

**INITIAL TRIAL OF SANARIA'S MALARIA VACCINE YIELDS POSITIVE RESULTS**  
*Findings Provide Evidence that Vaccine is Safe and Potent*  
*Clinical Trials in U.S. and Africa to Follow*

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(Rockville, MD, September 8, 2011) – Positive results from the initial Phase 1 clinical trial in 80 healthy volunteers and complementary pre-clinical studies of the Sanaria<sup>®</sup> PfSPZ Vaccine are published today in the online issue of *Science* ([www.sciencexpress.org](http://www.sciencexpress.org)).

“This is the first indication that a highly effective malaria vaccine may be available that can be used to eliminate *Plasmodium falciparum* malaria in geographically defined areas and prevent malaria in travelers” says Fred Binka, MD, PhD, Dean of the School of Public Health, University of Ghana.

Medical science has long been on a quest for an effective malaria vaccine. There are some 250 million malaria cases worldwide annually, with as many as 800,000 deaths, most of them children in Africa.

An effective vaccine that prevents malaria infection is considered the only tool that will eventually conquer this disease. Such a vaccine must prevent infection in greater than 80% of recipients for 6-24 months in order to be suitable for elimination campaigns and protecting travelers.

High level protection has only been achieved in humans who were immunized by the bite of mosquitoes that inoculated live, sporozoite stage *Plasmodium falciparum* parasites that had been weakened by irradiation or drugs. Immune cells called cytotoxic or killer CD8+ T cells that are activated by the sporozoites are responsible for the protection against malaria after immunization with irradiated sporozoites.

It is not feasible to immunize large numbers of humans by bite of mosquitoes carrying sporozoites, and it was considered impossible to manufacture a sporozoite vaccine that met regulatory standards.

“Therefore, despite the high level protection induced by sporozoites administered by mosquito bite, before the breakthroughs reported in the *Science* paper, no human had ever been immunized with a sporozoite vaccine administered by needle and syringe,” says Stephen L. Hoffman, MD, Sanaria’s Chief Executive and Scientific Officer.

Sanaria has developed a unique manufacturing process that meets FDA standards to produce the Sanaria<sup>®</sup> PfSPZ Vaccine. The vaccine is composed of attenuated (weakened) malaria sporozoites that are the stage transmitted to humans by mosquitoes.

The vaccine was tested by a team of biomedical scientists from the U.S. Military Malaria Vaccine Program (Naval Medical Research Center and Walter Reed Army Institute of Research); University of Maryland Center for Vaccine Development; Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Sanaria Inc.; PATH Malaria Vaccine Initiative; and Protein Potential, LLC. The principal findings and conclusions reported in ***Science*** are:

1. Sanaria<sup>®</sup> PfSPZ Vaccine was safe and well tolerated in this Phase 1 clinical trial in humans.
2. Sanaria<sup>®</sup> PfSPZ Vaccine administered in the skin by needle and syringe to humans was immunogenic and protective, but not nearly to the levels found after mosquito bite immunization.
3. Sanaria<sup>®</sup> PfSPZ Vaccine administered by intravenous injection to animals, triggered unprecedented high levels of malaria parasite-specific CD8+ T cells in the liver, the hallmark of protective immunity.
4. Sanaria<sup>®</sup> PfSPZ Vaccine is highly potent.

Based on these results, the PfSPZ Vaccine administered by intravenous injection will soon be assessed in a clinical trial at the Vaccine Research Center, NIAID, NIH in the United States. A trial in Tanzania is also being planned.

Professor Marcel Tanner, Director Swiss Tropical and Public Health Institute, comments, “Sanaria has ushered in a whole new era of malaria vaccine development and testing. We are heartened that a path toward a vaccine that can be used to entirely prevent infection with *Plasmodium falciparum* malaria has been established and will be rigorously pursued.”

Internationally renowned malariologist and vaccinologist Professor Michael Good of Griffith University, Australia says, “The results presented in *Science* represent an enormous step toward the development of the highly effective malaria preventative vaccine generally recognized as essential for the elimination and eventually the eradication of the malaria scourge.”

**About Sanaria Inc.:**

Sanaria Inc. was founded in 2003. The Company’s mission is to develop and commercialize whole-parasite malaria vaccines that confer high-level, long-lasting protection against *Plasmodium falciparum*, the parasite responsible for most of the malaria-associated severe illness and death worldwide, and the other parasites that cause human malaria. Sanaria’s corporate headquarters, administrative, research, development, and manufacturing operations are located in Rockville, Maryland. The Company’s website is <http://www.sanaria.com>.

Except for historical information, this news release contains certain forward-looking statements that involve known and unknown risk and uncertainties, which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by the statements made. Such statements include the availability of an effective vaccine, the expectations for conquering malaria, beliefs concerning the suitability of a successful vaccine, and the establishment of a path toward prevention of infection. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, the Company’s ability to raise sufficient funds, the regulatory approval process, dependence on third parties, clinical trials results, the Company’s patent portfolio, ability to commercialize the vaccine, dependence on key personnel and other risks associated with vaccine development.