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PATH Malaria Vaccine Initiative, Seattle Biomedical Research Institute Accelerate Search for Malaria Vaccine by Expanding "Human Challenge" Tests

SEATTLE, WASHINGTON, March 5, 2008— In a move that should expedite the clinical assessment of malaria vaccine candidates, the PATH Malaria Vaccine Initiative (MVI) and Seattle Biomedical Research Institute (SBRI) today announced a new collaboration to establish a center devoted to testing the safety and efficacy of malaria vaccine candidates in humans. The new Human Challenge Center at SBRI will be one of only a handful of facilities of its kind worldwide and will help meet the growing demand to test new interventions against the deadly malaria parasite.

The Human Challenge Center is the first of a number of undertakings outlined in a master collaboration agreement entered into by MVI and SBRI in late 2007. MVI, a global program of PATH, will provide technical and financial support for the development of the Center at SBRI, which will be built this year. The Human Challenge Center is the critical foundation of the Malaria Clinical Trials Center, an innovative center for the integration of basic science and clinical research uniquely focused on addressing the burden of malaria with the goal of bringing new solutions to the world. In addition to its well-established malaria research program, SBRI already has another key component of the Malaria Clinical Trials Center in place: the Center for Mosquito Production and Malaria Infection Research (CeMPMIR), which includes an insectary that produces mosquitoes needed for the human challenge trials.

After a malaria vaccine candidate has been tested for safety in a small number of healthy adult volunteers, some candidates (typically those targeting the early stage of malaria infection) may undergo a challenge phase of testing. Volunteers vaccinated with a malaria vaccine candidate are deliberately infected with malaria through the bite of malaria-infected mosquitoes to assess whether or not the candidate vaccine can prevent or delay malaria infection. This human challenge phase of malaria vaccine development can provide researchers with valuable data to decide whether or not to move a vaccine candidate forward. The Human Challenge Center will provide the high level of care required to ensure the safety of volunteers, in accordance with protocols approved by the US Food and Drug Administration.

"This center will allow us to greatly increase our ability to evaluate whether a new vaccine formulation should advance to testing in clinical trials in malaria-endemic populations," said MVI Director Christian Loucq, MD. "We're particularly excited by the center's location in Seattle, a community where many people have an interest in global health issues and, as a result, are willing to volunteer for such an important cause—to help save the lives of young children in some of the world's poorest countries."

"We see an opportunity here to provide the entire malaria vaccine research community with additional capacity for testing the many exciting approaches to fighting this disease that are being developed not just at SBRI, but by scientists around the world," said SBRI's President and Founder Ken Stuart, PhD. "Our role is to help the PATH Malaria Vaccine Initiative continue to stock the malaria vaccine pipeline with a large cadre of strong candidates backed by hard evidence of their potential effectiveness."

MVI will look to SBRI to optimize the use of human challenge testing to expand evaluations of individual vaccine formulations that seek to arrest *P. falciparum* at different points in its deadly journey through the body. *P. falciparum* is the malaria parasite responsible for more than one million deaths each year. Testing will involve vaccine candidates designed to elicit an immune response against the parasite's pre-erythrocytic stage (the earliest stage of malaria infection in humans) and candidates that focus on the destructive blood stage of infection.

"By accelerating the search for new malaria vaccines, this center will bring us closer to the ultimate goal of eradicating malaria," said Regina Rabinovich, MD, Director of Infectious Diseases Development at the Bill & Melinda Gates Foundation, which provides funding to both SBRI and the PATH program.

MVI views the Human Challenge Center as a way to assess not just the potential of individual vaccine candidates but, more broadly, to provide new insights into the mechanisms of malaria immunity and malaria vaccinology.

"We look forward to working with SBRI on this and future projects that will help answer important questions facing the quest for a malaria vaccine and move the field closer to the development of one that is as effective as possible against this deadly disease," said Dr. Loucq.

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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 promising malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world where all children are safe from malaria. For more information, please visit www.malariavaccine.org.

Since our inception 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.

SBRI advances global health. Our infectious disease research is the foundation for new drugs, vaccines, and diagnostics that benefit those who need our help most: the 14 million who will otherwise die each year from infectious diseases. A nonprofit organization founded in 1976, SBRI has nearly 250 staff members working in research labs in Seattle and field labs in Tanzania. By partnering with key collaborators around the globe, we ensure that our discoveries will save lives sooner. For more information, visit www.sbri.org.