



MTN Regional Meeting

Cape Town, South Africa
October, 2014






Achievements From the Last Year



MTN-003 (VOICE)

- Primary manuscript accepted for publication by the New England Journal of Medicine
- New data on the impact of TFV gel on herpes simplex acquisition being presented at HIV R4P meeting
- MTN-003B generating important data on the impact of TFV / Truvada on bone density in Sub-Saharan women

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- MTN-003D helping to contextualize why women not to use study products in the VOICE trial and investigating the prevalence and context of receptive anal sex in microbicide trials

MTN-011

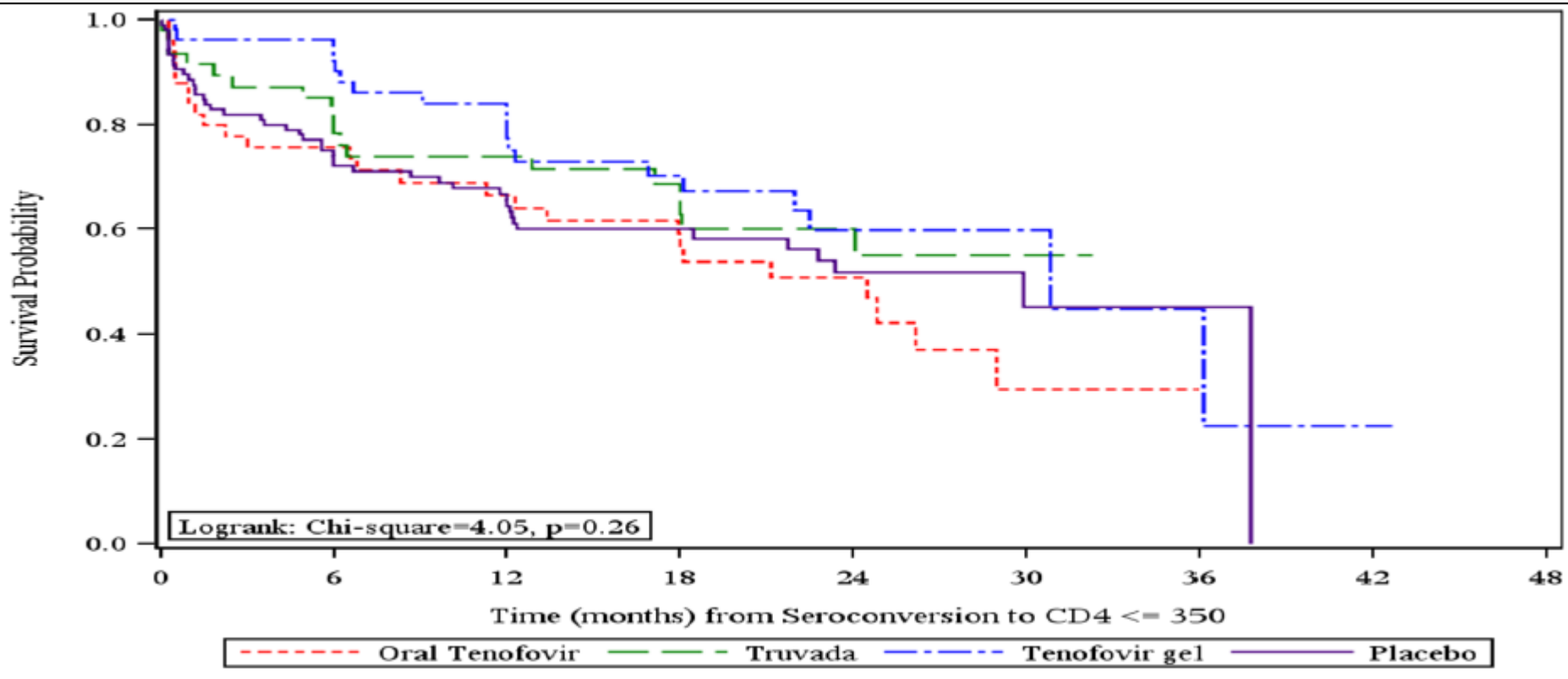
- Exploring the impact of coitus on PK
- Extremely challenging study to enroll requiring engagement of male and female partners
- Study completed and data being presented as a late breaker at HIV R4P



MTN-014

- Phase 1 evaluation of TFV gel given vaginally and rectally
- Study rapidly enrolled by the Bronx Lebanon site in New York
- Demonstrated the feasibility of implementing directly observed therapy (DOT) in a microbicide trial that included vaginal and rectal sampling for PK

MTN-015



Formulation did not impact time to CD4 count $<$ 350 (HIV R4P)

MTN-016

- MTN Pregnancy registry
- Among women who became pregnant during VOICE, 261 (62%) were eligible to enroll in MTN-016.
- Of these, 213/261 (82%) women and 185/201 (92%) of their infants enrolled in MTN-016.
- Baseline characteristics of MTN-016 enrollees from VOICE will be presented at the HIV R4P meeting

MTN-017

- The first Phase 2 rectal safety and acceptability study ever conducted
- Clinical trial sites on four continents
- 176/186 (95%) participants enrolled
- Novel use of SMS technology to monitor participant behavior
- Real time PK monitoring of product adherence shared with study participants
- Final data anticipated in Q4 2015

