OA-022 SAFETY AND IMMUNOGENICITY OF CO-ADMINISTERED HOOKWORM VACCINE CANDIDATES NA-GST-1 AND NA-APR-1 WITH ALHYDROGEL® AND GLUCOPYRANOSYL-LIPID A IN GABONESE ADULTS: INTERIM RESULTS

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Background Hookworm disease is one of the most prevalent of the neglected tropical diseases. To date, the control of hookworm infection has been limited to mass-administration of anthelminthic drugs. Despite this, the global hookworm prevalence does not decrease, thus there is a need for a vaccine. We evaluated the Na-GST-1 and Na-APR-1 hookworm vaccine candidates simultaneously in a hookworm endemic Gabonese population.

Methods Eligible healthy Gabonese adults aged 18–50 years were enrolled in a randomised, double blind, controlled phase I trial. The first cohort received 30 μg Na-GST-1 co-administered with 30 μg Na-APR-1. The second cohort received 100 μg Na-GST-1 and 100 μg Na-APR-1. All doses were administered after mixing with 5 μg of an aqueous formulation of glucopyranosyl Lipid A (GLA-AF), a Toll-like Receptor-4 agonist. Hepatitis B vaccination (HBV) was administered as a comparator. Study subjects were vaccinated on days 0, 28 and 180 by intramuscular injection. IgG antibody levels were measured by qualified ELISA. This study evaluated the safety, reactogenicity,

and immunogenicity of *Na*-GST-1/Alhydrogel® co-administered with Na-APR-1/Alhydrogel®.

Results Thirty-two study participants were enrolled. No serious adverse events or significant changes in haematological, renal or liver function parameters were observed. Mild-to-moderate injection-site pain, headache and fever were common adverse events. Elevated Na-GST-1 and Na-APR-1 IgG antibody levels were detected on day 194. Significant differences in mean antibody levels were observed between dose groups for Na-APR-1 [30 μg: 18 (50–86.9) *vs* 100 μg: 197 (131– 264); p< 0.0001] but not for Na-GST-1 [30 μg: 338 (213–463) *vs* 100 μg: 402.54 (283.65–521); p=0.5].

Conclusions Co-administration of the hookworm vaccine candidates (Na-GST-1 and Na-APR-1) was safe and well tolerated. In order to achieve optimal antibody levels, a series of three high doses needs to be administered. Additional investigations are necessary to consider this combination as a potential bivalent vaccine candidate.