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The first results from ongoing Phase III trial show that malaria vaccine candidate RTS,S reduces the risk of malaria by half in African children aged 5 to 17 months

The largest clinical trial in children ever conducted in Africa

Seattle-Barcelona, 18 October, 2011.- The first results from the Phase III trial of RTS,S show that the malaria vaccine provides significant protection against clinical and severe malaria in African children according to an announcement made today at the Malaria Forum in Seattle hosted by the Bill & Melinda Gates Foundation. The results were published online today in the New England Journal of Medicine (NEJM).

The ongoing trial being conducted at 11 trial sites in 7 countries across sub-Saharan Africa showed that 3 doses of RTS,S reduced the risk of children experiencing clinical malaria by 56% and severe malaria by 47%. These findings refer to the analysis of results from the first 6,000 children aged 5 to 17 months over a 12-month period following vaccination. The trial, which has enrolled over 15,000 African children, started in May 2009 and is expected to finish in 2014.

Malaria is a parasitic disease responsible for some 225 clinical cases and close to 800,000 deaths a year. The principal symptom is fever, but in some cases the disease can progress rapidly to severe malaria with complications, including anaemia, cerebral malaria, the involvement of other vital organs, and in some cases, death. The RTS,S vaccine is effective against *Plasmodium falciparum,* the parasite responsible for the most lethal form of malaria, which primarily affects the countries of sub-Saharan Africa.

The results announced today represent a great scientific advance and an important step in the fight against this disease. The vaccine could contribute to the control of malaria together with other preventive measures, including the use of insecticide-impregnated mosquito nets, indoor spraying with insecticides, improvement of healthcare systems, and the development of new drugs to treat the disease.

These Phase III results confirm the findings of research conducted over the last 10 years by the team led by Dr. Pedro Alonso, the Manhiça Health Research Centre (CISM) in Mozambique, and the Barcelona Centre for International Health Research (CRESIB, Hospital Clínic and Universitat de Barcelona). Dr. Pedro Alonso welcomed the findings as “great news” but went on to say that “it is essential to continue researching and developing new tools to combat disease”.

The trials carried out in Mozambique since 2001 played a key role in the development of this vaccine. CISM, a research centre created in 1996 by the

Hospital Clínic de Barcelona, the Mozambican Ministry of Health and the Spanish Agency for International Development Cooperation is an example of Spanish cooperation in the fight against poverty through research on priority diseases.

The vaccine developed by the laboratories of GlaxoSmithKline is the result of collaboration between several public and private institutions and has been financed primarily by the Bill & Melinda Gates Foundation and the PATH Malaria Vaccine Initiative (MVI). The development of the RTS,S vaccine is a successful result of public-private cooperation and an example of how research can contribute to the development of the World's most vulnerable countries.

If the current findings on the safety and efficacy of the vaccine are confirmed at the end of the Phase III trial, the World Heath Organisation could recommend the use of this vaccine in areas with endemic malaria by 2015, a development that would open the way for the implementation of malaria vaccine programs in the countries where they are most needed.

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