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## Press Release

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### Related News

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Hale Named Laureate in Health for 2003  
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Hale is Named Schwab Outstanding  
Social Entrepreneur  
OneWorld Health Press Release 08.25.03

### INSTITUTE FOR ONEWORLD HEALTH RECEIVES GATES FOUNDATION GRANT TO FUND DEVELOPMENT OF MALARIA VACCINE

OneWorld Health to Work with Sanaria Inc. on Novel Malaria Vaccine Approach

**07.13.04** San Francisco, Calif. The Institute for OneWorld Health, the first nonprofit pharmaceutical company in the U.S., announced today it has received a \$1.4 million grant from the Bill & Melinda Gates Foundation to support development of a vaccine for the prevention and treatment of malaria, including for infants and children in the developing world.

Globally, more than 300 million cases of malaria occur annually and one million people, mostly children, die of the disease. Resistance to existing drugs and lack of both affordable and adequate treatments continue to make 40 percent of the world's population susceptible to malaria, especially in Africa, where a child dies every 30 seconds from the disease.

OneWorld Health has chosen to use part of its Gates Foundation grant to enter into a funded research arrangement with Sanaria Inc., a company that is developing a novel malaria vaccine. In addition to funding research and development activities, over the next 12 months, OneWorld Health will provide to Sanaria regulatory consulting and expertise on the project. This may include guidance in developing the quality assurance and quality control program for monitoring the manufacturing process, as well as planning for an Investigational New Drug (IND) application. Sanaria, based in Rockville, Md., will conduct various studies to confirm that key vaccine components can be produced with the ultimate goal of meeting U.S. Food and Drug Administration requirements.

Various independent studies conducted from the early 1970s through the late 1990s showed that exposure of human volunteers to the bites of mosquitoes infected with weakened (attenuated) malaria parasites, called sporozoites, protected more than 90 percent of those volunteers against developing malaria for at least 10 months. However, until Sanaria was launched, little effort was made to develop a malaria vaccine based on this approach. Sanaria is applying its unique manufacturing techniques and expertise in malaria and vaccine development to develop a novel, effective, practical and safe malaria vaccine.

"Exposure to radiation-attenuated sporozoites has reproducibly provided high-level protection of humans against malaria," said Stephen L. Hoffman, M.D., CEO and founder of Sanaria. "Our partnership with OneWorld Health will support further development of Sanaria's unique vaccine platform to determine whether we can produce a potent vaccine, practically, that we expect will meet FDA standards."

"We welcome the opportunity to work with Dr. Hoffman to determine whether Sanaria's simple and elegant approach could form the basis for an effective malaria vaccine," said Victoria Hale, Ph.D., CEO and Founder of OneWorld Health. "We also value the confidence the Gates Foundation has entrusted in us to apply our regulatory expertise in the development of a malaria vaccine."

The Institute for OneWorld Health, the first U.S. nonprofit pharmaceutical company, develops new, affordable medicines for infectious diseases that disproportionately affect people in the developing world. OneWorld Health applies its entrepreneurial business model with a staff of experienced pharmaceutical scientists who identifies promising leads and drives development from pre-clinical studies to clinical trials through regulatory approval. The Institute for OneWorld Health, headquartered in San Francisco, Calif., is a tax-exempt 501(c) (3), U.S. corporation ([www.oneworldhealth.org](http://www.oneworldhealth.org)).

org).

Sanaria Inc.'s goal is to develop and commercialize a non-replicating, metabolically active (attenuated) malaria sporozoite vaccine against Plasmodium falciparum, the malaria 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 its primary laboratories and offices in Rockville, Md. ([www.sanaria.com](http://www.sanaria.com)).

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