



A PATH Program
7500 Old Georgetown Road, Suite 1200
Bethesda, MD 20814 USA
Tel: 240.395.2700 Fax: 240.395.2591
www.malariavaccine.org
info@malariavaccine.org

For further information, contact:

CISM and Hospital Clinic of the University of Barcelona, Marc de Semir +34 93 227 5700

Malaria Vaccine Initiative, Amy Ekola Dye, +1 301 652 1558 x112

or Carol Hooks +1 301 7705377 x191

GlaxoSmithKline Biologicals, Anne P Walsh, + 32 2 656 9831

For immediate release

Clinical Trial of Advanced Malaria Vaccine Candidate Begins in Mozambique

MAPUTO, 1 July 2002 - The Mozambique Ministry of Health today announced the commencement of a clinical trial to continue the clinical evaluation of a promising malaria vaccine candidate to protect children from the world's deadliest tropical disease. The trial, which began today, is a collaborative effort involving the MOH, Centro de Investigaçao em Saude de Manhica (CISM), the Hospital Clinic of the University of Barcelona, GlaxoSmithKline (GSK) Biologicals, and the Malaria Vaccine Initiative (MVI).

In previous tests, this vaccine candidate-developed by GSK and known as RTS,S/AS02-protected adults in the US and The Gambia from infection for several months. Initial safety data from Phase I trials in children in The Gambia are encouraging. The effort just underway in Mozambique will test RTS,S in 60 children from one to four years old as part of a Phase I trial to reconfirm the vaccine's safety. If the results in Mozambique are similar to the results in the same age group in The Gambia, the project will expand later this year to a Phase II trial, which assesses preliminary efficacy-i.e., whether the candidate vaccine has any impact on disease-in a larger group of children.

Developing a vaccine for children is critical because children under the age of five represent at least 75 percent of the estimated 2.7 million deaths caused by malaria worldwide each year. Here in Mozambique, high rates of malaria can be found in all provinces, with 60 out of every 100 patients seeking medical care diagnosed with the infection and malaria patients occupying about 40 percent of the nation's hospital beds.

"We know this vaccine candidate will require additional testing and wouldn't be available until several years from now, but we are eager to assist in its evaluation, given the suffering malaria inflicts on people in our country, especially our children," said Francisco Songane, Mozambique's Minister of Health. "It is also important for people in Mozambique to be assured that there has been and continues to be considerable attention to the ethical and safety standards of this trial, and that includes independent monitoring by national and international observers."

"Our team has been eager to get out in the field and see how well this vaccine works because we know that an effective vaccine is critical to making long-term progress against the disease," noted Ricardo Thompson, MOH, co-principal investigator on the CISM project. "Many people in

our country don't have access to malaria drugs, and for those who do, it is not always enough to effectively fight the disease given the growing problem of drug-resistant parasites that can make drugs less effective."

"The start of the clinical trial in Mozambique is an important milestone in the effort to develop a malaria vaccine to protect children, said Jean Stéphenne, President and General Manager, GSK Biologicals. "It is only made possible by the strong partnership between scientists who have developed a promising vaccine candidate, the Mozambican Ministry of Health, the research group at CISM that will undertake the evaluation of the vaccine in children, and MVI, which funds the study."

Regina Rabinovich, M.D., Director of MVI, added, "It is critical to test promising vaccines in places where malaria is endemic, and in CISM we have a respected institution that has the expertise and capacity to implement a rigorous trial."

Progress toward a malaria vaccine has proven to be a tremendous scientific and technical challenge. The parasites responsible for the disease are highly complex and learn to evade the human immune system. Also, in places like Mozambique, some parasites have developed resistance to drugs used to treat malaria.

GSK Biologicals' RTS,S candidate vaccine is designed to protect young children living in endemic areas against infection and clinical disease by targeting *Plasmodium falciparum*, the most deadly form of the malaria parasite. Clinical evaluation of RTS,S started in 1995. Trials with adult men in The Gambia showed that, in addition to being safe, the vaccine protected most participants for two months, after which its effects began to wane.

It is possible that due to differences in their immune system, children could either be protected from infection longer or be protected from severe disease. In addition, the vaccine can be reformulated based on results of the trials, in a continuing effort to improve it. Even if it were to only limit rather than halt the parasite's invasion, the vaccine could still save many children.

If RTS,S proves effective, GSK Biologicals and MVI are committed to working together to ensure that it is licensed, produced in sufficient quantities, and made available at an affordable price so that it benefits the developing world, including the communities that are participating in the current trial.

The field trial is being conducted at the Manhica Health Center under the auspices of CISM, which is affiliated with the Ministry of Health and the Centre for International Health of the Hospital Clinic of the University of Barcelona. The Mozambican Ministry of Health and National Committee for Bioethics in Health have reviewed and approved the study. In addition, the protocol is in full compliance with the International Conference of Harmonisation for Good Clinical Practice and the Investigational New Drug regulations of the U.S. Food and Drug Agency (FDA).

The Ministry of Health of Mozambique has as its mission to promote and preserve the health of the Mozambican population and to promote and provide quality and sustainable health care services, gradually increasing its accessibility to all Mozambicans with equity and efficiency.

Founded in 1996, the Centro de Investigaçao em Saude Manhica (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 Hospital Clinic of the University of Barcelona with core funding from the Spanish Agency for International Cooperation.

The Malaria Vaccine Initiative (MVI) was established through an initial grant from the Bill & Melinda Gates Foundation to Program for Appropriate Technology in Health (PATH). MVI seeks to accelerate the development of promising malaria vaccine candidates and ensure their availability for the developing world. For further information, visit the Web site at 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.

GlaxoSmithKline (GSK) 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. 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.