.janssen.com/emea). Follow us at @JanssenEMEA.

### **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

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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/emea](http://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., 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 January 3, 2021, 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](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of 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.

### **References**

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<sup>6</sup> UNAIDS. GLOBAL HIV STATISTICS – Fact Sheet 2021. Available at: [https://www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_FactSheet\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf). Last accessed: August 2021.

<sup>7</sup> Janssen Data on File, Imbokodo Study Protocol. 2021.

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