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## HIV DNA remaining not detectable two years after Tat Oyi vaccination in HIV infected volunteers under cART

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A synthetic vaccine targeting the HIV Tat protein was tested on HIV infected volunteers under antiretroviral treatment (cART) at Marseille. BIOSANTECH is the sponsor of this monocentric clinical trial divided in a phase I/IIa and in a phase IIb. The protocol, based on the hypothesis that neutralizing antibodies against Tat may contribute to eliminate HIV infected cells, was authorized by the French drug administration (ANSM) on January 24th, 2013. Long term HIV infected volunteers (n=48) were randomized in four groups having at M0, M1 and M2 double blinded intradermal injections respectively with 0, 11, 33 or 99 µg of a synthetic protein called as Tat Oyi in a phosphate buffer complemented with NaCl (9 g/l) without adjuvant. The result of Phase I/IIa revealed that the Tat Oyi vaccine was safe and was statistically effective at lowering the extent of HIV RNA (Mann and Whitney test, p=0.07, 95% confidence interval) following a cART interruption from M5 to M6 (Loret et al., 2016). Follow up of volunteers showed that HIV DNA remains no longer detectable at M24 in those who got the vaccine (Figure 1). HIV DNA not detectable for a long period of time is never observed in HIV infected patients under cART. This is the first step toward HIV eradication reached by the Berlin patients in 2009. The second step is a decrease of antibodies against HIV (retro seroconversion) that the Berlin patient reached in 2012. A phase IIb will begin soon on volunteers who participated to phase I/IIa. The main outcome is that Tat Oyi vaccinated volunteers who are HIV DNA not detectable, with a rétroseroconversion, can stop cART and remain HIV RNA and HIV DNA not detectable. In that case, the Tat Oyi vaccine would allow HIV infected patient to reach a functional cure.

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## T-cell therapeutic vaccine for autoimmune components of viral infections

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In some autoimmune diseases T-cell populations have been identified as responding to self-antigens and acting as effectors in the pathological autoimmunity. In the procedure of T-cell vaccination (TCV), such cells are cultivated, expanded and re-injected as vaccine into the patient after fixation, in order to induce an immune response against them and protect the organism from their pathological activity. Extensive animal experimentation has shown that TCV was effective in treating various models of autoimmune diseases. Clinical trials have produced positive results on multiple sclerosis, rheumatoid arthritis and lupus. Some viral infections trigger autoimmune pathological activity which can develop later into an autonomous way in addition to the direct effects of the virus. Results of TCV against the autoimmune component of the physiopathology of HIV infection will be presented. A similar approach could be used in other such virus induced pathologies like hepatitis C induced autoimmunity.

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