

***Embargoed until 2:00 p.m. GMT; 9:00 a.m. EST, Wednesday, December 5, 2001***

## ***Clinical Trials of Advanced Malaria Vaccine Candidate Expand to Mozambique***

Rockville, MD, and Rixensart, Belgium, December 6, 2001. The Malaria Vaccine Initiative at PATH (Program for Appropriate Technology in Health, a U.S.-based nonprofit organization) and GlaxoSmithKline Biologicals (GSK Biologicals) today announced plans to test the world's most advanced malaria vaccine candidate in Mozambique. The Centro de Investigaçao em Saude de Manhiça (CISM) will begin clinical trials in 2002. In limited clinical trials, the vaccine being tested – GSK Biologicals' RTS,S/AS02 – has already demonstrated promising results against malaria, the world's deadliest tropical disease.

GSK Biologicals and the Malaria Vaccine Initiative (MVI) joined forces early this year to accelerate the development of RTS,S/AS02 for children, since children under the age of five represent at least 75 percent of the estimated 2.7 million deaths caused by malaria each year. In April, under the MVI-GSK agreement, the Medical Research Council (MRC) in The Gambia began Phase I clinical trials of the vaccine in children between six and twelve years old. Phase I trials assess safety and immune response in volunteers. The initial safety data are encouraging, and a Phase I trial with younger children continues in The Gambia.

The MVI-GSK Joint Product Development Committee has decided to conduct the Phase II clinical trials in Mozambique because that nation experiences year-round malaria transmission, which allows for a more complete evaluation of the vaccine and its effects. Phase II trials assess preliminary efficacy. CISM, which is affiliated with Mozambique's Ministry of Health and Spain's Centre for International Health, Clinic Hospital of Barcelona, will conduct both Phase I and Phase II trials with children between one and five years old.

"Expansion of the clinical trial program to Mozambique will help move us forward in the search for an effective vaccine, not only by allowing year-round evaluation, but also by adding another excellent African clinical trial site to the malaria network," said Regina Rabinovich, M.D., Director of MVI.

"We look forward to contributing to the development of such an important vaccine and will put a highly dedicated and motivated team of scientists to the task," commented Dr. Pedro Alonso, Head of the Hospital Clinic of Barcelona and Scientific Director of CISM.

MRC in The Gambia and CISM in Mozambique are both centres of excellence for clinical studies, with highly experienced and motivated scientists. GSK Biologicals has

been collaborating with the MRC in The Gambia for the past four years. This is GSK's first collaboration with CISM.

"Clinical research centers with qualified staff and the capacity to conduct malaria vaccine trials in real life field conditions according to the high standards of Good Clinical Practice are critical to the successful development of a malaria vaccine" said Jean Stéphenne, President and General Manager, GSK Biologicals. "Sharing expertise between several institutions is an important step towards a successful clinical trial programme and prepares us for the more complex, larger trials in the next phase of clinical development, assuming favorable results from the Phase I and II trials."

Malaria has plagued the earth for tens of thousands of years. The World Health Organization estimates that 300-500 million cases occur annually. Forty percent of the world's population is at risk. Malaria has devastating health, social, and economic consequences, especially in the world's poorest countries. Development and implementation of an effective malaria vaccine would make a tremendous difference in the battle against this misery-producing disease.

However, developing a malaria vaccine is a tremendous technical and scientific challenge as the parasites responsible for the disease are highly complex and able to adapt to and escape the human immune system's defenses.

GSK Biologicals' RTS,S/AS02 candidate vaccine is designed to protect young children living in endemic areas against infection and clinical disease caused by *Plasmodium falciparum*, the most serious and deadly form of the malaria parasite. Clinical evaluation of the candidate vaccine started in 1995. Recent safety and preliminary efficacy (Phase IIb) field trials with adult men in The Gambia and Kenya showed that, in addition to being safe, the vaccine was partially efficacious, providing short-term protection. The MVI-funded project aims to assess the vaccine's effectiveness in children in malaria endemic areas and to extend the duration of protection.

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Program for Appropriate Technology in Health (PATH) established the Malaria Vaccine Initiative (MVI) through a \$50 million seed grant from the Bill & Melinda Gates Foundation. MVI seeks to accelerate the development of promising malaria vaccine candidates and ensure their availability for the developing world. For further information about MVI, visit the Web site at [www.MalariaVaccine.org](http://www.MalariaVaccine.org). PATH is dedicated to improving health, especially the health of women and children. Visit PATH's Web site at [www.path.org](http://www.path.org).

GlaxoSmithKline Biologicals, the world's leading vaccine manufacturer, last year distributed over 1.1 billion doses of vaccines to 177 countries, an average of 35 per second. For information, visit GSK Biologicals' vaccine Web site at [www.worldwidevaccines.com](http://www.worldwidevaccines.com). GSK Biologicals' parent company, GlaxoSmithKline PLC – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

Founded in 1996, the Centro de Investigaçao em Saude Manhiça (CISM) is the first peripheral health research centre in Mozambique to undertake medical research into the key health problems in that country. CISM was developed under a collaborative programme between the Mozambique Ministry of Health, the Maputo School of Medicine (Universidade Eduardo Mondlane) and the Clinic Hospital in Barcelona with core funding from the Spanish Agency for International Cooperation (AECI).

The Medical Research Council (MRC) has worked in The Gambia for 50 years and has developed a strong relationship with the community and the Government. More than 90 percent of The Gambia's children are immunized against the major childhood diseases. For more information about MRC, visit [www.mrc.ac.uk](http://www.mrc.ac.uk)