

2013 Update of PrEP Candidates

PHASE I	PHASE II	PHASE II/III	PHASE III	OPEN LABEL	DEMONSTRATION PROJECTS
Intermittent Oral TDF/FTC HPTN 066 (Ongoing/HPTN)	Intermittent Oral TDF/FTC HPTN 067 (Ongoing/HPTN, Gilead, NIAID, NIMH)	Daily Oral TDF CDC 4370 (Ongoing/CDC, Thailand Ministry of Public Health)	Intermittent Oral TDF/FTC ANRS IPERGAY (Ongoing/ANRS)	Daily Oral TDF/FTC - iPrEx OLE (Ongoing/NIAID) - CDC 494/TDF2 OLE (Ongoing/Botswana Ministry of Health, CDC, Gilead) - PROUD (Ongoing/UK MRC, UK Health Protection Agency) - HPTN 073 (Ongoing/HPTN, NIAID)	Daily Oral TDF/FTC - Partners PrEP Demonstration Project (Ongoing/NIH, USAID, BMGF) - Country-led projects in Kenya, Nigeria and South Africa (Planned/O'Neill Institute, LSHTM, Imperial College London, UNAIDS, WHO, BMGF) - The Demo Project (Ongoing/SFDPH, Florida DOH, NIH) - East Bay Consortium (Planned/California HIV/AIDS Research Program at the University of California) - LAC PATH PrEP Demo Project (Ongoing/California HIV/AIDS Research Program of the University of California) - California Collaborative Treatment Group Consortium/ALERT (Planned/California HIV/AIDS Research Program at the University of California) - US CDC Foundation Demonstration Project (Planned/funding pending) - Strategies to Combine PrEP with Prevention Efforts (SCOPE) (Planned/FHI360, Family Health Options Kenya, Kenya AIDS Control Project, USAID) - Choices for Adolescent Methods of Prevention in South Africa (Ongoing/NIAID) - NYC PrEP Demo Project (Planned/CLCHC, NIAAA)
TMC 278 Long-acting TMC278-MWRI-01 (Ongoing/Janssen)	Daily Oral MVC HPTN 069 (Ongoing/ACTG, HPTN, NIAID)				
GSK1265744 LAI115428 (Ongoing/GSK/ViiV)	Daily Oral MVC + FTC HPTN 069 (Ongoing/ACTG, HPTN, NIAID)				
	Daily Oral MVC + TDF HPTN 069 (Ongoing/ACTG, HPTN, NIAID)				

TRIAL PHASE DEFINITIONS:

Phase I Controlled clinical study done in the first stage of evaluating experimental products in humans.

Phase II Controlled clinical study done in the second stage of testing new products in humans.

Phase III Large, controlled, efficacy clinical study done in the third stage of human testing, to determine if and how well a product works that should gather sufficient data so the product can be approved for licensure if it is found to work. This usually includes further safety data for evaluating the overall benefit-risk relationship of the product.

Open-label extension Study in which both the researchers and participants know which treatment is being administered. This is in contrast to "blinded" studies in which the researcher and/or participant does not know whether an active drug or placebo is being used by any given participant. These studies provide additional safety information on the product as well as new data on behavior over a longer term.

Demonstration projects Projects designed to better understand product implementation in a real-world setting. These projects come before full-scale introduction and they incorporate intensive monitoring, so that results and outcomes can be used to determine whether to move forward with product introduction.

DOSING

- Daily
- Intermittent
- Long-acting

2013 Update of Microbicide Candidates

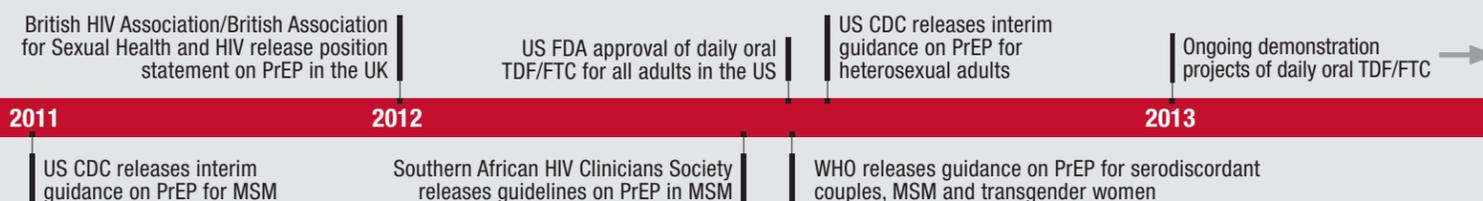
PRECLINICAL	PHASE I	PHASE II	PHASE III	OPEN LABEL
MIV 150/zinc acetate/carrageenan ring (Ongoing/Population Council)	DPV-MVC ring MTN 013/IPM 026 (Data analysis/MTN, IPM)	Reduced-Glycerin 1% TFV gel MTN 017 (Planned/CONRAD, MTN) <i>Results expected early-2015</i>	1% TFV gel FACTS 001 (Ongoing/BMGF, CONRAD, South Africa DST, South Africa DOH, USAID) <i>Results expected early-2015</i>	1% TFV gel CAPRISA 008 (Ongoing/CONRAD, South Africa DST, USAID)
IQP 0528 ring (ImQuest BioSciences)	MVC ring MTN 013/IPM 026 (Data analysis/MTN, IPM)		4-week DPV ring MTN 020 (Ongoing/IPM, MTN) IPM 027 (Ongoing/IPM) <i>Results expected early-2015</i>	
PIE12 trimer ring (Navigen Pharmaceuticals)	TDF ring (Planned/Albert Einstein)			
Griffithsin (MWRI)	TFV-FTC fast-dissolve suppository tablet A11-117 (Ongoing/CONRAD)			
TNF film (MWRI)	TFV-only fast-dissolve suppository tablet A11-117 (Ongoing/CONRAD)			
BMS793 (DS003) (IPM)	FTC-only fast-dissolve suppository tablet A11-117 (Ongoing/CONRAD)			
IQP 0528 gel (ImQuest BioSciences)	TMC 278 Long-acting TMC278-MWRI-01 (Ongoing/Janssen)			
IQP 0528/TFV combination gel (ImQuest BioSciences)	GSK1265744 LAI115428 (Ongoing/GSK, ViiV)			
PIE12 trimer gel (Navigen Pharmaceuticals)	DPV film FAME 02 (Ongoing/MWRI, IPM)			
mAB (DAIDS)	DPV gel FAME 02 (Ongoing/MWRI, IPM)			
	5P12 RANTES gel (Completed/Mintaka Foundation for Medical Research)			
	Glycerol monolaurate (GML) (Completed/University of Minnesota)			

Look for the HIV Vaccine Product Pipeline update in time for HIV Vaccine Awareness Day on May 18.

DELIVERY METHOD

- Vaginal gel
- Rectal gel
- Vaginal ring
- Vaginal tablet
- Injectable
- Vaginal film
- Preclinical compound
- Topical antibodies

PRODUCT TIMELINE SNAPSHOT



PRODUCT TIMELINE SNAPSHOT

