

•Australia offers a simple, supportive and robust regulatory process to initiate human trials efficiently•

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US-based Uvax Bio, LLC, a spin-off vaccine company from Scripps Research, employs proprietary 1c-SApNP platform technology invented by Dr Jiang Zhu of Scripps Research to develop and commercialise prophylactic vaccines for challenging infectious diseases. The firm is currently conducting phase 1 trials of its HIV vaccine in Australia. Dr Pedro Garbes, Vice President and Global Medical Lead, Uvax Bio elucidates why the firm has chosen Australia for its phase 1 trial.



What makes Uvax Bio's technology different from other vaccine technologies?

Recombinant protein vaccines are well-known and have delivered some of the most safe and successful vaccines, such as Hepatitis B (HBV) vaccines and the Human Papilloma Virus (HPV) vaccines. But the goal of our technology is to present a protein-based nanoparticle that closely resembles the target virus in size, and shape and with multiple copies of the antigen presented in a stabilised pre-fusion configuration. Our scientists use computational tools to analyse viral structures and rationally design our vaccine antigens. They have also designed a stable, multilayered, protein particle scaffold that can display and deliver 20-60 antigens.

Other vaccine technologies utilise the spike antigens alone that may not be in a stable prefusion state. This innovative approach has clear applications in several different disease areas, such as respiratory viruses (Influenza, SARS-CoV-2, RSV, etc.), pandemic preparedness (Lassa, Marburg, Dengue, Zika, etc.), Malaria, Tuberculosis and Hepatitis C. The Uvax Bio 1c-SApNP protein platform can be utilised for most if not all 'enveloped' viruses which do not have protein core like HPV and

HBV.

How are UVAX-1197 and UVAX-1107 different from HIV prevention vaccines that have failed in clinical trials, such as those studied in the PrEPVacc trial?

There are three key differences in the Uvax Bio HIV-1 vaccines that have been shown to dramatically increase the vaccine responder rates and produce robust and broad neutralising antibodies in preclinical models:

1. A novel 'uncleaved prefusion-optimised (UFO)' HIV-1 trimer with stable, native-like structures.
2. The Uvax HIV-1 vaccines deliver 20 prefusion trimers on each stable, 'multilayered' protein nanoparticle with a built-in T-cell activator.
3. Introduction of glycan trimming to remove part of the HIV-1 Env spike's glycan shield thereby making conserved, neutralising epitopes on the virus surface more accessible to the immune system.

Why is the clinical trial being conducted in Australia?

Australia offers a simple, supportive and robust regulatory process that enables small biotech companies to initiate human trials efficiently. Australia also has a strong reputation for the quality of its scientific and medical research. Australia is internationally recognised for its highly trained clinical workforce, and the high-quality data produced by its experienced, trained (and accredited) research teams and regulatory agencies.

What is the global and APAC HIV data? Why is this particularly significant for the APAC region?

UNAIDS estimates that 38.4 million people worldwide are currently living with HIV, and 1.5 million people became newly infected with HIV in 2021 alone. Asia is second only to sub-Saharan Africa as the region with the greatest number of people with HIV. Although HIV prevalence is low, the absolute number of people living with HIV was high at more than 2.2 million in reporting countries and territories in 2021, because of APAC's large population. Over the past years, many countries in APAC responded to HIV/AIDS successfully and incidence rates have declined. However, certain countries have experienced increases in infections. According to UNAIDS, the Philippines more than tripled the number of new cases of HIV infection between 2000 and 2018.

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