

reactogenicity symptoms were reported beyond the already mild to moderate intensity symptoms reported during the first 28 days' post injection. No severe (grade 3) adverse event was reported. Median haematology and biochemistry values were within site normal ranges at month 12.

**Conclusion** The vaccine dose of  $2 \times 10^7$  PFU showed an acceptable safety and tolerability profile in our volunteers' age 6–17 years, living in a setting endemic for Ebola virus transmission. This acceptable safety profile seen in adolescents and children is similar to that previously reported in adults.

OA-023 **ONE-YEAR SAFETY OF THE rVSVΔG-ZEBOV-GP VACCINE IN ADOLESCENTS AND CHILDREN IN LAMBARÉNE, GABON**

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**Background** The rVSVΔG-ZEBOV-GP vaccine was safe and immunogenic in American, European and African adults. Few cases of transient, self-limiting arthritis have been reported in some adult participants in Geneva. We describe one-year safety of a single dose ( $2 \times 10^7$  plaque forming unit (PFU)) of the vaccine administered to adolescents and children living in Lambaréné.

**Methods** A phase I, open label randomized trial conducted in Lambaréné, Gabon, to assess the clinical safety (adverse events (local/systemic symptoms, and laboratory anomalies)) for 365 days' post injection. The primary objective was to assess the nature, frequency, and severity of adverse events (AEs) and/or serious adverse events (SAEs) associated with the administration of the vaccine.

**Results** From 08-May 2015 to 07-Jul-2015, a total of 20 adolescents and 20 children aged 13–17 and 6–12 years respectively, were vaccinated with a single intramuscular dose of  $2 \times 10^7$  PFU rVSVΔG-ZEBOV-GP vaccine. Two serious adverse events (SAE) were reported over one year of follow-up. Two adolescents were hospitalized for *Plasmodium falciparum* malaria and pneumonia infection. Up to 12 months' (6 months of extended follow-up) of both active and passive reporting, the most frequently reported symptoms by vaccinees are classified under the following system organ classes (SOC): Gastrointestinal disorders 30%(6/20) and 40%(8/20), respiratory-thoracic and mediasternal disorders 5%(1/20) and 45%(9/20), and infections/infestations 20%(4/20) and 20%(4/20) for adolescents and children respectively. No case of arthritis was observed, few cases 13%(5/40) of mild to moderate arthralgia, unrelated to the vaccine were reported. No delayed