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Clinical Trial of Advanced Malaria Vaccine Candidate to Begin in Mozambique

London, 8 July 2003 – An international partnership today announced the impending start of the first Phase 2 pediatric clinical trial of the world's most advanced malaria vaccine candidate. The trial will test the safety and efficacy of GlaxoSmithKline Biologicals' (GSK Bio's) RTS,S/AS02A vaccine in children in Mozambique. Mozambique suffers very high rates of malaria—the disease that kills more African children under the age of five than any other. The trial is a collaborative effort involving GSK, Mozambique's Ministry of Health (MOH) and Centro de Investigação em Saude de Manhica (CISM), the Hospital Clinic of the University of Barcelona, and PATH's Malaria Vaccine Initiative (MVI).

The GSK vaccine was first shown safe and able to generate an immune response in adults in Belgium, Kenya, The Gambia, and the US. It has since been found safe and immunogenic in children in The Gambia and Mozambique. Importantly, it also protected adults in the U.S. and The Gambia from infection for approximately two months. While there is no guarantee of success, it is hoped that this protection will last longer in children.

"We are excited about the progress this clinical trial represents for the entire malaria vaccine field," said Melinda Moree, Ph.D., Director of MVI. "It will give us critical information about the impact of a promising candidate vaccine for children and is a good example of the non-profit and public sectors partnering with industry for the global public good."

African children under the age of five represent most of the more than one million deaths malaria causes each year. Adding a vaccine to the malaria control toolbox will allow the world to hope for an end to these deaths. Right now, GSK Bio is the only major pharmaceutical company pursuing a malaria vaccine.

"GSK is proud to have spearheaded the development of a candidate vaccine that has progressed to a Phase 2 pediatric trial," said Jean Stéphenne, President and General Manager, GSK Biologicals. "We hope the trial results will be favorable, and we will use the findings to continue to improve the vaccine. We understand the importance of high-quality vaccines in saving children's lives."

GSK and MVI joined forces in 2001 to pursue development of RTS,S/AS02A for children in the developing world. Consistent with its mission to accelerate malaria vaccine development, MVI stepped forward with financial support, a collaborative management style, and a total commitment to a vaccine for the children most at risk—enabling the RTS,S program to advance at a meaningful pace.

Malaria is the most important health problem in Mozambique according to the Ministry of Health, and it is a major health problem in most of Sub-Saharan Africa and Asia. Mozambique's government is all too familiar with its day-to-day and long-term impact and is determined to be part of the solution.

"We know that most vaccine candidates fail to be licensed, but we believe GSK's vaccine could be successful," commented Francisco Songane, Mozambique's Minister of Health.

"Mozambique's participation in this trial is one way in which we can help save the lives of our children and children around the world."

Leaders in malaria research, CISM physician-scientists are recognized around the world for the quality of their work and will conduct the trial according to the highest international standards.

"Our team is committed to finding ways to prevent malaria from remaining the number one killer of Africa's children," said Dr. Pedro Alonso, of the Hospital Clinic of Barcelona and Scientific Director of CISM. "This trial is an important contribution to that effort and brings us that much closer to the goal of immunizing children against malaria."

Progress towards a malaria vaccine is accelerated through partnerships such as this one, which share the financial and technical risk inherent in vaccine development and amplified in the development of a vaccine against a complex parasite for a developing world market. Results from the trial are expected in approximately two years.

Mozambique's Ministry of Health 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 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 Hospital Clinic of the University of Barcelona with core funding from the Spanish Agency for International Cooperation.

GlaxoSmithKline Biologicals (GSK Biologicals), the world's leading vaccine manufacturer, is located in Rixensart, Belgium. In 2002, an average of 25 GSK Biologicals vaccine doses per second were delivered to 156 countries in both the industrialised and developing world. For information, visit GSK Biologicals' vaccines website site at www.gsk-bio.com. GlaxoSmithKline - 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.

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.