MALARIA VACCINE TRIAL SHOWS PROMISING RESULTS

WHO WELCOMES PROGRESS

Geneva — The World Health Organization (WHO) welcomes the results of a clinical trial demonstrating that a candidate malaria vaccine has conferred protection in young children in Africa and comments as follows:

Dr Marie-Paule Kieny, Director, Initiative for Vaccine Research (IVR), WHO:

The results of this trial indicate that an effective vaccine against malaria that could potentially save the lives of millions of children is possible. While much more work on this vaccine is still required, this constitutes a breakthrough in malaria vaccine research.

This step forward also highlights the crucial role that African governments, research institutions and scientists in the malaria endemic areas of Africa play in developing tools and strategies against this major killer of children.

While many candidate malaria vaccines have been developed over the past 25 years, the RTS,S/AS02A vaccine is the first that has demonstrated a significant capability to protect human adult volunteers against an experimental infection with the malaria parasite. The new results indicate that the vaccine induces protection against malaria in children one to four years old in Africa.

Although the 57.7% reported vaccine efficacy against severe disease is less than that of classical childhood vaccines, which is often greater than 80%, the outcome of the trial is very encouraging for the future of malaria vaccines because it is the first demonstration of any efficacy against severe malaria in children.

The partners (see Background below) involved in the clinical trial participated in the WHO/IVR Malaria Vaccine Advisory Committee in Montreux, Switzerland on 13 October. Established in 2002, the MALVAC Committee monitors global malaria vaccine development, identifies scientific knowledge gaps and new research areas and convenes funding agencies who support malaria vaccine development.
Background
The most advanced candidate malaria vaccine, RTS, S/AS02A, was developed through the partnership of GlaxoSmithKline Biologicals and the Malaria Vaccine Initiative (MVI) of the Program for Appropriate Technology in Health (PATH). RTS, S/AS02A was tested in a Phase 2b clinical trial involving 2022 one to four year old children in Maputo Province, southern Mozambique, from April 2003 to May 2004. The children received three doses of the candidate vaccine. The trial site has perennial malaria transmission mostly due to *Plasmodium falciparum*, one of the most common and the most deadly type of malaria infection. The candidate vaccine delayed the time to new infections with the *P. falciparum* malaria parasite by 45%, reduced the risk of a clinical episode of malaria by 29.9% and reduced new episodes of severe malaria by 57.7%.

Over 40% of the world’s children live in malaria-endemic countries. Around 90% of these deaths occur in Africa, mostly in young children. There are 300-500 million malaria infections each year globally, resulting in more than one million deaths. Malaria is Africa’s leading cause of under-five mortality. It kills one African child every 30 seconds. Children who survive an episode of severe malaria may suffer from learning impairments or brain damage.

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WHO Facts and figures on malaria are available at: http://www.who.int/mediacentre/factsheets/fs094/en/

Further details about the clinical trial are available from Anne P. Walsh, GlaxoSmithKline Biologicals (www.gsk-bio.com), Tel.: +32 2 656 9831, Mobile: +32 475 835 782; and Ellen Wilson or Preeti Singh, the Malaria Vaccine Initiative (MVI) of the Program for Appropriate Technology in Health (PATH) (www.malaria vaccine.org, www.path.org), Tel.: +1 301 652 1558, ext. 108. The trial was conducted at the Centro de Investigação em Saúde de Maniça (CISM) in Mozambique (www.manchica.org) which is a joint programme of the Ministry of Health, Mozambique, the Eduardo Mondlane University School of Medicine, Maputo, the Hospital Clinic of the University of Barcelona, and the Spanish Agency for International Cooperation who provides core funding. Further information is also available from Marc de Semir, CISM/Hospital Clinic, Tel.: +34 93 227 5700, Mobile: +34 62 794 7528.

The clinical trial results will be published in the Lancet on 16 October 2004. The lead author and principal investigator is Dr Pedro Alonso, M.D., Ph.D; he heads the Center for International Health of the Hospital Clinic at the University of Barcelona (www.hospitalclinic.org).

WHO's IVR (http://www.who.int/vaccine_research/en/) provides guidance and support to enable and facilitate the development, clinical evaluation and world-wide access to safe, effective and affordable vaccines against infectious diseases of public health importance. IVR provided technical advice on the formulation of the malaria vaccine and other aspects of the research.

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