

Press Release

Boost for malaria vaccine development by combining strengths of Dutch and American researchers

Leiden, The Netherlands, 16 January 2008

Today Top Institute Pharma announces a highly promising research project that is aimed at the development of a malaria vaccine. This TI Pharma project will be an expansion of extremely promising findings from previous studies. This project aims to develop a highly protective malaria vaccine that would save the lives of millions of people in developing countries, especially infants and children. No malaria vaccine is currently commercially available, despite several decades of research. Multiple drugs have been developed to treat malaria infections. However, increasing numbers of both drug-resistant parasites and insecticide-resistant mosquitoes make the fight against malaria more and more difficult. As a result an efficacious vaccine is urgently needed. The United Nations recognizes this urgency and has made limiting malaria by 2015 a millennium goal.

The TI Pharma project has a budget of 16 million Euros (\$23.6 million) over 4 years and will be carried out by a consortium that includes the American biotechnology company Sanaria Inc. of Rockville, Maryland, Radboud University Nijmegen Medical Centre and Leiden University Medical Center (LUMC). Sanaria Inc. is exclusively dedicated to the production of a vaccine against malaria.

Malaria is one of the most prevalent infections in tropical and subtropical areas. The disease is caused by mosquito-transmitted protozoan parasites of the genus *Plasmodium*. Each year, malaria affects at least 300 million and kills at least 1 million people, principally in developing countries with emerging economies. *Plasmodium falciparum* infection produces the most lethal form of the disease and accounts for the majority of deaths.

Many attempts have been made to develop malaria vaccines based on a single or very restricted number of antigens and different delivery platforms. However, the greatest degree of protective immunity has been obtained using live, radiation attenuated, sporozoite-stage parasites administered by the bite of infected mosquitoes. Human studies showing greater than 90% protection against experimental malaria challenge lasting at least 10 months represent the conceptual framework upon which Sanaria's vaccine strategy is based, according to Dr. Stephen L. Hoffman, Founder, CEO and Scientific Director of Sanaria Inc.

The mission of Sanaria Inc. is the development, production, and commercialization of a malaria vaccine based on attenuated sporozoites. Radboud University Nijmegen Medical Centre (RUNMC) - one of the world leaders in malaria parasite and mosquito production - and Sanaria have been collaborating on the production of sporozoites in mosquitoes for a number of years. Both teams have experience in conducting experimental human malaria infections. In addition to radiation-attenuated sporozoites, Sanaria is also pursuing work on genetically attenuated *P. falciparum* sporozoites. "Regardless of whether the *P. falciparum* sporozoites are attenuated by radiation or genetic manipulation in the laboratory, they still have to be manufactured in a way that meets regulatory standards and cost of goods requirements, and Sanaria is the only organization in the world that has developed technology that meets these requirements," explained Hoffman.

Recent collaborative efforts of LUMC (a world-leading center for the genetic manipulation of malaria parasites, led by Dr. Chris Janse) and Radboud University Nijmegen Medical Centre have resulted in the generation of attenuated sporozoites by genetic modification in a model malaria parasite of rodents. Prof. Robert Sauerwein of Radboud University Nijmegen Medical Centre, the principal investigator and coordinator of this TI Pharma project, states: "These genetically attenuated sporozoites were able to induce protective immunity in mice at levels comparable to radiation-attenuated sporozoites and also give a degree of cross-species protection. This finding opens up greater possibilities for human malaria vaccine development and this will be explored in this program."

RUNMC and LUMC have jointly submitted a patent for the development of genetically attenuated sporozoites.

For further information about the projects detailed above, please contact Hanneke Heeres, Communications Manager TI Pharma on + 31 6 46122482. For general information please visit our website: www.tipharma.com.

For information about Sanaria Inc, please contact Dr. Adam Richman, public affairs officer (301-770-3222, arichman@sanaria.com).

About Sanaria

Sanaria Inc. was founded in 2003. The company's primary mission is to develop and commercialize a malaria sporozoite vaccine against *Plasmodium falciparum*, the parasite responsible for more than 95 percent of malaria associated severe illness and death world-wide, and the malaria parasite for which there is the most significant drug resistance. Sanaria has overcome the initial technological and regulatory barriers and launched a clinical manufacturing facility with support from the National Institute of Allergy and Infectious Diseases, the U.S. Army Military Infectious Diseases Research Program, the Institute for OneWorld Health, and the PATH Malaria Vaccine Initiative. Sanaria's facilities are in Rockville, MD. For more information see <http://www.sanaria.com>.

About TI Pharma

Within TI Pharma, consortia of industrial and academic research teams conduct groundbreaking, cross-disciplinary research projects that fit into the *Priority Medicines* program of the WHO. Each year, the Dutch government funds the top institute to a tune of 30 million Euros. The pharmaceutical industry and academia each contribute an additional 15 million Euros per year. TI Pharma is becoming an international leader in (bio)pharmaceutical research, training and education. TI Pharma's fellows are trained in understanding the intricacies of the entire drug R&D process. See www.tipharma.com.

About Radboud University Nijmegen Medical Centre

Radboud University Nijmegen Medical Centre (www.umcn.nl) is a leading academic centre with expertise in medical science and healthcare. Expertise plays an essential part in our organisation and connects research, education and patient care. Our more than 8,500 staff and 3,000 students are committed and ambitious, helping to shape the future of healthcare and medical science. *Driven by knowledge, empowered by people.*

About Leiden University Medical Center

Leiden University Medical Center (LUMC) is strongly committed to the advancement of health care, through research and innovation. In particular, the focus is on translational research, with the overall aim to accelerate findings from the laboratory to clinical application, and to the market. LUMC has a reputation as a pioneering institute, both nationally and internationally. See <http://www.lumc.nl>