

Sanaria *Pf* SPZ Malaria Vaccine Candidate

The Project: Conduct a Safety and Test-of-Concept Trial

The PATH Malaria Vaccine Initiative (MVI) is partnering with Sanaria Inc. to accelerate development of a novel malaria vaccine candidate. This strategic partnership will focus on the development and manufacture of Sanaria's *Pf* SPZ malaria vaccine—one that uses a whole-organism approach to target the most deadly malaria parasite, *Plasmodium (P.) falciparum*.

The project aims to determine whether a vaccine using Sanaria's technology is safe, protective, and practical for vaccinating infants and children in Africa. MVI and Sanaria plan to conduct an initial safety and test-of-concept trial among US volunteers in 2008.

The Potential: Finding the Right Formula to Maximize Impact

Malaria kills more than one million people every year, most of them children in sub-Saharan Africa. A vaccine is viewed as a critical part of a long-term malaria-control strategy, especially in Africa, where the climate and environment highly favor malaria transmission. Childhood immunization programs, which are among the most cost-effective health interventions, already save the lives of millions of children every year. A safe, effective, and affordable malaria vaccine would have the potential to save even more lives.

Supporting the development of *Pf* SPZ is part of MVI's strategy to advance a diversity of vaccine candidates that have the potential to either halt the malaria parasite or greatly reduce the severity of infection. While the approach of much malaria vaccine development centers on using one or more components of the malaria parasite that the human immune system can recognize, Sanaria uses an attenuated (weakened) form of the whole parasite.

Live, attenuated parasites in the form of sporozoites are harvested from the salivary glands of irradiated mosquitoes, purified, and used as the basis for vaccine formulation. The idea is that when this attenuated parasite is given to individuals, they will become immune to malaria but not get sick.

Evidence that this approach may work is based on previous studies in which volunteers were exposed to the bites of irradiated mosquitoes harboring attenuated parasites similar to those in Sanaria's vaccine. Inoculation by mosquito bite with these parasites resulted in high levels of protection against *P. falciparum*. While immunization of humans with attenuated malaria parasites has been considered for 40 years, the approach was not technically feasible until Sanaria developed technology capable of large-scale production of attenuated parasites from irradiated mosquitoes.

The Phase 1/2a clinical trial will be conducted at the Malaria Program Clinical Trials Center at the National Naval Medical Center in Bethesda, Maryland, and at the University of Maryland's Center for Vaccine Development.

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The PATH Malaria Vaccine Initiative (MVI) is a global program established at PATH through an initial grant of \$50 million from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of promising malaria vaccines and ensure their availability and accessibility in the developing world. For more information, please visit www.malariavaccine.org. **PATH** is an international, nonprofit organization that creates sustainable, culturally relevant solutions that enable communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being. For more information, please visit www.path.org.

Sanaria Inc. was founded in 2003. The company's mission is to develop and commercialize a malaria sporozoite vaccine against *Plasmodium falciparum*, the parasite responsible for more than 95 percent of malaria-associated severe illness and death worldwide, and the malaria parasite for which there is the most significant drug resistance. Sanaria has overcome the initial technological and regulatory barriers with support from the National Institute of Allergy and Infectious Diseases, the US Army Military Infectious Diseases Research Program, and the Institute for OneWorld Health. Sanaria's facilities are in Rockville, Maryland. For more information, please visit www.sanaria.com.