Schistosoma vaccine to enter phase Ib clinical trial

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Researchers at Baylor College of Medicine, in collaboration with a team of researchers at the George Washington University and the Rene Rachou Institute, have received funding from the National Institutes of Health for a Phase Ib clinical trial for a Schistosomiasis vaccine in an endemic area of Brazil. The same group also led the initial Phase I study performed at Baylor.

The vaccine was developed by a consortium of partners of the product development partnership led by Texas Children's Hospital Center for Vaccine Development.

"It's exciting to see this vaccine advance through clinical development," said Dr. Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine. "Schistosomiasis ranks among the most devastating poverty related neglected diseases - and a schistosomiasis vaccine would be a game changer both for global public health and poverty reduction."

Hotez and Dr. Maria Elena Bottazzi, associate dean of the National School of Tropical Medicine at Baylor, serve as co-directors of the product development partnership.

Schistosomiasis is the second most deadly parasitic infection in humans, following malaria. The chronic, often debilitating, infection afflicts more than 200 million people worldwide. Its toll on society is measured in terms of disability-adjusted life years lost, including losses due to

premature death and losses of healthy life and productivity caused by poor health and disability. The disease most often occurs in sub-Saharan Africa and Latin America.

The vaccine target in this study is the intestinal/liver schistosomiasis caused by Schistosoma mansoni, one of two species that accounts for approximately one-third of the total number of schistosomiasis cases and almost one-half of deaths worldwide, including all of the cases occurring in the Americas.

The Sm-TSP-2 antigen was selected as the lead candidate to target the disease caused by S. mansoni. The first study to examine the vaccine's safety and immunogenicity was conducted at the Baylor College of Medicine Vaccine Treatment and Evaluation Unit in 2015 in persons who had not lived in an area where the disease is endemic. The current trial will be conducted in Brazil, where S. mansoni is endemic. Investigators from the George Washington University will enroll subjects at a clinical site they have developed in Americaninhas, Brazil with Brazilian colleagues from the René Rachou Institute that is part of the Oswaldo Cruz Foundation (FIOCRUZ) of the federal Brazilian government.

The study will recruit up to 60 healthy males and non-pregnant females for a clinical trial of a vaccine to protect against schistosomiasis caused by infection with S. mansoni. Two formulations of the vaccine will be tested using a double-blind, randomized and controlled study design.

"The main purpose of the study is to assess the vaccine safety in a group of healthy adults who may have previously been exposed to schistosomiasis," said Dr. Robert Atmar, professor of infectious diseases at Baylor and co-principal investigator of the trial. "The investigative team will also evaluate the ability of different doses of the vaccine with or without adjuvant to induce antibody and cellular immune responses to

the vaccine agent."

Samples collected during the study will be analyzed at the George Washington University.

"Right now, people are treated for schistosomiasis only to be rapidly reinfected. Creating a vaccine is critical to stopping this cycle," said Dr. David Diemert, principal investigator of the study and associate professor of microbiology, immunology, and tropical medicine at the George Washington University School of Medicine and Health Sciences.

"We are excited to be collaborating with the research teams from Baylor College of Medicine and FIOCRUZ on this important trial," stated Dr. Jeffrey Bethony, professor of microbiology, immunology, and tropical medicine at the George Washington University School of Medicine and Health Sciences, who will lead the laboratory evaluations of the immune response to the vaccine.

Provided by George Washington University