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U.S. Army Joins Forces with Malaria Vaccine Initiative to Launch Clinical Trial in Kenya

Candidate Vaccine to Be Tested in Adults, then Children

ROCKVILLE, MARYLAND, USA (25 April 2002) – The Malaria Vaccine Initiative (MVI), the Walter Reed Army Institute of Research (WRAIR), the Kenya Medical Research Institute (KEMRI), and the U.S. Agency for International Development (USAID) marked today's observance of Africa Malaria Day with the announcement of field trials of a promising malaria vaccine candidate. The project is a collaboration of the four groups. MVI will provide technical support and US\$2.8 million in funding.

The trial, launched this month in adult volunteers in Western Kenya—an area of Africa severely affected by malaria—ultimately will test whether the vaccine can help children fight the infection before it causes severe illness. Africa currently accounts for about 90 percent of the estimated 2.7 million people killed each year by malaria, with the majority of those fatalities involving children under age five.

"We're fortunate to have found in WRAIR a partner with longstanding commitment and extensive experience in developing malaria vaccines," said MVI's director, Regina Rabinovich, MD. "WRAIR also has developed a strong partnership with the Kenya Medical Research Institute, and we're pleased that as part of this project we'll have KEMRI's scientific and clinical expertise to help move the trial forward."

The vaccine, which was first tested for safety in 60 U.S. civilian and military volunteers, was developed by WRAIR's highly regarded Army Malaria Vaccine Program (now headed by Colonel Gray Heppner) in collaboration with GlaxoSmithKline Biologicals (GSK) and USAID under a Cooperative Research and Development Agreement between WRAIR and GSK.

"Our goal is to produce a vaccine that will protect military personnel in malaria endemic regions, but it's clear that this vaccine candidate also holds tremendous potential for children," said Major General Lester Martinez-Lopez, commanding general of the U.S. Army Medical Research and Materiel Command, which oversees WRAIR's work. "With MVI adding critical support for these trials, we all can move that much faster toward our respective goals."

The participation of Kenyan scientists will be critical to the evaluation of this malaria vaccine candidate. In its 20+ years of existence, KEMRI has built a physical and professional

infrastructure—and a strong relationship with WRAIR—that make it an ideal partner for conducting the field trials required to successfully evaluate a vaccine.

"We see this project as not only a chance to test a vaccine, but also as an opportunity to expand our collaborations with the malaria vaccine development community in the fight against one of Africa's most stubborn public health problems," said Davy Koech, PhD, KEMRI's director and chief executive.

The clinical trials MVI supports are being carried out by the WRAIR U.S. Army Medical Research Unit (USAMRU-Kenya) and KEMRI near Kisumu, Kenya. If the results of the adult trial are encouraging, the project will continue with a safety and preliminary efficacy trial involving children, MVI's ultimate target group for a vaccine.

The vaccine focuses on the "blood stage" of the infection, the point at which the malaria parasite rapidly reproduces and relentlessly attacks red blood cells, causing actual disease. The key component of WRAIR's vaccine is the merozoite surface protein-1 antigen, or MSP-1. Antigens are parts of the malaria parasite that are capable of generating an immune response. To enhance the immune response of MSP-1, the formulation includes GSK's adjuvant AS02. MSP-1 has long interested scientists because many adults who carry the parasite but do not get sick have developed an immune response to blood-stage antigens. Producing even this level of immunity in children via a vaccine could save millions of lives.

If successful, the formulation could become part of a vaccine comprised of multiple antigens, as most scientists believe that a highly effective malaria vaccine will require a "combination" vaccine capable of targeting several parts of the malaria parasite. Currently, no vaccine is licensed to protect against malaria, but a vaccine is viewed as critical to subduing the epidemic. While anti-malarial drugs are available, the parasite has consistently developed resistance to them, leaving millions vulnerable to the disease.

USAID, which supported the development, production, and early testing of the vaccine, sees MVI involvement as bringing added momentum to the long-term campaign against malaria.

"This kind of collaboration is a good example of the relationships that must be nurtured if we are to make progress against a complex disease like malaria," said Carter Diggs, MD, PhD, Senior Advisor of USAID's Malaria Vaccine Development Program. "In particular, by sponsoring the field trial phase of the project, MVI has greatly accelerated testing of this vaccine."

Oversight for the trial comes from several areas. KEMRI conducts scientific and ethical reviews of the protocols and must grant approval before each trial commences. Institutional Review Boards from both the U.S. Army Surgeon General and Program for Appropriate Technology in Health (PATH), MVI's home organization, also approve and monitor the trials. The U.S. Food and Drug Administration provides regulatory oversight for this vaccine. In addition, an independent Data Safety Monitoring Board will be appointed to review trial safety data and reports of any adverse events.

The Malaria Vaccine Initiative (MVI) was established by Program for Appropriate Technology in Health (PATH) through a US\$50 million seed grant from the Bill & Melinda Gates Foundation. MVI seeks to accelerate the development of promising malaria vaccines and ensure their availability for the developing world. For further information about MVI and PATH, visit the Web sites at www.MalariaVaccine.org and www.path.org.

The Army Malaria Vaccine Program at the Walter Reed Army Institute of Research (WRAIR), a division of the U.S. Army Medical Research and Materiel Command, is the most active malaria vaccine development program in the world. With industry and NGO partners, WRAIR scientists have developed and evaluated more than 20 candidate malaria vaccines. Visit <http://wrair-www.army.mil> and www.usamrukenya.org for further details about WRAIR and the medical research unit in Kenya.

The Kenya Medical Research Institute (KEMRI) in Nairobi, Kenya, conducts biomedical research and serves as a centre of excellence for health research in Africa. KEMRI is within the Kenyan Ministry of Health, and works closely with various national councils and committees on issues of research policy and priorities. For additional information, visit the web site at <http://www.kemri.org>.

The U.S. Agency for International Development (USAID) has provided economic and humanitarian assistance worldwide for more than 40 years. For further information about USAID, please visit its Web site at www.usaid.gov.

