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PATH Malaria Vaccine Initiative Announces New Partnership to Accelerate Development of Novel Malaria Vaccine Candidate

MVI and Sanaria Inc. to Conduct Initial Safety and Test-of-Concept Trial

FOR IMMEDIATE RELEASE

Bethesda, MD, USA (December 14, 2006) – In a move that promises to expand the types of malaria vaccine candidates in clinical development, the PATH Malaria Vaccine Initiative (MVI) today announced a new partnership with Sanaria Inc., a Maryland company, to accelerate development of a unique malaria vaccine candidate.

Supported by a \$29.3 million grant to PATH from the Bill & Melinda Gates Foundation, this strategic partnership will focus on the development and manufacture of Sanaria’s malaria vaccine candidate—one that uses a novel, whole-parasite approach to preventing infection from the most deadly malaria parasite, *Plasmodium falciparum*. MVI and Sanaria will move quickly to conduct an initial safety and test-of-concept trial of the Sanaria candidate among volunteers in the United States.

“Close to one million children die of malaria each year,” said Dr. Melinda Moree, Director of MVI. “With this support, we can examine another promising malaria vaccine technology and bring the field closer to delivering a safe, effective, and affordable pediatric malaria vaccine to at-risk communities in Africa.”

Of the more than one million people who die of malaria every year, most of them are African children under five years old. Hundreds of millions more people suffer the effects of the mosquito-borne, parasitic disease each year. Scientists have been working for years to develop a preventive malaria vaccine and have recently demonstrated that such a vaccine is possible.

While the approach of much malaria vaccine research and development has centered on using one or more components of the malaria parasite that the human immune system can recognize, Sanaria is focused on using an attenuated, or weakened, form of the whole parasite. The idea is that when this attenuated parasite is given to individuals, they will become immune to malaria but will not get sick. This is the first vaccine candidate of its kind in the MVI portfolio.

“Sanaria’s sole mission is to develop and deploy a vaccine to prevent disease and death caused by malaria,” said Dr. Stephen L. Hoffman, CEO of Sanaria. “We are confident that teaming with

MVI will dramatically reduce the time it takes to fulfill our goal, and we are extremely excited about this partnership.”

Evidence that this 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 very high levels of protection against *Plasmodium 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 an attenuated malaria candidate vaccine. This project aims to determine whether a vaccine using Sanaria’s technology is safe, protective, and practical for vaccinating infants and children in Africa.

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The PATH Malaria Vaccine Initiative (MVI) is a global program established through an initial grant of \$50 million from the Bill & Melinda Gates Foundation, which awarded it an additional \$100 million in 2003 and \$107 million in 2005. MVI’s mission is to accelerate the development of promising malaria vaccines and ensure their availability and accessibility for the developing world. MVI’s vision is a world where vaccines protect children from death and severe disease caused by malaria. For information, visit <http://www.malariavaccine.org>. PATH is an international, non-profit organization that creates sustainable, culturally relevant solutions enabling communities worldwide to break longstanding cycles of poor health. 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 and the Institute for OneWorld Health. Sanaria’s facilities are in Rockville, MD. For more information see <http://www.sanaria.com>.