

HIV Prevention products in the pipeline

THIJS REYNIERS
DEPARTMENT OF PUBLIC HEALTH, ITM

BREACH spring meeting 07/05/2022

HIV prevention products in the pipeline

Novel products ready
for implementation

ARV-based products in
development (phase III)

Vaccines and antibody-
mediated prevention

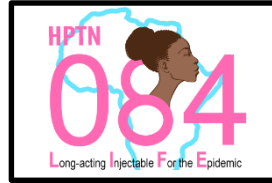


Long-Acting
Injectable

Cabotegravir



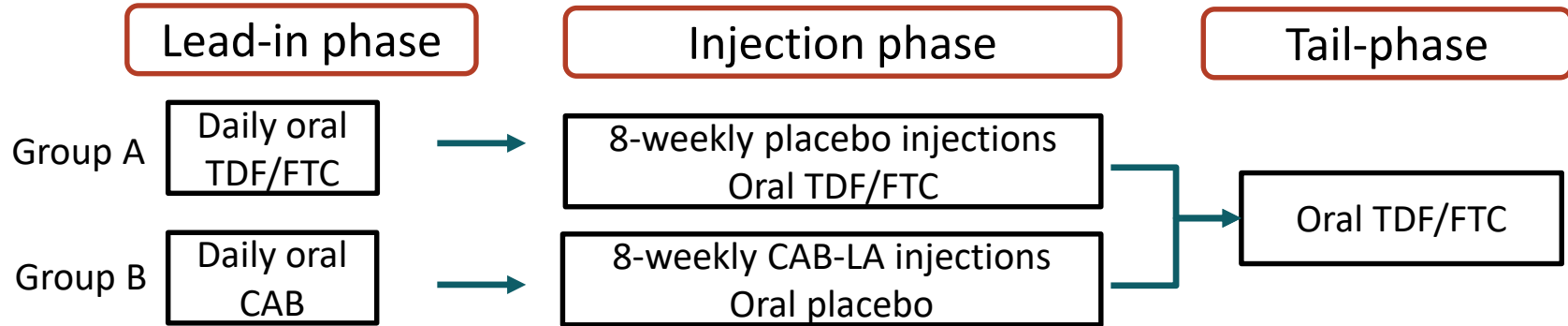
4570 MSM and TGW¹



3224 cis-women²



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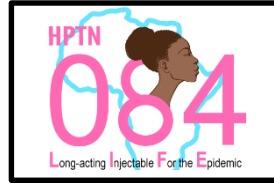
Prematurely stopped in 2020: CAB-LA superior to TDF/FTC

1 Landovitz et al. NEJM, 2021

2 Delany-Moretlwe et al. Lancet, 2022



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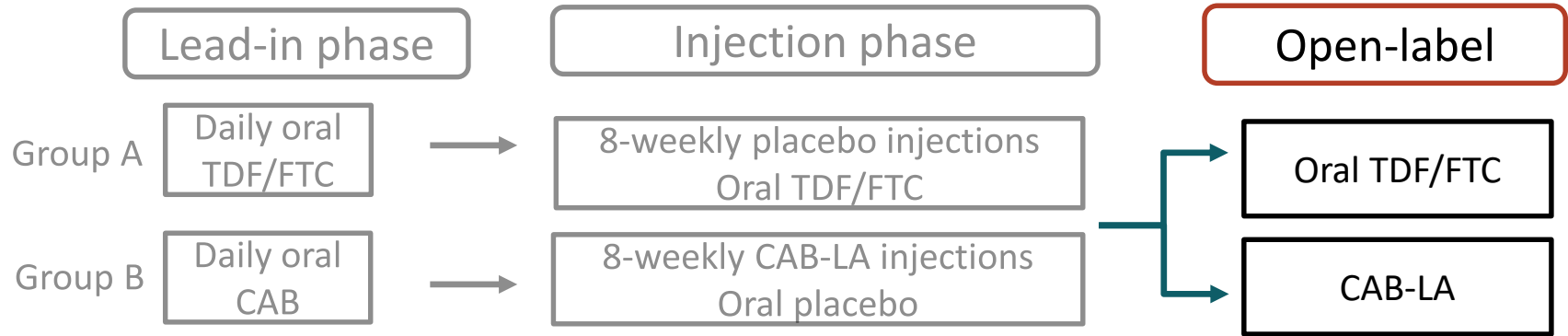


