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► **To cite this version:**

Dominique Salmon-Céron, Christine Durier, Corinne Desaint, Lise Cuzin, Mathieu Surenaud, et al.. OA04-01. Safety and immunogenicity of LIPO-5, a HIV-1 lipopeptide vaccine: results of ANRS VAC18, a phase 2, randomized, double-blind, placebo-controlled trial. *AIDS Vaccine* 2009, Oct 2009, Paris, France. *BioMed Central*, 6 (Suppl 3), pp.O25, 2009, *Retrovirology*. <10.1186/1742-4690-6-S3-O25>. <inserm-00663582>

**HAL Id: inserm-00663582**

**<http://www.hal.inserm.fr/inserm-00663582>**

Submitted on 27 Jan 2012

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## OA04-01. Safety and immunogenicity of LIPO-5, a HIV-1 lipopeptide vaccine: results of ANRS VAC18, a phase 2, randomized, double-blind, placebo-controlled trial

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from AIDS Vaccine 2009  
Paris, France. 19–22 October 2009

Published: 22 October 2009

Retrovirology 2009, 6(Suppl 3):O25 doi:10.1186/1742-4690-6-S3-O25

This abstract is available from: <http://www.retrovirology.com/content/6/S3/O25>

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### Background

ANRS HIV-LIPO-5 vaccine includes 5 long peptides, Gag17–35, 253–284, Pol325–355, Nef66–97 and 116–145, containing multiple CD8+ and CD4+ T-cell epitopes, coupled to a palmytoil tail. Phase 1 studies have shown that vaccine dosage at 500 µg/lipopeptide elicits cellular immune responses. Whether HIV-LIPO5 immunogenicity varies with the dosage is unknown.

### Methods

One hundred and thirty two 21- to 55-year-old HIV negative volunteers, enrolled in 6 HIV-vaccine clinical sites, were randomized to receive either the HIV-LIPO-5 vaccine at 50 µg/lipopeptide (N = 32; LIPO-5 50), 150 µg (N = 32; LIPO-5 150), 500 µg (N = 33; LIPO-5 500) or placebo (N = 34). Vaccinations were given IM at weeks 0, 4, 12 and 24. HIV-1 specific CD8+ (IFN-gamma ELISpot on PBMC cultured 12-days) and CD4+ responses (PBMC lymphoproliferation) were assessed at baseline, two weeks after each injection, and at week 48.

### Results

No adverse events attributable to vaccine were noted throughout the study. Local reactions appeared dose-dependent; no differences in systemic reactions were observed between groups. Sustained (at least on 2 separate occasions) CD8+ response rates to at least one HIV-1 pool were: 5/32 (16%) for placebo, 22/32 (69%) for LIPO-5 50, 21/33 (64%) for LIPO-5 150 and 21/34 (62%) for LIPO-5 500 groups ( $P \leq .0001$  for all comparisons to placebo). Cumulative CD4+ response rates were: placebo: 2/32 (6%), LIPO-5 50: 15/32 (47%), LIPO-5 150: 18/33 (55%) and LIPO-5 500: 15/34 (44%) ( $P < .0001$  for all comparisons to placebo). The majority of CD4+ (75%) and CD8+ (60%) responses were directed towards Gag253–284. CD8+ responses against Nef, Pol were noted in 36% and 33% of vaccinees, respectively. At week 48, CD8+ responses persisted in 47/91 (52%) HIV-LIPO-5 recipients.

### Conclusion

ANRS VAC18 shows that low and high doses of HIV-LIPO-5 vaccine elicit sustained CD8+ and CD4+ T-cell responses. According to the good tolerance of the vaccine,

the lowest dose of 50 µg appears as the most appropriate to be used in further trials.

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