Dapivirine Vaginal Ring Results

Study		tudy (IPM 027), ership for Microbicides		E (MTN-020), le Trials Network
		Study design and enrollment		
Objectives	Long-term safety and effectiveness		Safety and effectiveness	
Study design	Double-blind randomized placebo controlled with 2:1 randomization (active: placebo)		Double-blind randomized placebo controlled with 1:1 randomization (active: placebo)	
Enrollment	Total: 1959 women, ages 18-45; active arm: ~1300		Total: 2629 women, ages 18-45; active arm: ~1325	
Regulatory requirement	3000 women on dapivirine	e ring for at least one year follow	v-up; 1500 women on dapivirine ring for two year follow-up	
Participant follow-up	Two years + six weeks fo	llowing ring discontinuation	Minimum one year + four weeks following ring discontinuation	
Research sites	Seven IPM research center partners in South Africa and Uganda		Fifteen MTN research centers in Malawi, South Africa, Uganda, Zimbabwe	
		Results		
Overall results	31% effective, confidence interval 1-51		27% effective, confidence interval 1-46	
Secondary analysis that exclud	ed data from two sites with lower retention and adherence		37% effective, confidence interval 12-56	
	Results	<i>by age stratification (</i> post hoc	analysis)	
Women over 21 years of age	37% effective, confidence interval 3.5-59		56% effective, confidence interval 31-71	
Women 18-21 years of age	No statisticall	y significant effect	No stastistically significant effect	
		HIV incidence		
Overall	4.1% among women in active arm 6.1% among women in placebo arm		3.3% among women in active arm 4.5% among women in placebo arm	
Resul	ts announced at CROI 2016			
2015	2016	2017	2018	2019
The Ring study (IPM 027) Resi	ults released Q1, 2016 DR	EAM (IPM OLE) Expected to sta	art Q3 2016	
ASPIRE (MTN-020) Results rel	eased Q1, 2016 HO	PE (MTN-025) Expected to star	t Q3 2016	
Safety and PK studies (data	to be used in regulatory sub	mission)		
Efficacy trialsIs	Additional data from efficacy trials and new research on women's perspective			
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Move to open label		2017 anticipated submission of a product		African country-level
Open-label extension stu	idies	dossier to European,		submissions Earliest
Additional Ring research		US and South African regulatory agencies	Approvals, WHO guidance?	and approval introduction processes
Regulatory				→(?)
Related	oral DrED introduction in	cluding to young women in cour	trico where ring is being it	
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