

LAUNCH OF THE PHASE II TRIAL OF THE HIV-1 TAT VACCINE IN SOUTH AFRICA

The Istituto Superiore di Sanità and the South African National Department of Health announce today the launch of the phase II clinical trial *ISS T-003* in South Africa based on the biologically active HIV-1 Tat protein, developed by the Italian research group coordinated by Barbara Ensoli at the National AIDS Centre of the Italian Istituto Superiore di Sanità chaired by Prof. Enrico Garaci.

The Tat vaccine has shown to be safe and capable of inducing specific antibody and cellular immune responses in previous phase I and II clinical studies conducted in Italy and represents a promising tool to improve immune functions in HIV-infected patients treated with antiretroviral drugs.

“On these bases, the clinical trial ISS T-003 is starting today in South Africa”– says Enrico Garaci, President of the Istituto Superiore di Sanità - This trial is conducted thanks to the efforts based on the funding of the Italian Ministry of Health and of the Italian Ministry of Foreign Affairs, part of a cooperative program between the Governments of Italy and South Africa” (‘Program to support the Ministry of Health of South Africa in the implementation of a National Program of Global Response to HIV & AIDS’).

This initiative, funded by the Italian Ministry of Foreign Affairs, Directorate General of Development Cooperation (MAE-DGCS), is implemented by the National AIDS Center of the Istituto Superiore di Sanità in collaboration with the South African National Department of Health (NDOH) and the South African AIDS Vaccine Initiative of the Medical Research Council (MRC-SAAVI).

The trial is being conducted at the Medunsa Clinical Research Unit (MeCRU), Ga-Rankuwa, Gauteng Province, South Africa. The involvement of an additional site, the Walter Sisulu University HIV Vaccine Research Unit (WSUHVRU) (Mthatha, Eastern Cape), is envisaged by the last quarter of 2011 once the Research Unit is fully capacitated.

The study is double-blinded, placebo-controlled and will involve 200 participants between 18 and 45 years of age.

The therapeutic immunization will be performed by three monthly administration of the Tat vaccine to HIV infected individuals on antiretroviral therapy (HAART). The primary objective of the study is the evaluation of the immunogenicity of the vaccine candidate as well as the confirmation of the safety of the candidate vaccine as previously tested in Italy.

The T-003 protocol has been approved by the South African National regulatory authority (Medicine Control Council/MCC) and by the Medunsa Ethics and Research Committee (MREC).

The study is supported by the following independent committees, each with a specific function:

- the Data Safety Monitoring Board (“DSMB”) – composed of international experts of well-documented experience in the field of HIV/AIDS. The DSMB will monitor the safety of the volunteers by periodically evaluating all the clinical and laboratory data collected during the trial.

- the International Advisory Board (“IAB”) - composed of international experts in the immunological, virological and vaccine field will provide independent advice to the Sponsor in taking decisions and solutions in any critical situations that may ensue from the study.
- the Community Advisory Group (CAG) and Community Advisory Board (CAB) composed of representatives of patients and local communities hit by HIV. These Community bodies will play a key role in the involvement of the community, through the organisation of educational activities and awareness events. Furthermore, they will give advice to the Principal Investigator and to the Sponsor in ensuring the well being of the trial participants.

The results of the phase II (ISS T-002) clinical trial conducted in Italy in 11 clinical centers and now in phase of completion, show that the vaccination with Tat is safe and immunogenic and that the Tat vaccine is capable to improve immune functions in HIV-infected patients treated with antiretroviral drugs [Ensoli et al, *PLoS One*, 2010, 5 (11): e13540]. The Tat vaccine showed a novel and key role in reducing the immune system alterations observed in HIV infection and usually persisting even under successful antiretroviral treatment. In addition, the trial showed that those patients who are the most immunocompromised appeared to benefit the most from Tat vaccination.