Clinical trial of human hookworm vaccine begins at Children's National Medical Center

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Today, the Sabin Vaccine Institute, in partnership with the George Washington University and the Children's National Medical Center, began vaccinating participants for a Phase 1 clinical trial of a novel human hookworm vaccine. The trial will investigate the Na-GST-1 antigen developed by the Sabin Vaccine Institute Product Development Partnership (Sabin PDP) to prevent hookworm infections in endemic areas.

"This trial signifies the great progress global health leaders are making to help combat diseases of poverty," said Dr. Peter Hotez, president of the Sabin Vaccine Institute and director of the Sabin Vaccine Institute and Texas Children's Hospital Center for Vaccine Development. "This trial helps advance our goal to develop a safe, efficacious and low-cost vaccine to reduce the global burden of human hookworm, which infects nearly 600 million people worldwide." Dr. Hotez is also the founding dean of the National School of Tropical Medicine at Baylor College of Medicine.

This study will help to quickly determine the optimal vaccine formulation for future clinical testing of the Na-GST-1 antigen. A critical component of the vaccine being tested is a novel adjuvant developed by the Infectious Disease Research Institute (IDRI) of Seattle, Washington. The adjuvant, GLA-AF, could potentially help to stimulate the immune system for an improved specific antibody response to the vaccine antigen.

"We hope that this trial will offer us the breakthrough we need to ultimately stop transmission of this parasite, especially among the world's poorest," said Dr. Jeff Bethony, Associate Professor of Microbiology, Immunology and Tropical Medicine at the George Washington University.

The clinical trial is based at the Children's National Medical Center in Washington, D.C. The trial will enroll 72 healthy adults between the ages of 18 and 45 residing within the Washington, DC metropolitan area. Each volunteer will receive three injections over four months. The researchers will then follow each volunteer for 12 additional months, monitoring the vaccine's safety and analyzing the recipients' immune responses.

A concurrent trial of the Na-GST-1 antigen began in November 2011 in Brazil, an area with a high hookworm disease burden in endemic regions. The Brazil trial is being conducted by a team based at the Oswaldo Cruz Foundation (FIOCRUZ) of the Brazilian Ministry of Health, a member of the Sabin PDP.

"By conducting clinical trials in both Brazil and here in the United States, we will be able to rapidly determine the best formulation of the Na-GST-1 vaccine to advance into future vaccine trials in children, the population most at risk of hookworm disease. At the same time, we will help improve biotechnology capacity in an endemic country," said Dr. David Diemert, Principal Investigator of both clinical trials and an Associate Research Professor at the George Washington University.

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, hookworm infection causes severe intestinal blood loss leading to iron-deficiency anemia and protein malnutrition, which in turn can result in impaired physical and cognitive development in children.

Provided by Sabin Vaccine Institute