

## Clinical trials for first-ever human hookworm vaccine advance

5 November 2012

The Sabin Vaccine Institute (Sabin) today announced the start of Part II of its Phase I clinical trial of the Na-GST-1 vaccine candidate, marking another major milestone in the progress toward developing a human hookworm vaccine. Part II of the trial commenced in Americaninhas, Brazil, following successful vaccinations in Part I of the study, which began in Belo Horizonte, Brazil in late 2011.

An independent Safety Monitoring Committee (SMC) recently reviewed results from Part I of the study and determined that no safety issues had been observed after vaccinating healthy adults who had never been exposed to hookworm. They concluded that these promising results were sufficient to allow researchers to proceed to the next stage of the trial, in which hookworm-exposed adults will receive the vaccine candidate.

Part II of the study is taking place in Americaninhas, a hookworm-endemic region of Brazil. The trial will enroll 66 healthy, hookworm-exposed adults between the ages of 18 and 45. Each volunteer will receive three injections over four months. Researchers will then follow each volunteer for 12 additional months, monitoring the vaccine's safety and analyzing the recipients' immune responses.

"Eventually, a human hookworm vaccine will be used to protect children at risk of infection. Because the hookworm-exposed population being vaccinated in Part II of this trial is representative of the eventual target population, we're closer to making this goal a reality," said Dr. David Diemert, the trial's principal investigator.

The trial is being conducted in partnership with a team based at the Oswaldo Cruz Foundation (FIOCRUZ) of the Brazilian Ministry of Health, a member of the Sabin Vaccine Institute Product Development Partnership (Sabin PDP).

"Moving forward with this trial helps advance the Sabin PDP's larger goal to develop safe, efficacious and low-cost vaccines for diseases of poverty," said Dr. Peter Hotez, president of the Sabin Vaccine Institute. "A human hookworm vaccine will help more than 600 million people worldwide who currently suffer from the infection."

Hookworm is a soil-transmitted helminth infection caused by the intestinal parasites Necator americanus and Ancylostoma duodenale. Although people living in most middle- and upper-income countries are largely free from the suffering caused by hookworm, the infection remains widespread in tropical and sub-tropical climates of Africa, Asia and Latin America. Left untreated, <a href="hookworm">hookworm</a> infection causes intestinal blood loss leading to irondeficiency anemia and protein malnutrition, which in turn can result in impaired physical and cognitive development in children.

Provided by Sabin Vaccine Institute

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