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New malaria vaccine shows a reduction in infections and illness in children

Dar Es Salaam, (8 December 2008)—Results of a study on malaria vaccine candidate in Africa conducted by Ifakara Health Institute (IHI), the Korogwe branch of the National Institute for Medical Research (NIMR) and the Kenya Medical Research Institute (KEMRI) are published online today in the *New England Journal of Medicine*. The exciting findings revealed that the world's most clinically advanced malaria vaccine candidate provides both infants and young children with substantial protection against malaria.

The IHI lead researcher who is also the Acting Director Dr. Salim Abdulla says the infant study conducted in Bagamoyo district found that RTS,S/AS02D when co-administered with other common childhood vaccines at 8, 12, and 16 weeks of age did not interfere with the other vaccines' effectiveness. In Tanzania, childhood vaccines include polio, tetanus and pertussis which are all administered through a vaccine schedule for infants under the Expanded Program on Immunization (EPI).

Researchers at IHI in Bagamoyo branch enrolled 340 infants and administered the RTS,S/AS02 vaccine in conjunction with an EPI schedule. It was a randomized double-blind trial with participants receiving either: RTS,S with diphtheria, pertussis, tetanus, and *Haemophilus influenzae* type b (DTP/Hib) and oral polio vaccine; or a hepatitis B vaccine with DTP/Hib and oral polio vaccine. The findings confirmed that this schedule is safe and would provide a very good delivery system for this vaccine.

Additionally, the study reported 65 percent reduction against first infection from malaria in those infants over six-month follow up period. This study builds upon results published in October 2007 in *The Lancet*, which found similar efficacy for RTS,S/AS02D when administered in a staggered schedule, alternating with the standard childhood immunization schedule.



Dr. Abdulla says results of the “RTS,S vaccine are very encouraging when administered alongside the childhood vaccines now widely in use and those vaccines maintain their desired efficacy alongside RTS,S.” Dr. Abdulla and Prof. Marcel Tanner led a team that included researchers from the Swiss Tropical Institute, the London School of Hygiene and Tropical Medicine, GSK Biologicals, the Programme for Appropriate Technology in Health (PATH) and Malaria Vaccine Initiative (MVI). Dr. Abdulla said this is the first time in history a vaccine against human parasites is discovered. Such great advances in science “will put our researchers and our African institutions in the world’s history book,” says Dr. Abdulla.

The other trial carried out in Korogwe, Tanzania and Kilifi in Kenya between 2007 and 2008 enrolled 894 children 5-17 months old. The trial in Korogwe led by Dr. Lorenz von Seidlein and Dr. John Lusingu of NIMR was designed to test the safety and efficacy of RTS,S malaria vaccine using GSK’s proprietary vaccine adjuvant known as AS01. Children who participated in this randomized clinical trial received either three doses of the RTS,S/AS01 vaccine or a human rabies vaccine. With this sample, the candidate RTS,S/AS01E was shown to reduce clinical malaria episodes by 53% for up to an average of eight months. Dr. Lusingu says the results provide evidence that RTS,S/AS01E malaria vaccine was able to prevent to a larger extent the clinical cases of malaria in young children who are the main victims of the disease.

Dr. Martha Lemnge from NIMR Tanga says: “This is an exciting moment in the history of malaria research and control because an effective malaria vaccine will add on to other effective tools like the insecticide-treated mosquito bed-net and antimalarials” to halt malaria. Commenting on the results, the Director General of NIMR Dr. Andrew Kitua said his institute is “particularly pleased with the progress made so far and look forward to working with other partners to eventually eliminate malaria.”

RTS,S is designed to trigger the immune system to defend against the *Plasmodium falciparum* malaria parasite as soon as it enters the human host’s bloodstream and/or when the parasite infects liver cells. This prevents the parasite from maturing and multiplying in the liver and from reentering the bloodstream, where the host would begin to show symptoms of infection. To stimulate an immune response to the malaria parasite, RTS,S fuses a critical circumsporozoite (CS) protein, the surface protein that helps the parasite invade human liver cells, with a protein found in GSK Bio’s hepatitis B vaccine. The addition of GSK’s proprietary Adjuvant System strengthens the immune response even further.

The pediatric clinical development of RTS,S in Africa began in 2001 through a public-private partnership between Malaria Vaccine Initiative (MVI) and GlaxoSmithKline (GSK). The vaccine was first formulated in laboratories at GSK Biologicals’ headquarters in Belgium in the late 1980s as part of a collaboration with the US Walter Reed Army Institute of Research. A Phase III trial that will start in 2009 will enroll up to 16,000



infants and children across 10 sites in seven African countries including Tanzania. “We are looking forward to participating in the Phase III multi-centre trial,” concludes Dr. Lusingu.

In his concluding remarks, Dr. Abdulla said his institute is prepared to conduct Phase III assessment of the vaccine. Phase III trial will seek to evaluate the vaccine’s effectiveness in different parts of Africa, where intensity of malaria transmission may differ, and determine the length of the vaccine’s protection. In addition, safety will continue to be closely monitored. “This work will showcase African research centres and demonstrate the effective participation of African scientists in finding appropriate solutions for Africa,” says Dr. Abdulla.

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ABOUT THE PARTICIPATING INSTITUTIONS

Joint Malaria Programme, Tanzania (<http://196.45.36.203/Pages/projects/about.html>)

The Joint Malaria Programme (JMP) is a joint collaborative link between the National Institute for Medical Research (NIMR) in Tanzania, Kilimanjaro Christian Medical Centre (KCMC) in Tanzania, London School of Hygiene and Tropical Medicine (LSHTM) in the UK, and the Centre for Medical Parasitology (CMP) of the University of Copenhagen in Denmark. The Korogwe trial site, established in 2002 under NIMR Tanga Centre, aims to be a center of excellence in clinical and biomedical research. Its mission is to conduct health research to alleviate disease burden in Tanzania.

Ifakara Health Institute (www.ihl.or.tz)

The Ifakara Health Institute (IHI), formerly IHRDC, is an autonomous, non-profit health research institute. IHI was registered as a Tanzanian Trust in 1996 under the leadership of the Board of Trustees chaired by Ministry of Health and Social Welfare. The Bagamoyo branch was established in 2005 to further the mission of IHI, which is to develop and sustain a district-based health research and resource centre capable of generating new knowledge and relevant information for public health policy and action. The branch located in the premises of the Bagamoyo District Hospital supports clinical services and improvement of quality of care at the hospital and peripheral dispensaries in the district.

GlaxoSmithKline Biologicals (www.gsk.com/media)

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. GSK Biologicals (GSK Bio), one of the world's leading vaccine manufacturers based in Belgium, where the majority of GlaxoSmithKline's activities in the field of vaccine research, development and production are conducted.

PATH Malaria Vaccine Initiative (MVI) (www.malariavaccine.org; www.path.org)

The PATH Malaria Vaccine Initiative (MVI) is a global program established at PATH through an initial grant from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world free from malaria. Founded in 1977, PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being.