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

New Gates Funding Will Enable MVI and GSK Biologicals to Complete Development of World's Most Advanced Malaria Vaccine Candidate Collaborators Will Expand Clinical Evaluation of Malaria Vaccine Candidate in Infants in Preparation for Large-Scale Efficacy Trials

Bethesda, MD, US and London, UK (Oct. 31, 2005) – In an important step toward developing an effective malaria vaccine, the Bill & Melinda Gates Foundation today announced a $107.6 million grant to the PATH Malaria Vaccine Initiative (MVI) to extend the public-private partnership between MVI and GlaxoSmithKline Biologicals (GSK Bio) to develop GSK Bio's malaria vaccine for children in Africa.

The new project will expand clinical evaluation of the world's most advanced malaria vaccine candidate, known as RTS,S. If all the project milestones are achieved, this landmark agreement will take the vaccine through licensure and introduction to African immunization programs.

A 2004 proof-of-concept trial in Mozambique found that the vaccine reduced severe malaria by 58 percent in children ages one to four. The new trials will include studies to assess this promising vaccine candidate in younger age groups including infants, the groups that suffer most from malaria and that would benefit the most from an effective vaccine against the disease.

"Malaria takes the lives of more than one million people every year, most of them young children under five years old. We must have new tools to fight this deadly disease," said Dr. Melinda Moree, director of MVI, a global program created to accelerate development of malaria vaccines for poor countries. "The science is there, the will and commitment are there, and now we have a partnership among the right players to drive the development of this vaccine forward at a pace commensurate with the misery caused by malaria. We appreciate the Gates Foundation's confidence and investment in the project."

MVI and GSK Bio, which first entered into collaboration in 2000 to develop the vaccine for children, will launch small-scale trials in infants and young children and then proceed to a large-scale Phase III clinical trial to determine the efficacy of the vaccine. The clinical trials will be conducted in several African countries.

"This is a key step toward development of the most promising malaria vaccine candidate," said Jean Stéphenne, President of GSK Bio, one of the world's largest vaccine companies. "Approximately five years of work will be required before this vaccine is ready for licensure and implementation, but the international community must already begin preparing the environment for this vaccine so that it can reach those who are in greatest need as quickly as possible."

While continuing to make significant investments in the clinical development of the vaccine, GSK Bio will also begin preparations for large-scale manufacturing, registration, and supply of the vaccine should it prove to be effective. GSK Bio will provide the vaccine to public-sector markets in poor countries at prices that support its reliable, long-term production and distribution

to children who need it most. MVI and GSK Bio have developed a specific framework on pricing and supply of the vaccine in their collaboration agreement.

Among infectious diseases, malaria is one of the world's biggest killers. Every year, the disease kills more than one million people in the world's poorest countries and more children in sub-Saharan Africa than any other infectious disease. The economic costs of the disease for Africa alone are equivalent to US$12 billion annually. A vaccine is seen as a critically important tool for defeating malaria.

In October 2004, the British medical journal The Lancet published the results of a trial involving 2,022 children in southern Mozambique that showed the RTS,S vaccine to protect children from malaria. According to the study, which was jointly sponsored by MVI, GSK Bio, Mozambique's Ministry of Health, and conducted by the Manhiça Health Research Centre in Mozambique, vaccine efficacy against clinical malaria attacks was found to be 30 percent. Efficacy against infection was 45 percent, and efficacy against severe disease was 58 percent. Efficacy against severe malaria is expected to have an important impact on hospitalization, cost of treatment, and death.

By targeting the parasite as it is transmitted by mosquitoes, the RTS,S vaccine interferes with the malaria parasite's ability to cause disease in humans. The antibodies and white blood cells produced after immunization prevent the parasite from surviving or from developing further in the liver. GSK Bio performed the early development work on this vaccine in collaboration with the US government's Walter Reed Army Institute of Research.

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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 awarded it an additional $100 million in 2003 and $107 million in 2005. MVI's mission is to accelerate the development of promising malaria vaccines and ensure their availability and accessibility for the developing world. MVI's vision is a world where vaccines protect children from death and severe disease caused by malaria. For information, visit www.malariavaccine.org. 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, please visit www.path.org.

GlaxoSmithKline Biologicals (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 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.

Contacts:
PATH Malaria Vaccine Initiative, Ellen Wilson/Preeti Singh +1 301 652-1558 ext. 108
GlaxoSmithKline Biologicals, Anne P. Walsh + 32 2 656 9831 (T) +32 475 835 782 (M)
Alice Grasset +32 475 309 020 (M)