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## Therapeutic vaccination with Tat restores immune homeostasis, promotes proviral DNA decay and induces cross clade neutralizing antibodies in patients on HAART: Results from phase II clinical trials in Italy and South Africa

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Tat is a key regulatory protein and virulence factor of HIV playing major roles in virus gene expression, replication and transmission. Tat is also a key for virus reactivation, maintenance of the virus reservoir and in immune dysregulation, all unmet needs of HAART. In addition, by binding Env spikes, Tat forms an entry complex promoting an integrins mediated infection of DCs and efficient virus transmission to T-cells. By binding Env, Tat shields HIV from Env neutralizing antibodies (Abs); conversely, anti-Tat Abs, which is infrequently produced in natural infection, restores HIV neutralization. This provides a strong rationale for using Tat in HIV/AIDS vaccine development. Results from two phase II trials in Italy and South Africa in 168 and 200 anti-Tat Ab negative subjects under effective HAART, respectively, indicated that vaccination with Tat was safe and immunogenic and reverted signs of AIDS progression, since it reduced immunoactivation, increased T (CD4+), B lymphocyte and NK cell number and restored CD4+ and CD8+ central memory subsets, independently from CD4 nadir and particularly in the most immunocompromised patients. Remarkably, proviral DNA load progressively decreased in vaccines. Reduction correlated with anti-Tat Ab titers and neutralization of Tat mediated entry of Env in DCs. Further, vaccination induced cross clade neutralizing anti-Tat Abs and protected patients non-compliant to therapy from CD4+ T cell decay and viral load increase. Phase III studies are planned for vaccine registration.

### Biography

Barbara Ensoli is the Director of the National AIDS Center, Italy. She has spent over 10 years at NIH and returned back to Italy in 1996 and initiated an HIV Tat based vaccine program, currently in advanced clinical phase. She has coordinated national and international research programs in Europe and developing countries. She has also coordinated 7 clinical trials and 7 observational studies in Italy and South Africa. She was the Vice President of the National AIDS Committee for 8 years and a Member of EMBO and of the *European Research Council (ERC)*. She has over 300 publications in peer reviewed international journals.

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