PA-153 SAFETY OF RVSV EBOLA VACCINE, AFTER 6 MONTHS FOLLOW-UP, IN ADULTS: A PHASE 1 TRIAL CONDUCTED IN LAMBARÉNÉ, GABON

José Fernandes,[1,2,3] Emmanuel B. Bache,[1] Régis M Obiang Mba,[1] Anita L. Kabwende,[1] Benjamin Mordmüller,[1,2] Sanjeev Krishna,[1,2,4] Peter G. Kremsner,[1,2] Martin P. Grobusch,[1,2,3] Agnandji Selidji Todagbe[1,2]. [1]*Centre de Recherches Médicales de Lambaréné (CERMEL), Albert Schweitzer Hospital, Lambaréné, Gabon;* [2]*Institute for Tropical Medicine, University of Tübingen (Germany);* [3]*Centre of Tropical Medicine and Travel Medicine, Department of Infectious Diseases, Division of Internal Medicine, Academic Medical Centre, Amsterdam, The Netherlands;* [4]*Institute for Infection and Immunity, St. George's, University of London, UK*

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Introduction The Centre de Recherches Médicales de Lambaréné (CERMEL) in Gabon, member of the 'VSV-EBola CONsortium' (VEBCON), evaluated safety and immunogenicity of the rVSVΔG-ZEBOV-GP vaccine in African volunteers from an area with previous Ebola outbreaks before its use during the last outbreak in West Africa.

Methods From November 2014 to April 2015 we performed an open-label, dose escalation phase 1 trial to assess safety, side-effect profile, and immunogenicity of rVSV-ZEBOV. A total of 115 healthy adults both male and non-pregnant or lactating female volunteers aged 18–50 years old living in Lambaréné (Gabon) were included. Participants were allocated to five vaccine dose groups: 3×10^3 PFU (n=20), 3×10^4 PFU (n=20), 3×10^5 PFU (n=20), 3×10^6 PFU (n=39) and 2×10^7 PFU (n=16). Here, we present data on adverse events (AE) and serious adverse events (SAE) between days 180 and 365 after vaccine injection (Day 0).

Results From Month six to Month 12, the proportion of volunteers with AE as well as number and grade of AEs per volunteer were similar in the five groups. A higher total number of events occurred in the cohort 3×10^6 PFU, the largest group. Most symptoms were mild to moderate. No clinically significant laboratory changes were observed. Three events - two episodes of *P. falciparum* malaria and one snake bite - were graded as serious, because they required hospitalizations. Both SAE were judged as non-related to the vaccine and resolved without sequelae. None of the adverse events was related to rVSV-ZEBOV vaccine.

Conclusions Our results confirmed an acceptable profile of safety and tolerability of rVSV-ZEBOV up to 12 months of follow-up. In order to investigate possible late-stage safety signals follow-up period of the study was extended to five years. Integrating data (assessment until 60 months) from all the VEBCON study sites is the next key step allowing a final conclusion about safety of rVSV-ZEBOV. The trial was registered on the Pan African Clinical Trials Network website with the number PACTR201411000919191