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Effect of Chemokine Adjuvants on Safety and Immunogenicity of Serine Repeat Antigen (SERA) DNA Malaria Vaccine Candidate in Olive Baboons (*Papio anubis*)

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A safe and effective blood stage malaria vaccine could be a novel weapon in ameliorating the impact of malaria in endemic areas and reinforce hope for malaria eradication. The realization of an effective vaccine has been complicated due to lack of an appropriate adjuvant for human use. This study evaluated the effect of chemokine adjuvants CCL5 and CCL20 on tolerability, safety, immunogenicity of SERA DNA malaria vaccine constructs and cross protective efficacy against *Plasmodium knowlesi* H strain in the olive baboon *(Papio anubis)* model of malaria. Nine male malaria naïve olive baboons were randomly allocated into three experimental groups of three animals each depending on vaccine regimens (SERA with CCL5 in pIRES, SERA with CCL20 in pIRES and pIRES vector backbone alone). All baboons were immunized intramuscularly with a total medium dose of 1mg/ml of respective vaccines at 0-, 28-, and 56-days schedule. On day 84 all baboons were challenged with *P. knowlesi* H strain blood stage parasites to determine cross protective efficacy. There were no abnormal changes in animal health status, haematology and clinical biochemistry profiles. Immunization site local reactogenicity did not show any vaccine related adverse reactions. Analysis of cellular responses showed that the vaccines were immunogenic with a significant increase in T cell responses. Humoral immune responses showed an increase in anti SERA5 IgG titres throughout the vaccination phase. All experimental baboons developed patent parasitaemia showing that there was no vaccine efficacy as measured by delay in time to parasitaemia and development of clinical disease. SERA DNA vaccine constructs co-expressed with either CCL5 or CCL20 as chemokine adjuvants were safe, well tolerated, and immunogenic with no vaccine related serious adverse events in monkeys. Low cross protection efficacy against *P. knowlesi in vivo* was observed. The current research results provide an initial preclinical validation of CCL5 and CCL20 as immunomodulatory chemokine adjuvants for malaria blood stage vaccines.

- **19th International Scientific Conference,* 11th-13th September 2013, *at Southern Sun Mayfair Hotel, Nairobi*