

## **FACT SHEET: MVI Partnership with the Malaria Vaccine Development Branch at the National Institute of Allergy and Infectious Diseases**

### **The Project: Moving Blood Stage Vaccines from Lab to Clinical Trial**

In 2001, the PATH Malaria Vaccine Initiative (MVI) entered into a partnership with the Malaria Vaccine Development Branch (MVDB) of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, to accelerate the development of malaria vaccine candidates that appear capable of provoking an immune response during the blood stage of the disease.

Recombinant proteins of two blood stage malaria antigens, MSP-1<sub>42</sub> and AMA-1, are being advanced as vaccine candidates through process development (the identification of a suitable manufacturing process) and Phase 1 clinical trials to assess whether they are safe and produce an immune response in people. Tests in animals have shown that antibodies produced in response to the presence of AMA-1 and MSP-1<sub>42</sub> appear able to fight off the parasite's invasion of red blood cells. Key goals of the MSP-1<sub>42</sub> clinical trial are to determine whether the candidate vaccines are safe and capable of eliciting an effective immune response. Depending on how they perform in humans, a future vaccine formulation could combine the AMA-1 and MSP-1<sub>42</sub> antigens.

### **The Potential: Saving Millions of Lives by Reducing the Parasite's Impact**

The malaria parasite develops through four stages once inside the body, changing form at each stage. The mosquito injects sporozoites into the human body through its bite; they then enter the liver within minutes. Exiting the liver, the parasite invades red blood cells, multiplying rapidly and causing the cells to burst. It is at this stage, the blood stage, that the infected person becomes sick.

Blood stage vaccines such as those being developed by MVDB could save million of lives, particularly those of children, even if they do not completely prevent the invasion of red blood cells. Scientists believe that vaccines that reduce the multiplication of parasites in the blood could significantly reduce the severity of illness and thereby the number of malaria deaths.

### **The Partners: Keeping a Focus on Finding a Vaccine**

Scientists at MVDB are moving the malaria vaccine field forward by developing and rapidly screening promising malaria vaccine candidates. MVI's funding and project management support are intended to help MVDB move vaccine candidates from the laboratory into clinical trials by following up positive results with scale-up, clinical-grade manufacturing, and clinical trials in the United States and malaria-endemic countries.

The **National Institute of Allergy and Infectious Diseases (NIAID)** is a component of the **National Institutes of Health (NIH)**. NIAID conducts and supports research to prevent, diagnose and treat illnesses such as HIV disease and other sexually transmitted diseases, tuberculosis, malaria, asthma, and allergies. NIH is an agency of the U.S. Department of Health and Human Services. Press releases, fact sheets and other NIAID-related materials are available on the NIAID web site at <http://www.niaid.nih.gov>. For more information on malaria, please visit NIAID's malaria publications page at <http://www2.niaid.nih.gov/publications/malaria.htm>.

**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](http://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 invested an additional \$207.6 million in the program. This funding is a crucial part of the support needed. MVI's mission is to accelerate the development of promising malaria vaccines and ensure their availability and accessibility in the developing world. For information, visit [www.malariavaccine.org](http://www.malariavaccine.org).