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HOLD FOR RELEASE UNTIL 00:01 AM EDT ON THURSDAY, APRIL 23, 2009

Phase 1 trial of whole-parasite malaria vaccine to begin

FDA approval for testing in humans watershed moment for unique malaria vaccine approach

ROCKVILLE, Maryland, April 23, 2009 – In a move that highlights the strength of public-private collaboration in tackling international health challenges, the Maryland-based company Sanaria Inc., with support from the PATH Malaria Vaccine Initiative (MVI), has initiated a Phase 1 clinical trial—the first tests in adult volunteers—of its unique malaria vaccine candidate. Unlike other malaria vaccine candidates, Sanaria's approach deploys a weakened form of the whole malaria parasite harvested from irradiated mosquitoes instead of small portions of the parasite.

Having met the US Food and Drug Administration's (FDA) rigorous safety, sterility, purity, potency, and reproducibility requirements for testing in humans, Sanaria's vaccine candidate is to be assessed in healthy US volunteers at two sites in Maryland—the US Naval Medical Research Center Clinical Trials Center in Bethesda and the Center for Vaccine Development at the University of Maryland School of Medicine in Baltimore. Recruitment has begun for the safety and efficacy study that will involve some 104 volunteers, with inoculation of the first groups expected to begin in mid-May.

"Initiation of this trial expands the spectrum of malaria vaccines in clinical development today," said Dr. Christian Loucq, Director of MVI. "This trial marks a major achievement in a collaborative development effort that aims to determine whether Sanaria's vaccine candidate is safe and effective."

While most malaria vaccines in clinical development consist of recombinant or genetically engineered proteins that represent small portions of the parasite, Sanaria's *Plasmodium falciparum* sporozoite vaccine candidate contains a weakened form of the entire malaria parasite. While unique to the malaria vaccine field, such live vaccines are used for other diseases including smallpox, polio, and measles. When the attenuated

parasite is given to individuals, they are expected to become immune to malaria and not get sick.

Evidence that the Sanaria approach has the potential to confer high levels of protection against malaria comes from previous studies in which volunteers were exposed to the bites of mosquitoes harboring weakened parasites. While the technological challenges associated with translating this approach into an effective and safe vaccine based on live parasites had been widely viewed as insurmountable, Sanaria has developed novel technologies and constructed a unique manufacturing facility that allows scientists to manufacture the candidate vaccine.

“The Sanaria team has been able to systematically overcome obstacle after obstacle in a remarkably short time. I look forward to working with the rest of the team to bring this vaccine over the finish line and into widespread use to prevent the devastating illnesses and deaths caused by malaria,” said Adel Mahmoud, former president of Merck Vaccines and member of Sanaria’s board of directors.

Ultimately, the measure of success will be a safe, effective licensed vaccine that is widely deployed to prevent malaria, especially in African children.

“The first clinical trial of Sanaria’s candidate malaria vaccine is a watershed event. It is the culmination of a remarkable translational research effort by Sanaria directed at realizing the dream of a practical malaria vaccine preparation based upon whole parasites,” states Michael Good, Director of the Queensland Institute of Medical Research.

Myron M. Levine, Director of the University of Maryland School of Medicine’s Center for Vaccine Development notes, “Development of Sanaria’s vaccine candidate is based in part on the findings from parallel studies conducted in the early 1970s by teams at the Center for Vaccine Development and the Naval Medical Research Center—findings that were never translated into a vaccine development effort because the task was considered to be impossible.”

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Sanaria Inc. was founded in 2003. The company’s primary 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 many partners and colleagues, including those at the National Institute of Allergy and Infectious Diseases, the US Military Malaria Vaccine Program, the US Army Military Infectious Diseases Research Program, the Institute for One World Health, the PATH Malaria Vaccine Initiative, and the University of Maryland School of Medicine Center for Vaccine Development. Sanaria’s facilities are in Rockville, MD. For more information, see 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 assessment of the vaccine candidate, expectations for the number and timing of the inoculation of study subjects, the expectations for immunity of the vaccine, and belief concerning the measure of success. 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, and the ability to commercialize the vaccine.

The PATH Malaria Vaccine Initiative (MVI) is a global program established at PATH through an initial grant from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world free from malaria. For more information, please visit www.malariavaccine.org.

About PATH

PATH is an international nonprofit 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 www.path.org.