Vaccines and immunity

OC - (8521) - PRELIMINARY REPORT ON SAFETY OF CO-ADMINISTERED HUMAN HOOKWORM VACCINE CANDIDATES NA-APR-1 (M74)/ALHYDROGEL® AND NA-GST-1/ALHYDROGEL® IN GABONESE CHILDREN.

Zinsou, Jeannot Frejus (Gabon); Honpkehedji, Josiane (Gabon); Jean Claude, Dejon Agobe (Gabon); Adegbite, Romeo (Gabon); Edoa, Jean Ronald (Gabon); Van Leeuwen, Remko (Netherlands); Diemert, David (United States of America); Botazzi, Maria Elena (United States of America); Kremsner, Peter (Germany); Yazdanbakhsh, Maria (Netherlands); Hotez, Peter (United States of America); Grobusch, Martin P. (Netherlands); Adegnika, Ayola Akim (Gabon); De Vries, Sophie (Netherlands)

1 - Centre de Recherches Médicales de Lambaréné; 2 - Academic Medical center; 3 - George Washington University School of Medicine & Health Sciences; 4 - Baylor College of Medicine and Texas Children’s Hospital; 5 - Institut für Tropenmedizin, Universität Tübingen, Tübingen, Germany; 6 - Leiden University Medical Center

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 1 of a new hookworm vaccine candidate Na-APR-1 (M74)/Alhydrogel® and Na-GST-1/Alhydrogel in Gabonese school-age children.

Methods: Double-blind, randomized, controlled, dose-escalation Phase 1 clinical trial 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 ENGERIX-B. Children received three doses of assigned vaccines delivered intramuscularly (deltoid) 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 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 from 6 to 10 years old, were randomized 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.

Conclusions: The preliminary results confirm that co-administration of the 2 hookworm vaccine candidates is safe and well tolerated in Gabonese children.