For further information contact:

Àlex Argemí, IDIBAPS - Hospital Clínic Scientific, +34 93 227 57 00

Emma Griffiths, Weber Shandwick, +44 20 7067 0230

Meta-Analysis Demonstrates that Intermittent Preventive Treatment in Infants with Sulphadoxine-Pyrimethamine Reduces Malaria Episodes by 30%

Results published in The Lancet extend earlier findings on safety and efficacy of novel malaria control tool

BARCELONA, 17 September 2009 — *The Lancet* today publishes results from a meta-analysis which finds Intermittent Preventive Treatment of malaria in Infants (IPTi) with anti-malarial medication sulphadoxine-pyrimethamine (SP) has a protective efficacy of 30·3% (95% Confidence Intervals 19·8–39·4, p<0·0001) against clinical malaria, in areas of low to moderate resistance to SP during the first year of life.[i]

IPTi-SP is the administration of a therapeutic dose of the antimalarial drug SP to infants under 12 months at pre-defined time points, regardless of infection status. This meta-analysis pooled data from six double-blind, randomised, placebo-controlled trials (undertaken in four African countries between 1999-2008) that assessed the efficacy of IPT with SP in children. In all trials, SP or placebo was given to infants at the time of routine vaccinations delivered by WHO's Expanded Program on Immunisation. Data from the trials were reanalysed by use of standard outcome definitions and time periods.

"These results confirm the potential for IPTi using SP, which can be easily and rapidly implemented via existing WHO immunisation programmes, saving tens of thousands of lives every year across Africa," commented Dr Pedro Alonso, a principal investigator, head of the Secretariat of the IPTi Consortium, associated with University of Barcelona, Spain. "IPTi provides a valuable addition to efforts to fight malaria and so international policy-makers and heads of national Malaria Control Programmes should consider its immediate adoption and integration into existing programmes," he added.

The results from these six trials provided data on 7930 infants (IPT, n=3958; placebo, n=3972). In addition to the main findings, IPTi-SP was shown to have a protective efficacy of 21·3% (8·2–32·5, p=0·002) against the risk of anaemia, 38·1% (12·5–56·2, p=0·007) against hospital admissions associated with malaria parasitaemia, and 22·9% (10·0–34·0, p=0·001) against all-cause hospital admissions.[i]

Malaria represents an important public health burden in Africa, disproportionately affecting the youngest and most vulnerable. Of the 247 million cases of malaria worldwide in 2006, 86% occurred in Africa.[ii] African infants are most at risk of the worst forms of malaria, every 30 seconds an African child dies from malaria.[iii]

A separate study in Northern Tanzania shows that in areas of very high resistance to the medication, IPTi-SP is not efficacious and alternative anti-malarial drugs are needed. The long-acting medicine mefloquine was seen to reduce the incidence of clinical malaria in infants in the first year of life by 38%.[iv]

# # #

Notes to Editor

About the meta-analysis

The results of the six trials have been published individually. This meta-analysis pooled the individual trial results, using common definitions of outcomes and follow-up periods, allowing an overall assessment of the results. The efficacy results were re-analyzed by the statistician of each of the six trials, and an independent safety panel made up of experts in safety and pharmacovigilance in Africa conducted an analysis of the safety. The pooling of the results and meta-analysis was organised by the IPTi Consortium.

About the trials in the pooled analysis

Trials were conducted in Mozambique, Gabon, Tanzania and Ghana involving the following organisations in Africa and Europe: Barcelona Centre for International Health Research, Spain; Centro de Investigação em Saude de Manhiça, Mozambique; University of Tübingen, Germany; Ifakara Health Research Development Centre, Tanzania; University of Witwatersrand, Johannesburg, South Africa; Institute of Tropical Medicine and International Health, Charité, University Medicine Berlin, Germany; Kintampo Health Research Centre, Ghana Health Service/Ministry of Health, Ghana; London School of Hygiene and Tropical Medicine, London, UK; Albert Schweitzer Hospital, Lambaréné, Gabon; Ministry of Health/Ghana Health Service; Bernhard Nocht Institute for Tropical Medicine, Hamburg, Germany; Swiss Tropical Institute, Basel, Switzerland.

About the trial in Northern Tanzania

The trial was conducted in two sites in northern Tanzania, Korgewe and Same, by the following organisations; Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, London, UK; the National Institute for Medical Research,

Tanga Centre, Tanga, Tanzania; and the Kilimanjaro Christian Medical College, Moshi, Tanzania.

About the IPTi Consortium

The IPTi Consortium's Secretariat was the Barcelona Centre for International Health Research, Hospital Clinic, University of Barcelona, headed by Dr Pedro L. Alonso. The IPTi Consortium consists of leading centres of malaria research in Africa, Europe, United States and Papua New Guinea including the Albert Schweitzer Hospital, Lambaréné, Gabon; Barcelona Centre for International Health Research, Hospital Clinic, University of Barcelona, Spain; Case Western Reserve University, Cleveland, USA; Centers for Disease Control and Prevention, Atlanta, USA; Ifakara Health Research and Development Centre, Ifakara, Tanzania; Institut de Recherche pour le Développement, Dakar, Sénégal; Kenya Medical Research Institute, Kisumu, Kenya; Kilimanjaro Christian Medical Centre, Moshi, Tanzania; London School of Hygiene and Tropical Medicine, London, UK; Manhiça Health Research Centre, Manhiça, Mozambique; National Institute for Medical Research, Amani, Tanzania; PNG Institute of Medical Research, Goroka, Papua New Guinea; Swiss Tropical Institute, Basel, Switzerland; Université Cheikh Anta Diop de Dakar, Dakar, Sénégal; University of Copenhagen, Copenhagen, Denmark; University of Tübingen, Tübingen, Germany; Walter and Eliza Hall Institute of Medical Research, University of Melbourne, Australia; World Health Organization (WHO); United Nations Children's Fund (UNICEF).

---

[i] Aponte John J, Schellenberg David, Egan Andrea, et al. Efficacy and safety of intermittent preventive treatment with sulfadoxine-pyrimethamine for malaria in African infants: a pooled analysis of six randomised, placebo-controlled trials. *Lancet* (To be published 17 September 2009)

[ii] WHO. World Malaria Report 2008. World Health Organisation, 2008

[iii] *10 Facts on Malaria.*World Health Organisation, March 2009. (http://www.who.int/features/factfiles/malaria/en/index.html, accessed 7 September 2009)

[iv] Gosling Roly D, Gesase Samwel, Mosha Jacklin F, et al. Protective efficacy and safety of three antimalarial regimens for intermittent preventive treatment for malaria in infants: a randomised, placebo-controlled trial. *Lancet* (To be published 17 September 2009)