Studies show benefits of immediate antiretroviral treatment for HIV-infected infants

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Results from two studies presented today at the 19th Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle demonstrate the importance of identifying and treating HIV-infected infants within the first year of life both to prevent harm to the immune system and to enable normal neurological development.

Although immediate ART during infancy benefits HIV-infected babies, the prospect of lifelong treatment raises numerous concerns, including the risk of drug side effects and the potential for resistance to develop to available treatments. The "Children with HIV Early Antiretroviral Therapy" (CHER) trial, funded by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, launched in South Africa in 2005. It tested a novel strategy of giving immediate ART to HIV-infected infants (babies under 3 months of age) but stopping it after the period of infancy when the risks of consequences from HIV and other infections decreases. Treatment was not resumed until there was some evidence of health decline. The study initially compared immediate versus delayed treatment, but the delayed treatment arm was stopped in 2007 after a data and safety monitoring board found that infants given ART beginning at an average age of 7 weeks had a significantly lower risk of death within 48 weeks compared with infants in the deferred treatment group. Based on these findings, in 2008 the World Health Organization revised its treatment guidelines to recommend that in HIV-infected children under the age of one, ART be

started immediately after HIV diagnosis, regardless of their state of health.

Study results presented today by Mark Cotton, M.D., Ph.D., of Stellenbosch University in South Africa, showed that infants could safely stop ART after 1 to 2 years and continue to fare significantly better than those infants in whom the initiation of therapy was delayed until signs of illness or a weakened immune system appeared. Importantly, very few infants who received immediate ART had significant disease progression or died after treatment was stopped. Many of the infants who stopped therapy were able to remain off treatment for a long time. In follow up of the 375 study participants, 33 percent of infants who received 2 years of initial ART and 25 percent of the infants who received 1 year of initial therapy were still well and, therefore, able to remain off treatment for roughly 5 years after the study officially ended.

Another presentation highlighted new results from the PREDICT study. This Phase III clinical trial among HIV-infected children in Thailand and Cambodia examined the question of when to begin ART in children who were not diagnosed with HIV during infancy and, therefore, did not present for medical treatment until they became mild to moderately sick. The study, which began in 2006 and involved 299 children ages 2 to 12, compared beginning treatment immediately or delaying treatment until levels of CD4+ T cells, a key indication of immune system health, fell to a certain threshold. Jintanat Ananworanich, M.D., Ph.D., of the HIVNAT Research Collaboration, Thai Red Cross AIDS Research Center, Bangkok, presented findings at CROI today demonstrating that both study groups experienced comparably low rates of disease progression, while higher rates of drug toxicities and resistance were found in the immediate treatment group. Neurological development problems were frequent and equally prevalent in both groups.

Taken together, both the CHER and PREDICT studies illustrate the

importance of identifying and treating HIV-infected infants as soon as possible to preserve the immune system and ensure healthy brain development. If the treatment in infancy window is missed, ART in older HIV-infected children, whether begun immediately or delayed, can still provide comparable health benefits but it does not prevent or reverse neurological damage.

More information: Findings from both studies were presented today at the 19th Conference on Retroviruses and Opportunistic Infections at the Washington State Convention Center in Seattle.

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