

Microbicides Development Programme announces successful completion of enrolment in MDP301 Phase III trial of PRO 2000/5 Microbicide gel

The Microbicides Development Programme announced on Wednesday 20th August 2008 that it had completed enrolment in its Phase III clinical trial of the PRO 2000/5 vaginal microbicide gel, and is now closed to new participants. The trial is evaluating PRO 2000/5 vaginal microbicide gel for both safety and efficacy in preventing HIV transmission. It is the largest microbicide licensure trial to date and is being conducted across six sites in South Africa, Tanzania, Uganda and Zambia. Participants remain in the trial for a full year following their enrolment.

As of 15th August 2008, a total of 9395 women participants (98.8% of the target of 9510) had been enrolled in the trial. An independent monitoring committee has carried out routine reviews of unblinded data from the trial and has raised no significant safety concerns to date.

"We are all excited about this achievement which has been a coordinated effort by all partners and most importantly by the enthusiasm from the women participants. It's encouraging that the trial is on track and we all look forward to the valuable results this trial will generate", commented Dr. Anatoli Kamali from the Medical Research Council, Uganda.

Prof Helen Rees, Executive Director of the Reproductive Health and HIV Research Unit, University of the Witwatersrand, Johannesburg, South Africa, said *"This is an amazing achievement in the challenging field of HIV prevention. The researchers in this study have partnered with communities and enrolled thousands of women with the shared vision of developing a vaginal microbicide against HIV. As the investigator in Johannesburg I would like to congratulate all the research teams involved in this study, and thank the many women who have committed themselves to this important project."*

The follow-up of participants should be completed by the end of August 2009 and the final results of the phase III trial are expected to be available by the end of 2009.



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