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New Results Show the RTS,S Malaria Vaccine Candidate Protects Children for at least 18 Months

Yaoundé, Cameroon and London, UK (November 15, 2005) – GlaxoSmithKline (GSK) Biologicals, the Hospital Clínic of the University of Barcelona, the Manhica Health Research Centre (CISM), and the PATH Malaria Vaccine Initiative (MVI) today released new data on the duration of efficacy of GSK Biologicals' malaria vaccine candidate, RTS,S/AS02A, in children. A follow-up to the landmark six-month efficacy study results published by The Lancet in 2004, today's findings show that RTS,S/AS02A remained efficacious over an 18-month observation period.

The findings are published in the November 15, 2005 on-line edition of The Lancet and are presented at the Multilateral Initiative on Malaria's Pan-African Malaria Conference in Yaoundé, Cameroon.

CISM conducted the study in partnership with Mozambique's Ministry of Health. Fourteen hundred forty-two children who had received a three-dose regimen of the vaccine in 2003 were followed for continued assessment of safety, immunogenicity, and efficacy. No further malaria vaccinations were given. For the 18-month period of follow-up, RTS,S/AS02A was shown to reduce clinical malaria episodes by 35 percent and severe malaria episodes by 49 percent.

"These results answer an essential question remaining from the release of the six-month efficacy data a year ago," said Pedro Alonso, MD, PhD, lead author of the Lancet article, scientific director of CISM, and head of the Center for International Health at the Hospital Clínic of the University of Barcelona. "The unprecedented response demonstrated in this study is further evidence that an effective vaccine to help control the malaria pandemic, which kills more than one million people a year in developing countries, is very possible."

"Several more years of clinical investigation will be needed before this vaccine is ready for licensure and implementation, but today's results move us an important step closer to developing a vaccine that can provide lasting protection to help save millions of lives," said Jean Stéphenne, president of GSK Biologicals, which has been working on the development of this vaccine for more than 15 years. "The world should now take all required actions in order to get this vaccine to all who need it."

The immunogenicity and safety profiles of the vaccine remained promising. In addition, children vaccinated with RTS,S/AS02A were found at the end of the follow-up period to be 29 percent less likely to be infected with the *Plasmodium falciparum* malaria parasite. The participants in the current study will continue to be followed, and MVI and GSK—with CISM and other clinical trial partners in Africa—will continue clinical development of the RTS,S/AS02A vaccine. In October, the Bill & Melinda Gates Foundation announced a \$107.6 million grant to MVI to support this work.

“The ability of this vaccine to protect children from severe malaria for at least 18 months makes it a very promising potential public health tool for the developing world,” said Dr. Melinda Moree, PhD, director of MVI, a global program created to overcome barriers to malaria vaccine development. “We are committed to making an affordable, safe, and effective malaria vaccine available as quickly as possible to those who need it most.”

The reported results are from the single-blind follow-up phase of a randomized, double-blind, controlled proof-of-concept study in children one to four years of age. The RTS,S/AS02A vaccine candidate uses a recombinant protein that fuses a part of the *Plasmodium falciparum* circumsporozoite protein with the hepatitis B surface antigen and targets immune responses against the stage injected by mosquitoes. Early development of this candidate was undertaken by GSK in close collaboration with the Walter Reed Army Institute of Research. In January 2001, GSK Biologicals and MVI entered into an agreement to develop the vaccine for children in developing countries. PATH launched MVI in 1999 with a grant from the Bill & Melinda Gates Foundation.

[Visit The Lancet's web site for a summary of the article \(subscription required for full text\).](#)

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About GSK Biologicals

GlaxoSmithKline (GSK) Biologicals, one of the world's leading vaccine manufacturers, is located in Rixensart, Belgium. GSK Biologicals employs more than 1,100 research scientists who are devoted to discovering new vaccines and developing more cost-effective and convenient combination products to prevent infections that cause serious medical problems worldwide. In 2004, GSK Biologicals distributed more than 1.5 billion doses of vaccines to 168 countries in both the developed and developing world, an average of 45 doses per second. 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. For more information, see www.gsk.com.

About the PATH Malaria Vaccine Initiative

PATH is an international, non-profit organization that creates sustainable, culturally relevant solutions enabling communities worldwide to break longstanding cycles of poor health. For more information, visit www.path.org. The PATH Malaria Vaccine Initiative (MVI) is a global program established through an initial grant of \$50 million from the Bill & Melinda Gates Foundation, which has since awarded it an additional \$207.6 million, including \$107.6 million to complete development of the RTS,S vaccine. MVI's mission is to accelerate the development of

promising malaria vaccines and ensure their availability and accessibility for the developing world. For information, visit www.malariavaccine.org.

About the Center for International Health Hospital Clínic of the University of Barcelona

The Center for International Health (CIH) is a pioneering structure within Barcelona's Hospital Clínic, the leading Spanish biomedical research center. The CIH is involved in health care, training and research in global health issues. The collaborative programs in Africa, particularly the development of the Manhica Health Research Center in close partnership with Mozambican institutions, are a central component of its activities. For more information, visit www.hospitalclinic.org.

About the Centro de Investigação em Saude da Manhica

Centro de Investigação em Saude da Manhica (CISM) is the first peripheral health research centre in Mozambique to undertake medical research into the key health problems in that country. Founded in 1996, CISM was developed under a collaborative program between the Mozambique Ministry of Health, the Maputo School of Medicine (Universidade Eduardo Mondlane), and the Hospital Clínic of the University of Barcelona with core funding from the Spanish Agency for International Cooperation. Visit CISM's web site at www.manhica.org.

About Mozambique's Ministry of Health

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.

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