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## **PATH Malaria Vaccine Initiative shares strategy for developing “next-generation” malaria vaccines**

### **Plan marks ten successful years; raises bar, heightens focus on achieving 80 percent effective vaccine**

**NAIROBI, Kenya, November 2, 2009** – Marking its tenth anniversary year, the PATH Malaria Vaccine Initiative (MVI) today unveiled a new strategy that sets the stage for an aggressive push targeting the long-term goal of eliminating and eradicating malaria. Malaria is one of the world’s deadliest infectious diseases, killing nearly 900,000 people a year, most of them children in sub-Saharan Africa.

Released at the Fifth Multilateral Initiative on Malaria Pan-African Malaria Conference, the MVI strategy represents a multi-pronged approach to developing the next generation of malaria vaccines. The international community in 2006 set a long-term goal of having a malaria vaccine by 2025 that is at least 80 percent effective against clinical disease and lasts longer than four years.

“The malaria community has made impressive strides in reducing deaths in the last ten years, but malaria still incurs a crushing global burden,” said Dr. Christian Loucq, Director of MVI. “History has shown us that a vaccine would add a powerful, cost-effective way to save lives and help eliminate this disease.”

A key component of MVI’s approach will build on the success-to-date of GlaxoSmithKline Biologicals’ (GSK Bio) RTS,S malaria vaccine candidate, which has advanced to a further stage of development than ever seen before. In a Phase 2 study reported in 2008 in the *New England Journal of Medicine*, this vaccine was found to be 53 percent effective against clinical disease in young children. RTS,S is being developed through a partnership among MVI, GSK Bio, and study centers located across Africa.

If successful in Phase 3 testing and licensure, RTS,S could satisfy the intermediate goal set forth in the international community’s Malaria Vaccine Technology Roadmap of a “first-generation” malaria vaccine that is at least 50 percent effective against severe disease and death and lasts more than one year. While this would be a landmark achievement, the road to elimination and eradication requires filling the vaccine pipeline with promising new candidates that both build on the success of RTS,S and take different paths toward immunization.

“Our new strategy will build, efficiently and aggressively, on the incredible knowledge generated in MVI’s first decade of operation,” Loucq added.

## **Cultivating new approaches**

While most malaria vaccine candidates use one or more components of the malaria parasite to elicit an immune response, another approach uses a weakened form of the whole parasite. MVI is working with Sanaria Inc. to develop a novel vaccine candidate that uses this approach with *Plasmodium falciparum*. Sanaria's vaccine approach is currently being tested in adult volunteers in the United States.

In addition to these vaccine approaches being tested in humans, MVI has numerous feasibility studies underway to develop the vaccine candidates of the future, most focused on developing specific vaccine components. Only the most promising of these will advance to clinical development.

Like RTS,S, many of these studies are focused on the pre-erythrocytic approach. They aim to trigger the immune system to defend against the parasite as soon as it enters a person's bloodstream or infects liver cells. This prevents the parasite from maturing and multiplying in the liver, reentering the bloodstream, and infecting red blood cells.

Another approach targets the malaria parasite when it is most destructive: at the blood stage, when the parasite replicates rapidly in red blood cells. Blood-stage vaccines are not expected to block all infection. Instead, they aim to decrease the number of parasites in the blood, reducing the severity of malaria. MVI will continue to make limited investments in this area, but sees the fruit of this effort as yielding additional components that could be combined with a pre-erythrocytic vaccine, for example, to further boost its effectiveness.

## **Targeting the mosquito *and* the most widespread form of malaria**

MVI is also looking for vaccine candidates that block the transmission of malaria from mosquitoes to humans. Transmission-blocking vaccines attempt to interrupt the life cycle of the parasite by inducing antibodies that prevent the parasite from maturing in the mosquito after it bites a vaccinated person. Transmission-blocking vaccines would not prevent people from getting malaria, but they could significantly limit the spread of infection.

Another element of MVI's strategy addresses the need to develop vaccines against *P. vivax*, the less severe but more widespread malaria parasite affecting humans. MVI plans to intensify its support for *vivax* approaches in hopes of eventually combining them with vaccines targeting *P. falciparum*, the parasite most deadly to humans and the one targeted by most vaccine research, including MVI's.

## **Developing tools to measure success**

As the number of potential malaria vaccine candidates increases, scientists will need new and better technologies to assess their potential efficacy and decide which should go forward. MVI is supporting the refinement and development of both laboratory tools and methodologies for evaluating vaccine candidates in humans. For example, MVI is supporting development of the Human Challenge Center at the Seattle Biomedical Research Institute that, beginning in 2010, will offer early-stage testing in humans of the safety and efficacy of malaria vaccine candidates.

## **Continuing need for collaboration**

Over the past ten years, MVI has worked with a wide range of partners and the numbers continue to grow.

“We are looking both inside and outside the malaria research community, towards investing aggressively in approaches and technologies that are at an earlier stage of development,” Loucq said. “This approach involves many smaller investments in projects that are evaluated as quickly as possible for their feasibility, another way we seek to maximize efficiency and use of scarce resources.”

This partnership-based approach has yielded positive results, according to MVI, as seen in the advancement of RTS,S to a Phase 3 trial, the upgrading of clinical trial and research capacity in locations across Africa, and in the decisions by several African countries to put in place mechanisms to facilitate informed decision-making on malaria vaccine use, once one becomes available.

“We see the scientific aspects of our work resulting in a toolbox containing the components for highly effective vaccines against malaria,” said Ashley Birkett, MVI’s Director of Preclinical Research and Development. “But we are always conscious that our first priority is simply to save the lives of those who need it most—the children of Africa.”

MVI stresses, however, that its new strategy is a work in progress and one that will require sustained support.

“Our plan is to maintain sufficient flexibility so that if one or more of our approaches is highly successful, we will be able to realign budget and strategy to accelerate its development,” said Loucq. “But what is still as true today as ten years ago is that we cannot achieve our goals without the sustained commitment of partners, including national governments, industry, other researchers, and donors.”

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#### **About the PATH Malaria Vaccine Initiative (MVI)**

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. For more information, please visit [www.malariavaccine.org](http://www.malariavaccine.org).

#### **About PATH**

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. For more information, please visit [www.path.org](http://www.path.org).