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Malaria Vaccine Initiative And GlaxoSmithKline Form Partnership To Develop Malaria Vaccine For Children In Africa

Agreement to Accelerate Development of Advanced Malaria Vaccine Candidate

ROCKVILLE, MD and RIXENSART, BELGIUM (1 MARCH 2001) - In an unprecedented move, a nonprofit organization and a major vaccine manufacturer will join forces to dramatically accelerate the development of a vaccine to protect children in Africa against malaria. The agreement between the Malaria Vaccine Initiative at PATH (Program for Appropriate Technology in Health, a US-based non-profit organization), and GlaxoSmithKline Biologicals (GSK), the world's largest vaccine manufacturer, will fast-track development and testing of the only malaria vaccine candidate yet to show effectiveness in preventing malaria. The new collaboration is a forward-thinking effort that could save the lives of millions of children.

GSK's vaccine candidate has been in development since 1983, and is considered the most advanced for protecting children in Africa against the Plasmodium falciparum strain of the parasite, which is endemic to most of the African continent. In an initial trial conducted by GSK with the US Army's Walter Reed Army Institute of Research, six of seven Army volunteers were protected from malaria. A subsequent field trial in adult men in The Gambia, West Africa, conducted with the support of the European Commission and the World Health Organization, showed an efficacy of 70 percent in providing protection over a short period.

"Our hope is that the protection we have seen in adults will translate into life-saving protection in children," said Regina Rabinovich, MD, Director of the Malaria Vaccine Initiative at PATH. "In this new partnership, MVI is sharing the financial risk of malaria vaccine development with GSK, working jointly toward a vaccine that will serve and be accessible to the developing world." Other vaccines have been tested in children and failed, so success would mark a major breakthrough in malaria vaccine development.

"GSK is fully committed to developing this vaccine for children and distributing it in Africa," said Jean-Pierre Garnier, PhD, Chief Executive Officer of GSK. "This partnership is evidence of GSK's drive to find new models for product development to help address the health care crisis in the developing world."

The new MVI-GSK alliance addresses the tremendous public health need for a malaria vaccine and engages the expertise of industry in developing such a vaccine. The agreement breaks with past models of public-private partnerships in an effort to overcome marketplace limitations. MVI and GSK will jointly develop GSK's proprietary malaria vaccine candidate for use in Africa. MVI will provide funding to GSK for vaccine development and will participate fully in the decision-making process guiding the vaccine's accelerated development. GSK will provide its extensive know-how in vaccine development and manufacturing, its long experience, and its proprietary technology in the specific field of malaria vaccine research and development. Moreover, the agreement lays out a pathway, pending favorable clinical trial results, to jointly pursue later stages of the vaccine's development including Phase 3 trials, production, and distribution.

Key components of the agreement include a Joint Steering Committee with equal representation from the Malaria Vaccine Initiative (MVI) at PATH and GSK, and a commitment from MVI to provide US\$6.7 million to support the accelerated clinical development of the GSK vaccine.

"This is a true partnership in which the funds we bring are a form of social venture capital, and the return we anticipate is a vaccine accessible to the developing world," said Rabinovich.

"We are committed to developing new vaccines and treatments to protect against diseases like malaria, HIV, and TB, and we will not limit ourselves to the conventional models that industry has utilized in the past," said Jean Stéphenne, President and General Manager GlaxoSmithKline Biologicals. "This is a new age, and partnerships like our new joint effort with MVI are the wave of the future." GlaxoSmithKline provides more vaccine to the developing world than any other pharmaceutical company and provides vaccines to UNICEF at prices that are deeply discounted from developed world prices.

Malaria is a parasitic infection transmitted through the bite of the Anopheles mosquito. The World Health Organization (WHO) estimates that between 300 million and 500 million people are currently infected and that 2.3 billion are at risk of the disease. Those most vulnerable to malaria are children under five years of age and pregnant women. Most of the more than one million people who die of malaria every year are children under five. Currently, no vaccine is licensed to protect against malaria. Anti-malarial drugs are available, but the parasite has consistently developed resistance to them, leaving millions vulnerable to the disease.

In hyper-endemic regions (including much of sub-Saharan Africa), where mosquitoes breed year-round, residents can expect hundreds of infectious bites each year. Although traditional means of controlling malaria save lives, they alone cannot adequately prevent the health, social, and economic devastation caused by this disease. The development of a malaria vaccine has become a global public health priority.

"PATH applauds this innovative partnership to bring the world a malaria vaccine," said Christopher Elias, MD, President of PATH. "It is exhilarating for us to be part of an effort that aims to save the lives of so many people by preventing this dangerous disease."

Progress on any malaria vaccine depends on two key elements: conducting clinical trials in human volunteers and producing a vaccine at the highest quality standards in large enough quantities to yield thousands of uniform doses. Vaccine production on this scale is extremely costly and requires both scientific and manufacturing expertise. And since the countries that most need the vaccine are among the world's poorest, the market for such a vaccine has been uncertain. The alliance between GlaxoSmithKline and the Malaria Vaccine Initiative represents a big step forward in overcoming these obstacles.

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. GlaxoSmithKline Biologicals is not only the world's leading vaccine manufacturer but also commits significant resources to one of the industry's premier R&D programs for diseases that affect the developing world. The GSK R&D program includes vaccine R&D for HIV, tuberculosis, dengue, meningitis, Hepatitis E, and many others. Moreover, GSK's product portfolio also includes several malaria therapeutics and new treatments currently in development. In 2000, GSK Biologicals provided over one billion doses of oral polio vaccine to WHO/UNICEF for the global polio eradication campaign and has provided UNICEF with billions of doses of low-cost vaccine for decades. For more information, visit GlaxoSmithKline's vaccine Web site at <http://www.gsk-bio.com>.

PATH, an international nonprofit organization whose mission is to improve health, especially the health of women and children, established the Malaria Vaccine Initiative through a US\$50 million award from the Bill & Melinda Gates Foundation. (Visit PATH's website at www.path.org.) MVI was created in the belief that the technology and knowledge needed to create a malaria vaccine exist, but that market forces alone will not lead to the aggressive development of a vaccine needed only by developing countries. MVI's mission is to accelerate the development of promising malaria vaccines and ensure their access and availability for the developing world. For further information about MVI, visit the Web site at <http://www.malariavaccine.org>