

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 anthelmintic 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.