

South African AIDS vaccine testing starts

Two South African developed HIV vaccines have begun clinical testing in the United States.

The South African AIDS Vaccine Initiative (SAAVI), which is a lead programme of the Medical Research Council and is supported by the South African government, this week announced the start of the phase I safety trial in the USA. The trial, called SAAVI 102/HVTN 073, will be conducted jointly with the HIV Vaccine Trials Network (HVTN) and the US National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH). It will test two vaccines developed by the University of Cape Town through joint funding from SAAVI and NIAID, NIH.

The development of these vaccines is the culmination of eight years of research and development which has involved scientists across South Africa and globally. The vaccine design is based on HIV subtype C, the dominant strain circulating in southern Africa. It is the first HIV test vaccine developed in Africa to make it into human clinical trials. This phase I trial will start in Boston, in the USA next week. Testing in South Africa will start in early January 2009. The trial has been approved by the South African Medicines Control Council (MCC) and the Directorate of Biosafety in the Department of Agriculture (which approves products using genetically modified organisms). The US arm of the trial will involve 12 participants whilst the South African arm, once approved, aims to recruit 36 participants from two sites, one in the Western Cape and another in Gauteng.

The test vaccines - called SAAVI MVA-C and SAAVI DNA-C2 - have shown promising results in animal testing. The DNA vaccine was wholly developed by South Africans while the MVA vaccine was designed by the team at UCT and constructed and manufactured in the USA.

“We are delighted that this vital project has reached such a critical stage in its development and I would like to take this opportunity to thank all of the people who have contributed their time and expertise to allow us to reach this point,” says Prof. Anna-Lise Williamson, leader of the team at University of Cape Town's Institute for Infectious Disease and Molecular Medicine. “This is a massive achievement, for us it is the culmination of eight years' work, made possible, to a large extent, by SAAVI funding and a strong partnership with NIH.”

The SAAVI DNA-C2 was constructed in South Africa and manufactured in the US by Althea Technologies. The MVA vaccine was manufactured by Therion Biologics, USA. The vaccines will be tested in a prime-boost approach where the SAAVI DNA-C2 vaccine will be given to prime the immune system and the SAAVI MVA-C vaccine to boost or enhance the immune system response.

“This clinical trial represents a milestone for South Africa, as one of the few developing countries to have developed an HIV vaccine and progressed it into human clinical trials. It is progress in the search for an HIV vaccine which would provide the best chance to halt the global HIV epidemic; as well as a significant step in South Africa's growing competence in complex

vaccine development,” says Prof. Anthony MBewu, President of the Medical Research Council.

A phase I trial for an HIV vaccine generally involves volunteers who do not engage in risky sexual behaviours or intravenous drug use and are therefore at low risk for infection. A phase I trial primarily tests for safety, tolerability and side-effects but also starts to look at the effect of the vaccine on the human immune system. If successful, a phase I trial is followed by larger phase II and III trials which involve more volunteers and provide information on whether the product is able to protect against infection. A vaccine can only be licensed for public use after it has been tested and found successful in all three phases of clinical trials.

“While there have been recent disappointments in vaccine research, we need to keep trying to find an HIV vaccine as this is our best hope of ultimately controlling this devastating epidemic,” says Glenda Gray, lead investigator on the clinical trials team.

“SAAVI is extremely gratified that these test HIV vaccines are entering human clinical trials,” says the Interim Director of SAAVI, Elise Levendal. “However, there is still a long way to go before we will know if these products will be in any way successful in preventing HIV infection.”

“Interventions to prevent the spread of HIV infection are urgently needed and the news that testing of a new vaccine in the USA will commence this week is thus welcomed, says Prof. Greg Hussey, Director of the Institute of Infectious Disease and Molecular Medicine. “The IIDMM and UCT are extremely proud to be associated with the SAAVI, who have been involved in the development of the vaccine.”

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