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## **Scientists Report Injectable Formulation of Cryopreserved Malaria Parasites Achieves “Controlled” Infection, Offering New Tool for Fight Against Major Killer**

*Speaking at ASTMH Annual Meeting, researchers say breakthrough could make it much easier to evaluate new drugs and vaccines while also becoming a vaccine itself*

ATLANTA (November 13, 2012) In a breakthrough that could accelerate malaria vaccine and drug development, scientists announced today that, for the first time ever, human volunteers were infected with malaria via a simple injection of cryopreserved sterile parasites that were harvested from the salivary glands of infected mosquitoes in compliance with regulatory standards. The parasites had been frozen in a vial for more than two years.

The established gold standard for deciding whether or not to proceed with the development of a new malaria drug or vaccine is known as a “human challenge” trial, in which volunteers exposed to the vaccine or experimental drugs are deliberately subjected to bites from infected mosquitoes. The findings from this study indicate that direct injection of cryopreserved parasites can be used in lieu of mosquito bites.

In a presentation at the annual meeting of the American Society of Tropical Medicine and Hygiene (ASTMH), researchers at Radboud University Medical Center in the Netherlands and their colleagues from Sanaria Inc. and Protein Potential LLC said the findings from this study eventually could lead to a powerful tool for testing promising malaria drugs and vaccines in trials that involve deliberately exposing subjects to a “controlled human malaria infection” (CHMI). Also, they said the injectable formulation of malaria parasites might be considered, by itself, as part of a novel approach to providing protection against a disease that each year kills at least 650,000 people, most of them young children in Africa. The findings were also published today online in the [American Journal of Tropical Medicine and Hygiene](#) and will be published in the January 2013 print issue.

“Our study shows it’s possible to manufacture and then administer controlled doses of malaria parasites using a needle and syringe to deliver a formulation that can meet regulatory standards for purity and dose consistency,” said Meta Roestenberg, MD, of the Radboud University Nijmegen Medical Center and the lead author of the study along with Else M. Bijker, MD.

The current “human trial challenge” method is technically complex and costly, and there are only a few places in the world today where such work is being done. Also, when using mosquitoes to deliver malaria parasites (or “sporozoites” as they are called when they first invade the human body), it can be difficult to ensure that all subjects receive the same level of infection. And scientists say that can influence the outcome of the treatment.

In a controlled human malaria infection trial, conducted at Radboud University Medical Center from October 2010 to July 2011, researchers injected eighteen healthy Dutch volunteers with cryopreserved *Plasmodium falciparum* malaria sporozoites (PfSPZ Challenge). The study showed that 84% of participants – five of the six volunteers in each group – were safely and successfully infected with no differences among the groups in the time it took for the infection to develop or the presentation of symptoms. The volunteers who developed infections subsequently received treatment and quickly recovered without incident.

“We have demonstrated the potential to develop what you might call the human challenge trial in a bottle that could be available to scientists anywhere who need to know how a new drug or vaccine would fare against a real but carefully controlled and calibrated malaria infection,” said Stephen L. Hoffman, MD, chief executive and scientific officer of Sanaria Inc. and the study’s co-senior author. “This accessibility could be particularly important for expanding malaria research capabilities at African research centers, which is critical to combating this resilient disease.”

The authors of the study also said that the results could provide evidence for developing what are known as “whole parasite” vaccines. Robert W. Sauerwein, MD, PhD, of Radboud University Medical Center said that the new study showing that infections could be accomplished with a simple shot in the arm could make the whole parasite approach more feasible.

“A major challenge to realizing the potential of whole parasite vaccines is the development of a stable, consistent formulation of sporozoites that can be manufactured, preserved and used like any other vaccine,” said Sauerwein, the study’s other senior author.

Sanaria is currently pursuing clinical trials to test two different approaches to whole parasite vaccination—irradiated sporozoites and inducing controlled infections in tandem with the administration of anti-malaria drugs. Also, researchers are planning additional trials to ensure the infection produced with the cryopreserved sporozoites mirrors what one would experience through bites from infected mosquitoes.

“This study is a great example of the innovative and dynamic research being done through partnerships across academic and corporate sectors that’s translating research into needed tools to control and ultimately eradicate malaria,” said James Kazura, president of the American Society of Tropical Medicine and Hygiene. “What we have here is a new avenue, a new clue to study how the infection develops, and with that we are moving closer to eliminating what is truly a global scourge.”

*Disclosure: Sanaria Inc. manufactured PfSPZ Challenge, and Protein Potential LLC is affiliated with Sanaria. Thus, all authors associated with Sanaria or Protein Potential have potential conflicts of interest.*

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**About the American Society of Tropical Medicine and Hygiene**

[ASTMH](#), founded in 1903, is a worldwide organization of scientists, clinicians and program professionals whose mission is to promote global health through the prevention and control of infectious and other diseases that disproportionately afflict the global poor.

**About the *American Journal of Tropical Medicine and Hygiene***

Continuously published since 1921, [AJTMH](#) is the peer-reviewed journal of the American Society of Tropical Medicine and Hygiene, and the world's leading voice in the fields of tropical medicine and global health. *AJTMH* disseminates new knowledge in fundamental, translational, clinical and public health sciences focusing on improving global health.