

New Agreement Expands Clinical Testing of a Chinese Malaria Vaccine Candidate

(Shanghai, China, March 15, 2006) – In a move that promises to expand the clinical testing of another promising malaria vaccine candidate, the US-based PATH Malaria Vaccine Initiative (MVI) and the Chinese company Shanghai Wanxing Bio-Pharmaceuticals today announced an agreement that supports the development of a pediatric malaria vaccine against *Plasmodium (P.) falciparum*, the most deadly strain of malaria.

The agreement focuses on the candidate vaccine known as PfCP2.9. Under development for close to a decade, the vaccine was created at the Shanghai Second Military Medical University by a team headed by Professor Pan Weiqing, whose research has long been recognized and supported by the World Health Organization (WHO). The technology was licensed to Wanxing Bio-Pharmaceuticals in 2001 for development.

The project announced today will allow improvements in the manufacturing process and will lead to the safety evaluation of the vaccine. It is the first step in a clinical development plan that is meant to generate proof that the product can safely and effectively prevent children from dying from infection with the deadly parasite.

“MVI is excited to be a partner in this project and is pleased to support the development of this promising vaccine candidate,” said MVI Director, Dr. Melinda Moree. “Malaria has been killing humans for millennia. The world will need multiple strategies—including a vaccine—to conquer the disease.”

Wanxing General Manager Mr. Yang Banjun said he expected the partnership to lead to the validation of his company’s expertise and its product. “The ultimate target population for this vaccine is young children who are at risk of infection with the parasite *P. falciparum*. This trial is an important step toward saving their lives.”

Malaria continues to exact a heavy toll on the health and economic welfare of the world’s poorest communities. *P. falciparum* is responsible for the annual deaths of more than one million people, the overwhelming majority of them children under the age of five in sub-Saharan Africa. Malaria is also a serious public health problem in other parts of the world. In China, which has witnessed a resurgence of the disease since 2000, the impact is greatest in the southern regions of Yunnan and Hainan.

No licensed malaria vaccine exists, but Mr. Yang, Dr. Moree, and others say that with many more quality vaccine candidates entering the clinical development process than

ever before, the world may not be far from licensing and delivering a safe, effective, and affordable product to communities that need it. MVI itself is working on 20 vaccine candidates through partnerships that span five continents.

“For the first time in malaria vaccine development, there is a robust pipeline of candidate vaccines to be evaluated in clinical trials,” said Dr. Marie-Paule Kieny, director of the WHO Initiative for Vaccine Research.

The Chinese vaccine candidate targets the malaria parasite at its most destructive stage—its rapid replication in human red blood cells. By combining the key segments of the blood-stage proteins MSP1 and AMA1 into one molecule, PfCP2.9 aims to elicit the antibodies necessary to inhibit the parasite’s invasion of red blood cells. Pre-clinical studies have demonstrated that with the correct conformation, this fusion protein is effective at accomplishing this function.

The trial, which began in February, is sponsored by Shanghai Wanxing Bio-pharmaceuticals in collaboration with MVI and WHO. It follows a previous WHO-supported trial that established initial safety of the vaccine in healthy adults in 2004. The new trial is meant to provide Wanxing and MVI with the data needed to determine the optimal dose levels and vaccination schedule required to maximize the vaccine’s safety and tolerability. Changhai Hospital in Shanghai will conduct the eight-month trial, which will involve 70 healthy adult volunteers. If successful, the trial will be followed by additional studies involving adults and children in malaria-endemic settings.

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PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. For more information, visit 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 awarded it an additional \$207.6 million, including \$107.6 million to complete development of the RTS,S vaccine. MVI’s mission is to accelerate the development of promising malaria vaccines and ensure their availability and accessibility in the developing world. For more information, visit www.malariavaccine.org.

Shanghai Wanxing Bio-Pharmaceuticals Co., Ltd. was established in 1996 as a bio-tech enterprise that integrates R&D, manufacturing, and market sales. Based in the Shanghai Pudong High-Tech Zone, Wanxing is known for its development of recombinant therapies. Its products are used in the treatment of hepatitis B, hepatitis C, viral infections, and other conditions. PfCP2.9 is the company’s first vaccine. For more information visit www.wanxing-bio.com.cn.

WHO promotes collaboration among public and private organizations in malaria vaccine development. WHO’s Initiative for Vaccine Research (IVR) provides technical advice to support a robust pipeline of vaccine candidates. Emphasizing normative activities, including support to new trial sites to conduct clinical trials according to good clinical practice and ethics, guidance on the preclinical and clinical evaluation of candidates following rigorous scientific, safety and regulatory principles is also provided. Ultimately, the organization aims to ensure that sound and credible research and analysis form the



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backbone of evidence in order to formulate recommendations for
decision and policy makers on a future malaria vaccine. For more
information please visit www.who.int/vaccine_research/en/.