Background Human hookworm infection is a major public health issue in tropical low and middle-income countries with severe consequences. To date, improvement of water supply, sanitation, and hygiene is the major contributor to disease control, and additional control tools are needed. Here, we assess a phase I trial of a new hookworm vaccine candidate Na-APR-1 (M74)/Alhydrogel and Na-GST-1/Alhydrogel in Gabonese school-age children.

Methods A double-blind, randomised, controlled, dose escalation phase I clinical trial that aims to evaluate safety, reactogenicity and immunogenicity of Na-APR-1 (M74)/Alhydrogel co-administered with Na-GST-1/Alhydrogel hookworm vaccines in children aged 6 to 10 years living in hookworm-endemic area of Lambaréné, compared to the hepatitis B vaccine (ENGERIX-B). Children received three doses of assigned vaccines, delivered intramuscularly (deltoide) on Days 0, 56, and 112 or 180. Safety is measured from Day 0 through Day 14 by the occurrence of solicited injection site and systemic reactogenicity events. Clinical laboratory evaluations were performed approximately 14 days after each immunisation. Unsolicited adverse events were collected from Day 0 through approximately 1 month after each vaccination.

Results A total of 135 children were screened, and 60, aged 6 to 10 years old, were randomised into 3 groups and received 10 μg, 30 μg or 100 μg of Na-APR-1 (M74)/Alhydrogel and Na-GST-1/Alhydrogel, respectively, compared to ENGERIX-B. At baseline, the mean age of the study population was 7.4 years and the sex ratio 1.3 (male: female). From Day 0 up to Day 14 after vaccination, the main solicited adverse events were pain and swelling at injection sites with 135 (26 of grade 2 and 1 of grade 3) and 9 events, respectively. Regarding systemic adverse events, 3 occurrences of grade 1 headache were recorded. Immunogenicity analyses are underway.

Conclusion The preliminary results confirm that co-administration of the two hookworm vaccine candidates is safe and well-tolerated in Gabonese children.