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# Tat Oyi-based candidate therapeutic vaccine: a successful phase 1 clinical trial in HIV-1 infected patients

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**Background:** Tat protein is an HIV virulence factor involved in several physiopathological pathways, and shown to be expressed even during HAART. Several studies have shown that an immune response to HIV-1 Tat is correlated with the control of HIV replication in animal models and a slower disease progression in human. Tat-based vaccine candidates were assessed in clinical trials with variable results. Our rational for using Tat Oyi as a novel vaccine candidate is provided by the isolation of the HIV-1 Oyi defective clone in an asymtomatic Gabonese. The Tat Oyi mutant is defective for transactivation. Further more, antibodies generated against Tat Oyi were able to cross-recognize all Tat variants of the five main world HIV-1 clades.

**Methods:** The Tat Oyi-based vaccine candidate was designed using the full length Tat. The immune response to Tat Oyi has been characterized in preclinical models.

A clinical trial phase I/II has been started for a therapeutic Tat Oyi vaccine application: In a double blind study, forty eight HIV seropositive were divided in four groups (twelve patients per group) received three consecutive injections of a candidate vaccine composed of 0 (group 1 control placebo), 10 (group 2), 33 (group 3) and 100 µg (group 4) of synthetic Tat Oyi. In each case, the three injections were intradermal and achieved monthly (i.e. M0, M1 and M2).

**Results:** Preclinical studies have demonstrated the potency of Tat Oyi vaccination to generated neutralizing antibodies against conformational epitopes not found in other Tat vaccine candidates. Further more, a vaccination assay with Tat Oyi in a macaque model showed that injected animals had lower viremia levels after heterologous mucosal challenge with SHIV, moreover the virus-infected reservoir cells disappeared with time in the vaccine group. In clinical Phase I trial, the vaccine candidate with Tat Oyi proved to be safe and well tolerated.

**Conclusions:** The specific feature of this vaccine candidate versus other Tat based vaccine candidates relies on Tat 3D conformation and the ability to induce a cross reactive immune response to Tat variants, active against this extracellular HIV target. Biosantech's vaccine candidate therapeutic effect will be analyzed by measuring the immune response and HIV replication after stopping HAART for 2 months in the ongoing Phase IIa trial.

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