

MICROBICIDE CANDIDATES AND ANCILLARY DEVICES IN PLANNED AND FUNDED CLINICAL TRIALS SUMMARY AS OF MAY 2008

<i>Phase</i>	<i>Candidate Name</i>	<i>MoA</i>	<i>Title of Study</i>	<i>Sponsor*</i>	<i>Sites by Country</i>
3 ⁺	ACIDFORM™ / Amphora™	VDE	Trial of the diaphragm with a candidate microbicide to prevent sexually transmitted infections	CDC, CONRAD, NIH	Madagascar
3	Dapivirine (TMC120)	RI	Dapivirine efficacy study (IPM 009)	IPM	
2/3	Invisible Condom™	EFI	Effectiveness of Invisible Condom™ in high risk women		
2/2B	Tenofovir/PMPA gel	RI	Safety and effectiveness of tenofovir 1% gel (PMPA) with two oral HIV prevention approaches - tenofovir and Truvada™, a tenofovir-FTC drug combination (MTN 003 – VOICE)	MTN	Malawi, South Africa, Uganda, Zambia, Zimbabwe
2	Tenofovir/PMPA gel	RI	Adherence and pharmacokinetics study of oral and vaginal preparations of tenofovir (MTN 001)	MTN	South Africa, Uganda, United States
1/2	Dapivirine (TMC120)	RI	Safety and acceptability of dapivirine gel, conducted using daily monitored adherence in healthy HIV-negative women (IPM 014)	IPM	Malawi, South Africa, Tanzania
	Dapivirine (TMC120)	RI	Safety of an intravaginal matrix ring with dapivirine for the prevention of HIV infection in healthy HIV-negative women (IPM 015)	IPM	South Africa, Tanzania
	Dapivirine (TMC120)	RI	Dapivirine gel expanded safety study (IPM 020)	IPM	United States
	Dapivirine (TMC120)	RI	Dapivirine intravaginal ring expanded safety study (IPM 021)	IPM	Europe
1	CAP vaginal soft tablet	C	Safety and acceptability of CAP vaginal microbicide soft tablet	New York Blood Center, NIAID	United Kingdom
	Dapivirine (TMC120)	RI	Quantitative assessment of the effects of a vaginal ring containing 25mg dapivirine on the vaginal flora of healthy women (IPM 017)	IPM, EMPRO	Belgium
	Dapivirine (TMC120)	RI	Dapivirine gel male tolerance study (IPM 010)	IPM	Belgium
	Dapivirine (TMC120)	RI	PK study in healthy HIV-negative women to assess delivery of dapivirine from both matrix and reservoir intravaginal rings (IPM 013)	IPM	Belgium
	Duet®	C	Duet® acceptability and safety study	IPM, ReProtect, Inc., RTI International	Zimbabwe

	PC-815	C	Randomized, double blind, crossover safety study of two microbicide formulations: PC-815 and Carraguard®	Population Council	Dominican Republic, South Africa
	PC-815	C	Probing study of infectivity of vaginal lavages from HIV-positive women after vaginal administration of PC-815	Population Council	
	PRO 2000	EFI	Postcoital anti-viral activity of cervicovaginal secretions following intravaginal application of 0.5% PRO 2000/5 Gel (P)	AECOM, Indevus, NIH	United States
	Tenofovir/PMPA gel	RI	Device for Vaginal Drug Delivery (DVD2) with tenofovir gel vs. plain tenofovir gel	FHI	
	Tenofovir/PMPA gel	RI	Maternal pharmacokinetics and placental perfusion of tenofovir/PMPA gel (MTN 002)	MTN	United States
N/A	No product	RI	Seroconverter protocol (IPM 007)	IPM	

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For modifications, please contact Stephanie Tillman, email stillman@microbicide.org, tel. + 301-587-3302.

Definition of acronyms used in this table: Mechanism of Action (MoA), Entry/Fusion Inhibitor (EFI), Replication Inhibitor (RI), and Vaginal Defense Enhancer (VDE), Combination (C)

*The Alliance uses the term “sponsor” as defined by the International Conference on Harmonisation (Guideline for Good Clinical Practice, 1996) as follows: “An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.” For definitions of acronyms, please visit the Alliance website.

†This study concept is under review.