

Whole parasite malaria vaccine to be manufactured for clinical trials

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Sanaria Inc. and the PATH Malaria Vaccine Initiative has officially opened a one-of-a-kind clinical manufacturing facility to produce a vaccine that uses a weakened form of the malaria parasite to fight a disease that annually kills more than one million people, most of them African children.

The event marks a major milestone in the effort to translate Sanaria's approach into an effective weapon against the deadly malaria parasite *Plasmodium (P.) falciparum*.

Among those who marked the opening were US Representative Chris Van Hollen of Maryland's 8th District; economist Jeffrey Sachs, who has singled out fighting malaria as key to alleviating poverty in Africa; Ambassador of Ghana to the United States Dr. Kwame Bawuah-Edusei; and other African ambassadors.

The manufacturing facility has been carefully constructed to allow scientists to safely rear live, aseptically produced mosquitoes, feed them blood containing the malaria parasite, irradiate the insects to weaken the parasites, and then harvest the parasites from the mosquito salivary glands. The goal is to use these parasites as the main component of a "whole-parasite" vaccine to be tested in an initial clinical trial in adult US volunteers next year.

"The opening of this facility is an important step in the process to develop a whole-parasite malaria vaccine," said Dr. Stephen L. Hoffman, Sanaria's founder and CEO. "We are optimistic that the technology and expertise assembled here through our partnership with the PATH Malaria Vaccine Initiative and with support from the National Institutes of Health and the Department of Defense will allow us to take the vaccine through clinical trials."

"While attenuated mosquitoes were used in the late 1970s to demonstrate that protection against malaria with a vaccine was possible, the manufacturing challenges blocked further development," said Christian Loucq, director of the PATH Malaria Vaccine Initiative. "We believe with Sanaria that the technology it has developed and the facility unveiled today will allow it to overcome obstacles that have prevented large-scale production."

Evidence that the approach may work is based on previous studies in which volunteers were exposed to the bites of mosquitoes harboring weakened parasites similar to those in Sanaria's vaccine. Inoculation with these parasites resulted in high levels of protection. Ultimate success would be a safe, effective licensed vaccine that is widely deployed to prevent malaria,

especially in African children.

"A safe and effective malaria vaccine could be the key to saving millions of lives," said Dr. Regina Rabinovich, director of infectious diseases development at the Bill & Melinda Gates Foundation, which supports the project through a grant to PATH. "Sanaria's vaccine development program is a great example of the innovative research that could one day help eradicate malaria."

Most malaria vaccines under development today consist of recombinant or genetically engineered proteins that represent a portion of the parasite that is believed to be capable of eliciting an immune response against the disease. Sanaria is taking a different approach. The company seeks to induce protective immunity by producing a vaccine that contains a weakened form of the entire organism. The goal is that when the attenuated parasite is given to individuals, they will become immune to malaria but not get sick.

"This is an important day because it signifies that Sanaria is now equipped to answer two key questions about a whole-organism vaccine," said Loucq, the director of the PATH Malaria Vaccine Initiative. "Can this vaccine be reproducibly manufactured and if it can, will the vaccine work in experimental conditions?" The initiative works with partners in Africa, Asia, Europe, Australia, and North America as it supports a variety of approaches to developing a safe and effective malaria vaccine.

Sanaria's Manufacturing Process

Sanaria's vaccine manufacturing process begins with hatching and rearing uninfected mosquitoes. The mosquitoes are allowed to feed on blood containing *P. falciparum* malaria parasites. After they have fed on the infected blood, the mosquitoes are irradiated to weaken the parasite using a technique developed in consultation with (and monitored by) staff at the US National Institute of Standards and Technology.

Sanaria scientists then employ special equipment and processes to harvest large numbers of parasites from the salivary glands of the mosquitoes. The parasites are at the stage known as sporozoites. Though weakened and unable to cause disease, they remain biologically active and are placed in vials and stored at low temperature. Sanaria has worked to ensure all stages of production meet rigorous US Food and Drug Administration regulatory requirements.

Sachs, who serves as a non-compensated member of Sanaria's advisory board, noted that the Sanaria project and other cutting-edge endeavors are critical for conquering malaria.

"Sanaria's thrilling progress toward developing the first highly preventative malaria vaccine is causing excitement around the world," he said. "With Sanaria's important scientific breakthroughs to date, and with more on the horizon, the world has the realistic prospect of a fundamental breakthrough in malaria control. An effective malaria vaccine will offer Africa enormous gains in human wellbeing and in the continent's prospects for economic growth and development."

Many of the scientists working on the Sanaria project have years of experience at the front lines of malaria research and biotechnology. Much of it was gained in Maryland's bustling

commercial biotech sector.

"Maryland is home to more than 380 bioscience companies, and I am honored to participate in the opening ceremony of this manufacturing facility at Sanaria Inc., a company focusing on the global fight against malaria," said Governor O'Malley. "Sanaria's malaria vaccine candidate joins some of the most important medical applications in the world, and I am proud to announce that they are being developed right here in Maryland's biotech corridor."

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. MVI's vision is a world where all children are safe from malaria. For more information, please visit <http://www.malaria vaccine.org>.

Founded in 1977, PATH is an international, non-profit organization that creates sustainable, culturally relevant solutions, enabling 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 <http://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 world-wide, 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 U.S. Army Military Infectious Diseases Research Program, the Institute for OneWorld Health, and the PATH Malaria Vaccine Initiative. Sanaria's facilities are in Rockville, MD. For more information see <http://www.sanaria.com>.