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Approved by US FDA 12/2021

1 Landovitz et al. NEJM, 2021

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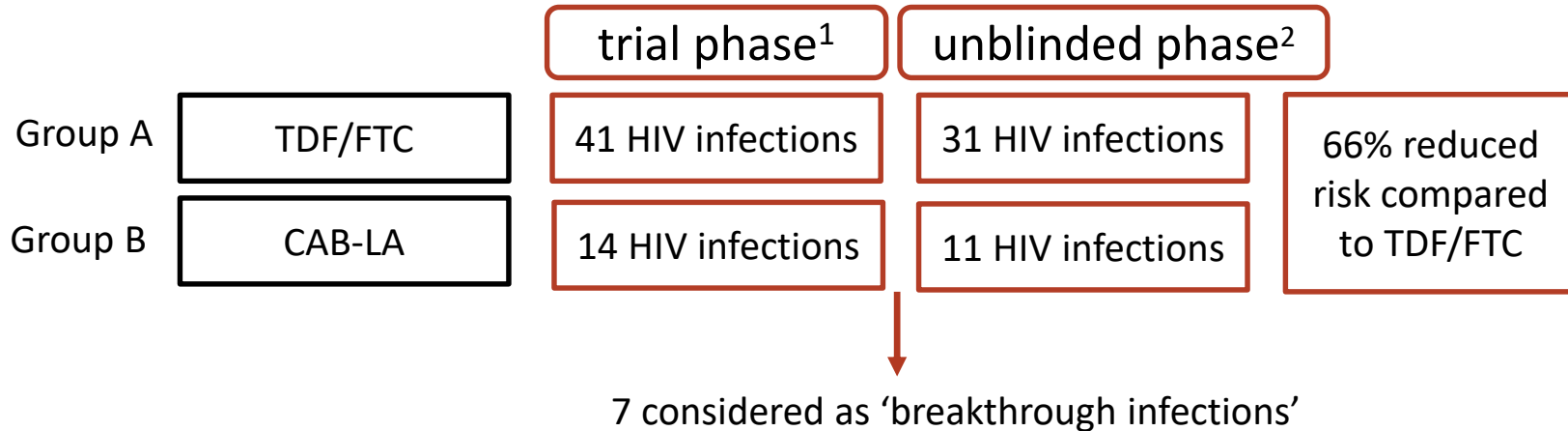
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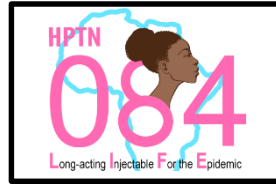


¹ Landovitz et al. NEJM, 2021

² Landovitz et al. CROI, 2022



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Group A

TDF/FTC

36 HIV infections

Group B

CAB-LA

4 HIV infections

88% reduced risk
compared to
TDF/FTC



2 had no exposure to CAB-LA
1 baseline infection
1 with delayed injection visits

2 Delany-Moretlwe et al. Lancet, 2022

Remaning questions for implementing CAB-LA



- Target population
- Acceptability



- Most optimal delivery sites and package
- Additional burden (8 instead of 12-weekly visits)
- Follow-up after 'injection phase'



- Feasibility (and cost) of sensitive HIV RNA assays
- Risk for drug resistance



- Cost-effectiveness

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Monthly vaginal ring (dapivirine)



2016^{1,2}



27% and 31% risk reduction (vs. Placebo)

2019^{3,4}



39% and 63% risk reduction

2020

EMA approval

2021

WHO recommendation

Future options

3-monthly ring
MPT-ring

1 J. Baeten et al. , NEJM, 2016

2 N Annalene et al. NEJM, 2016

3 J. Baeten et al. , Lancet HIV, 2021

4 N Annalene et al., Lancet HIV, 2021



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Other ARV-based HIV prevention products in development^{1,2}

	Method	Current status	Time to market
 Dual Prevention Pill	Day 1-21: PrEP+contraceptives Day 22-28: PrEP	Crossover acceptability study Bio-equivalence study	2024
 Oral PrEP Islatravir	One-monthly pill	IMPOWER 22 IMPOWER 24 ON HOLD Decreases in total lymphocyte and CD4 cell counts	?
 Long-Acting Injectable Lenacapavir	6-monthly injections	PURPOSE1 PURPOSE2 ON HOLD Glass vials incompatible	?

1 PrEPWatch <https://www.prepwatch.org/resource/developing-introducing-dpp/>

2 Gilead - Company statement: Gilead and Merck announce temporary pause in enrollment for phase 2 study evaluating an oral weekly combination regimen of investigational islatravir and investigational-lenacapavir

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Vaccines and antibody-
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A Journey of Hope to Prevent HIV

Prime-boost vaccine
against Clade C¹

STOPPED

02/2020



IMBOKODO

Adenovirus-26 based
'mosaic' vaccine²

STOPPED

08/2021



Also mosaic-approach
against B, C and others³

✓ IN PROGRESS

Results expected
in 2023

1 Gray et al, NEJM, 2021

2 NIH - <https://www.nih.gov/news-events/news-releases/hiv-vaccine-candidate-does-not-sufficiently-protect-women-against-hiv-infection>

3 <https://www.mosaicostudy.com/>

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Vaginal Ring

ARV-based products in
development (phase III)



Dual
Prevention
Pill



Long-Acting
Injectable

Lenacapavir



Oral PrEP

Islatravir

Vaccines and antibody-
mediated prevention



Preventive
Vaccine



Antibody

Antibody-mediated prevention¹



Passive immunization by infusing broadly-neutralizing antibodies



HVTN703/HPTN081: 1900 women
HVTN704/HPTN085: 2700 MSM & TG

	Regimen	HIV incidence	
Group A	VRC01 10mg/Kg	2.71 per 100PY	— No significant reduction in overall HIV risk
Group B	VRC01 30mg/Kg	2.12 per 100PY	
Group C	Placebo	3.04 per 100PY	+ 75% effective in preventing HIV strains that were susceptible to the bNAb

¹ Corey et al., NEJM, 2021



The future: more options!

- Promising times for HIV prevention
 - More options → responding to different needs
 - Renewed energy for HIV prevention (e.g. oral PrEP)
 - Potential to further reduce the number of HIV infections
- But... Wil it be enough?
 - No silver bullet
 - Maximise additional impact, rather than replace existing tools (e.g condom)
 - How to reach 'the highest fruit'?



Thank you!



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