

Phase I/II Trial of Pharmacological HIV-1 Prevention

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Project Description: This study is a randomized clinical trial to determine if daily oral tenofovir disoproxil fumarate (tenofovir) 300 mg prevents HIV-1 acquisition and has acceptable safety in initially HIV-1 persons. Its objectives are to determine if daily oral tenofovir 300 mg is associated with comparable rates of adverse events compared with placebo among HIV-1 uninfected and if daily oral tenofovir reduces HIV-1 incidence among uninfected persons.

The project was originally funded to take place in Cambodia with female sex workers. As of December 2004, the Cambodia site has closed. In collaboration with investigators in Thailand, we are conducting preparatory work in anticipation of initiating a safety and pharmacokinetic study of daily tenofovir in women at risk for HIV infection in Thailand.

We are currently collaborating with the Thai Red Cross Thai Red Cross AIDS Research Centre (TRCARC), NCHECR-UNSW. The TRCARC is an active member of the HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT, in collaboration with Chulalongkorn Hospital). HIV-NAT was established in 1996 as collaboration between the Thai Red Cross AIDS Research Centre (TRCARC), NCHECR-UNSW and the International Antiviral Therapy Evaluation Centre (IATEC), The Netherlands. HIV-NAT is currently conducting 16 clinical trials involving more than 1500 patients at 22 cooperating sites throughout Thailand.

Preparatory work including assessment of HIV incidence and community consultation will take place in parallel with protocol design at the Thai Red Cross Anonymous Clinic, a voluntary HIV counseling and testing (VCT) service. The Thai Red Cross Society (TRCS) has been managing this clinic since 1991 and currently provides VCT services to more than 10,000 clients per year. The clinic also provides CD4 count and HIV viral load monitoring for known HIV positive people. HIV-NAT personnel conduct twice weekly research clinics at this facility. On average 40 clients are tested for HIV per day, and approximately one third of these are women. Of these, approximately two to three women would be diagnosed as HIV positive per day. Women who are diagnosed HIV negative at the VCT will be recruited for the proposed study. HIV prevalence among female sex workers is lower in Thailand than Cambodia, nevertheless significant risk is still notable not only among sex workers but among female partners of men who visit sex workers.

Project Recruitment Dates: June-November 2005

Project End Date: December 2005