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VAC-3S vaccine, a novel approach to the therapeutic management of HIV infection. Overview of phase I and phase II clinical vaccine development programs

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Background: HIV infection is a chronic persistent inflammatory disease. Morbidity remains despite antiretroviral therapy (ART) Achieving functional cure is now a goal. VAC-3S vaccine is comprised of 3S peptide, a highly conserved gp41 motif, commercially used carrier and adjuvant. In cohort or primate studies, anti-3SAb correlate with lack of CD4 decrease, affect on immune/inflammatory biomarkers, HIV reservoirs.

Phase I: FTIH randomized, double-blind, placebo-controlled assessment of safety of 0.1, 1, 10, 20 µg, IM, q4wks in ART controlled patients (pts) & a booster in 1 & 10 µg groups. 33 HIV pts (29 M) were included. Age 47 yrs (32-54), none had detectable HIV RNA, CD4 710 c/mm3 (311-1187). No viral rebound under treatment. 1 SAE, non-related. Gr1-2 AEs: local reactions, fever, LFT increases (3) myalgia(1). Six pts in 1 to 20 µg doses increased anti-3SAb above the target 50 Units. Ab titers subsequently decrease but can be effectively re-boosted (n=3/6 pts).

Phase II: Assessment of therapeutic properties of VAC-3S, at 16, 32 & 64µg doses, combined with standard ART. This European multicenter, randomized, double blind, placebo-controlled study will assess immunogenicity and efficacy on HIV reservoir, inflammatory biomarkers, a full immunological panel in pts on ART with CD4 count 200-500 c/mm3. Statistical methodology will allow extensive subgroup analysis.

Conclusion: VAC-3S HIV therapeutic vaccine is immunogenic, it is safe at the 4 doses studied. In phase IIA, dose escalation continues. Phase IIB will notably assess VAC-3S in combinations that can potentially lead to full immune restoration and contribute to a functional cure of HIV.

Biography

Raphael Ho Tsong Fang possesses 15 years of experience in HIV field, immunology and pathophysiology. He is currently Associate Medical Chief Officer at InnaVirVax, a European clinical stage biotechnology developing cutting edge immune-based treatments for infectious and major chronic diseases. He actively participates into the development of therapeutic vaccines against the disease induced by HIV, from R&D to non-clinical and clinical development. He is a Doctor in Veterinary Medicine from the Medicine University of Nantes and holds a PhD in Medical Virology from Denis-Diderot University of Paris. He completed his Post-doctoral studies at the Department of Microbiology, Immunology and Molecular Genetics at UCLA.

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