

J&J announces PPP for Investigational Prophylactic HIV Vaccine

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Johnson & Johnson has announced that Janssen Vaccines & Prevention B.V., one of its Janssen Pharmaceutical Companies, together with a consortium of global partners are preparing to launch Mosaico, the first large-scale Phase 3 efficacy study of Janssen's investigational mosaic-based HIV-1 preventive vaccine. Janssen's mosaic vaccine is designed as a global vaccine with the goal of preventing infections from the wide range of viral strains responsible for the HIV pandemic.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), the HIV Vaccine Trials Network (HVTN) based at the Fred Hutchinson Cancer Research Center, and the U.S. Army Medical Research and Development Command (USAMRDC) are joining forces with Janssen to advance the potential global vaccine. The public-private partnership's plans for Mosaico will be described in more detail at the 10th IAS Conference on HIV Science (IAS 2019) in Mexico City, along with new late-breaking data regarding the mosaic-based vaccine regimen to be studied in Mosaico.

Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson said, "Our vision at Johnson & Johnson is to develop a preventive vaccine that can be deployed anywhere, worldwide, to halt the HIV epidemic. No single organization can tackle this historic challenge alone. By working with our global partners and leveraging cutting-edge technologies, we are optimistic that we can achieve an HIV vaccine in our lifetime."

Mosaico (HPX3002/HVTN 706) will have a target enrollment of 3,800 individuals in eight countries across North America, South America and Europe. It is expected to commence later in 2019. Conducted at approximately 55 clinical sites worldwide, the study will evaluate Janssen's mosaic-based HIV vaccine in men who have sex with men (MSM) and transgender people.

"We are determined to develop a globally effective HIV vaccine to reduce the trajectory of the estimated 1.5 million new HIV infections that are occurring," said Larry Corey M.D., Principal Investigator of the HVTN, virologist, and president and director emeritus at the Fred Hutchinson Cancer Research Center in Seattle.

Johan Van Hoof, M.D., Global Therapeutic Area Head, Vaccines, and Managing Director, Janssen Vaccines & Prevention B.V., Janssen Pharmaceutica NV said, "The search for a vaccine began the moment HIV was first identified over 35 years ago, but there have been many challenges along the way due to the unique properties of this virus, including its global

genetic diversity. Janssen is committed to advancing clinical trials to help build an HIV-free future. With each new study we are working to optimize the mosaic-based vaccine regimen.”

Mosaico will be the second, and largest, efficacy study for Janssen’s investigational HIV vaccine. The first efficacy study, the proof-of-concept Phase 2b clinical trial known as Imbokodo (HPX2008/HVTN 705), is currently evaluating a mosaic-based vaccine regimen in 2,600 young women (aged 18-35) across five southern African countries.