

**CIPRA-SA STATEMENT**  
**3 July 2007**

**CIPRA-SA Modifies Trial Involving Antiretroviral Therapy in  
HIV-infected Infants**

On June 20, 2007, an independent Data and Safety Monitoring Board (DSMB) of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), met to review interim data on safety and efficacy from a clinical trial examining strategies for the management of HIV-infected infants under 3 months of age.

The Children with HIV Early Antiretroviral Therapy (CHER) study is part of the CIPRA-SA programme and is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), with additional support from the Western Cape and Gauteng Health Departments and Glaxo Smith Kline plc. The study Principal Investigators are Dr Avy Violari and Prof Mark Cotton, and it is being conducted at two locations in South Africa: the Perinatal HIV Research Unit (PHRU) in Soweto and the Children's Infectious Diseases Clinical Research Unit (KID-CRU) at Tygerberg Hospital, Cape Town. The study is coordinated by an international team led by the CIPRA-SA programme at the PHRU of the University of the Witwatersrand in Johannesburg, including KID-CRU of the University of Stellenbosch, the UK MRC Clinical Trials Unit in London and the Division of AIDS of the NIAID. The study began enrollment in July 2005 and completed accrual of 377 infants in February 2007.

The trial was designed to evaluate whether early limited antiretroviral treatment (ARV) would delay the time when continuous ARV was required in vertically infected children; this included evaluation of the optimal time to begin ARV therapy. The DSMB reviewed the interim data, after an average of 32 weeks follow-up, and found a significant increase in survival among infants who received immediate ARV therapy (96 percent) compared to infants who received therapy later (84 percent) based on declining immune function linked to a defined CD4+ T-cell count, and/or clinical progression, which is the current World Health Organization standard of care in South Africa and other parts of the world.

## ***SAFEGUARDING THE HOUSEHOLD***

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Based on this finding, the DSMB recommended that no additional infants be placed in the deferred-treatment arm of the study, and infants in this arm be evaluated for potential initiation of ARV therapy. The DSMB also recommended that the two immediate therapy arms evaluating early ARV treatment in HIV-infected infants for defined lengths of time (to first or second birthdays) continue (planned follow-up for each infant in the study is a minimum 3.5 years from study entry). The study Principal Investigators, study team and NIAID Director Anthony S. Fauci, M.D., concurred with the DSMB recommendations.

The study investigators at each site are contacting the parents and legal guardians of the infants involved in the study to inform them of the findings and the changes to the study, and to evaluate all infants who have not yet started antiretroviral therapy (because they did not meet the existing criteria for treatment), for possible ARV initiation. Each infant participating in the study will be closely monitored for a minimum of 3.5 years from the time they entered the study. Information comparing results in the two immediate treatment arms combined, with those in the deferred arm, is also being communicated to the local ethics committees in Johannesburg and Stellenbosch, the MCC, South African national and provincial Departments of Health and other key stakeholders.

Findings from this study will be presented on Wednesday 25th July at the 2007 International AIDS Society Conference in Sydney, Australia.

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