**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.