Vaccines and immunity

OC - (8582) - A PHASE IA/B STUDY TO ASSESS SAFETY AND IMMUNOGENICITY OF PLACENTAL MALARIA VACCINE CANDIDATE: PRELIMINARY RESULTS OF THE PRIMALVAC TRIAL

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Background: Adhesion of *P. falciparum*-infected erythrocytes (PEs) to placental chondroitin-4-sulfate (CSA) has been linked to the severe placental malaria (PM) outcomes. Evidences strongly support the VAR2CSA variant surface antigen mediating PEs CSA-binding phenotype as the leading candidate for a PM vaccine. This study was conducted to assess the safety and immunogenicity of 3 different dosages (20µg, 50µg and 100µg) of the recombinant VAR2CSA protein (PRIMVAC), formulated with Alhydrogel or GLA-SE administered at days 0, 28 and 56.

Methods: A randomized double-blind phase Ia/ib dose-escalation vaccine trial was conducted in healthy adult women. Within 4 sequential cohorts, volunteers were randomized to 2 arms (PRIMVAC adjuvanted with Alhydrogel or GLA-SE) in the first phase conducted in France and then to 3 arms (PRIMVAC with Alhydrogel or GLA-SE or placebo) in Burkina Faso. Enrolled volunteers were observed for at least 1 hour following each vaccination then seen at 1 day and 7 days later for safety evaluations. Serious adverse events (SAE) were recorded throughout the study duration. Routine clinical laboratory safety analyses were performed prior first injection and at each subsequent visit.

Results: A total of 68 subjects were recruited in the four study cohorts No SAE was reported in any of the cohort A volunteers and enrolment in cohort B started. A Data Safety Monitoring Board (DSMB) reviewed the safety data for cohorts A (20µg) and B (50µg) before the trial was initiated in Burkina Faso. The DSMB also reviewed the safety data in Burkina to authorize the progression from the cohort C (50µg) to cohort D (100µg). Last vaccination of the last subject occurred in September 2017.

Conclusions: This was the first placental malaria vaccine phase Ia/b clinical trial conducted in France and Burkina. No serious adverse events have been recorded. Preliminary safety and immunogenicity results will be presented.