

The PATH Malaria Vaccine Initiative Announces Collaboration with US Food and Drug Administration

MVI and FDA to Develop Lab Tests for Promising Malaria Vaccine

BETHESDA, Maryland (25 September, 2008) — In a move that will help accelerate development of a promising type of malaria vaccine candidate, the PATH Malaria Vaccine Initiative (MVI) today announced a collaboration with the US Food and Drug Administration (FDA) to develop laboratory tests to predict the level of safety and activity of vaccine candidates based on live, attenuated (weakened) malaria parasites.

Currently, no method exists for testing their safety and virulence (their ability to cause malaria in those who receive the vaccine), and efficacy before use in human clinical trials. The goal of this collaboration is to fill this critical gap and provide the tools that will help expedite the development of safe and effective attenuated malaria vaccines. It will also support development of other attenuated sporozoite (first stage of the malaria life cycle) vaccines, specifically those that are genetically attenuated.

“This collaborative agreement will provide us with an independent evaluation of the safety of attenuated parasite vaccines,” said MVI Director Christian Loucq, MD. “We would like to have additional laboratory safety tests to take this vaccine candidate into large clinical trials.” To date, there are no approved vaccines to prevent malaria, but several vaccines are in development.

A live sporozoite-based vaccine should have predictable immunizing activity and should not be virulent. Given the diversity of potential recipients (e.g., children, travelers, and the elderly), the FDA and vaccine manufacturers must have the tools for ensuring vaccine safety and potency before large-scale clinical trials are initiated. By entering this collaboration, MVI is teaming with the FDA to lead in this critical aspect of malaria vaccine development.

The need for malaria vaccines is great: each year, 350-500 million cases of malaria occur worldwide, killing close to one million people, most of them young children in sub-Saharan Africa. In addition, US business travelers and tourists to such areas can be infected and fall ill, as can US service men and women who stationed in regions where malaria exists.

The project, which is expected to take three years, is being conducted under a cooperative research and development agreement with FDA’s Center for Biologics Evaluation and Research (CBER).

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The PATH Malaria Vaccine Initiative (MVI) is a global program established at PATH through an initial grant of \$50 million 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.

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. For more information, please visit www.path.org.

Center for Biologics Evaluation and Research (CBER) is the Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER is responsible for the review and licensing of biological products to ensure their safety and effectiveness before made available for public use. For more information, please visit www.fda.gov/Cber/.