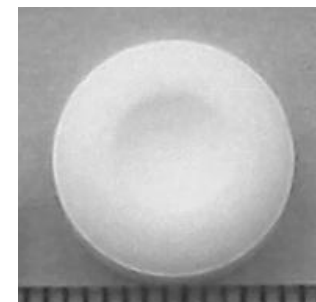
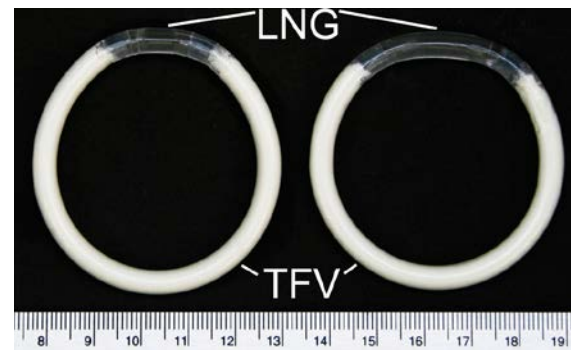
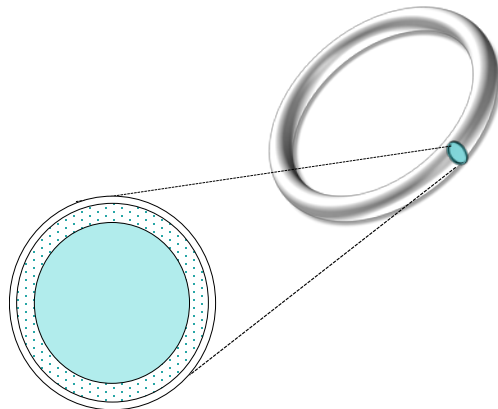
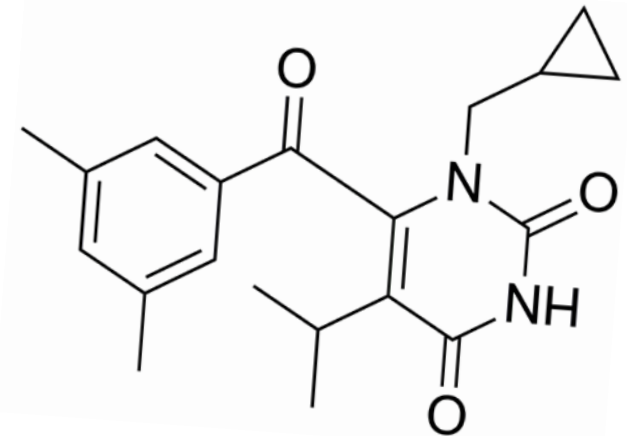
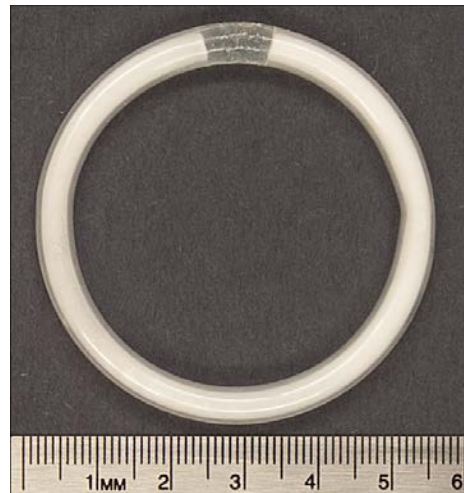
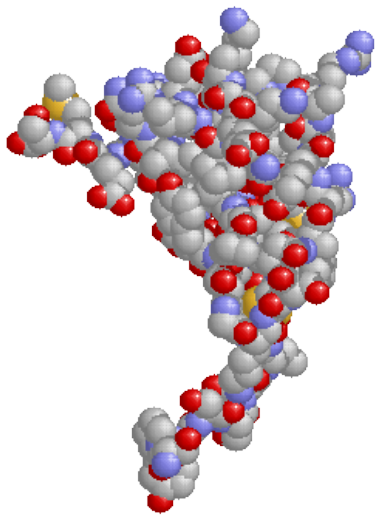
MTN-020 (The ASPIRE Study)

- Completion of enrollment and study follow-up anticipated to be completed by July 2015 with data analysis completed by the end of the year
- Implementation of PK monitoring based on plasma levels of dapivirine and residual drug levels in rings
- Intensive activity to optimize participant retention and product adherence

MTN-025 (HOPE) Study

- Phase 3B open label extension study
- Randomizes former ASPIRE participants to monthly versus quarterly follow-up
- PSRC approval obtained and protocol being submitted to local IRBs
- Protocol presented to South African MCC in August 2014
- DAIDS Strategic Working Group review supportive but requested simplified design

MTN Pipeline Prioritization



MTN at the HIV R4P Meeting

- 50 abstracts accepted
- 17 oral presentations / poster discussions including two late breakers
 - VOICE/HSV results
 - MTN-011 results
- 33 posters






Thank You

Challenges for 2015

- Complete follow-up ongoing studies
 - MTN-020 (ASPIRE)
 - MTN-017
- Respond to emerging data from key studies
 - FACTS 001
 - ASPIRE / Ring studies
 - MTN-017

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- Transition from ASPIRE to HOPE
 - Prioritize the MTN pipeline and move new candidates / formulations into Phase 1 studies
 - Define the strategy for moving ahead with rectal microbicide development
 - Rationalize the design of Phase 1 studies
 - Define the role of systems biology in microbicide development