



MICROBICIDES DEVELOPMENT PROGRAMME

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Monday 28 September 2009

EMBARGOED until Monday 28 September 2PM BST.

File name: MDP 301 Completion of follow up web announcement v1.5 (270909)
Approved: 25 Sept 09 (PLG)
Circulation: MDP Website

Microbicides Development Programme announces successful completion of last participant follow up visit in MDP 301 Phase III trial of PRO 2000 Microbicide gel

The Microbicides Development Programme announced on Monday 28 of September 2009 that it had completed the follow up of the last participant enrolled in the Phase III clinical trial assessing PRO 2000 vaginal microbicide gel. The trial is evaluating PRO 2000 vaginal microbicide gel for acceptability, safety and effectiveness in reducing the risk of HIV transmission. It is the largest microbicide trial to date and is being conducted in six research centres in South Africa, Tanzania, Uganda and Zambia. Most participants remained in the trial for a full year following their enrolment but at one site, which enrolled couples, participants were followed for up to two years. Routine reviews of unblinded data from the trial were carried out by an independent monitoring committee.

On Friday 18 September 2009, the last of the 9404 participants enrolled in the trial completed her final visit at the RHRU Soweto clinic in Johannesburg, where coincidentally the first woman enrolled on the 24th October 2005. The final window within which a participant who had previously defaulted from follow-up could attend did not close until the 25 September.

Professor Gita Ramjee, Director of the HIV Prevention Research Unit at the Medical Research Council, Durban, South Africa commented, *"This is a tremendous achievement for a trial of this size. We could not have done this without commitment from communities and participants and dedicated staff."*

Professor Janet Darbyshire, Head of the MRC Clinical Trials Unit and Joint Director of the UK Clinical Research Network (UKCRN) said *"This is a fantastic achievement in the challenging field of HIV prevention. The research teams have worked in partnership with communities and enrolled many thousands of women in the trial with the shared vision of developing a vaginal microbicide against HIV. I would like to thank the many women who have committed themselves to this important project for its successful completion and to congratulate all the research teams involved in this study."*

The final results of this phase III trial are expected to be available by the end of November 2009.

