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Lentiviral-based anti-HIV therapeutic vaccine: Design, preclinical studies and phase I/II clinical trial preliminary results

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Abstract

THERAVECTYS develops a new generation of prophylactic and therapeutic vaccines using optimized lentiviral vectors. It's most advanced product, a therapeutic anti-HIV vaccine treatment, has entered clinical Phase I/II end of 2012. This vaccination should allow seropositive patients to gain an immunological status identical to the so-called "Functional Cured" patients who develop an efficient immunological response capable of controlling the infection without therapy. Vaccine candidates are integrative and self-inactivated live-recombinant lentiviral vectors. They encode an HIV antigen, under the regulation of a patented promoter that is preferentially induced in APC (generating the specific immune response), and showing a basal level expression in all cells (allowing their elimination by the settled immune response).These vaccine candidates are classified as "Live recombinant vectored vaccines" (EMA, 2011).

Preclinical studies demonstrated i)the generation of a strong, specific and very long lasting T-cell immune response (up to 2 years in murine animal models), ii) the restricted diffusion of the vaccine candidates after injection and iii)their fast disappearance within few weeks, correlated with an absence of macroscopic and microscopic toxicity.

These data allowed the settlement of the anti-HIV therapeutic Phase I/II clinical trial that is held in France and Belgium and is actually enrolling 36 HIV-1 infected patients. Theravectys' anti-HIV vaccine treatment is assessed at three doses and safety, tolerability and immunogenicity compared to a placebo group. Furthermore, vaccine efficiency will be evaluated by the interruption of the HAART treatment in all patients, including placebo. Results are expected by 2014 with intermediary analysis in September 2013.

Biography

Bauche has completed her Ph.D. from the Paris University and postdoctoral studies from Pasteur Institute and Ecole Normale Supérieure. Since 2007, she leads Theravectys' research team to implement a technological platform for lentivectors production and to develop lentivector-based vaccine candidates. She managed the design and the production of Theravectys' first candidate, an anti-HIV therapeutic vaccine that has entered in clinical phase I/II in October 2012. She also designed and managed the preclinical studies to evaluate the vaccine candidate safety, and took part in the interactions with the European and French regulatory authorities for the application for clinical trial authorization.