Welcome to the 2026 Post AIDS Conference Webinar

We will begin shortly...

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Please utilize the Q&A Function to submit any questions you may have

For technical difficulties, please contact Keegan Girouard at (814) 404-5205

Wednesday, August 12, 2026
Virtual Webinar

2026 Post AIDS Conference Webinar

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Wednesday, August 12, 2026

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Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.

Agenda

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LA Prevention

- 4 years RWE
  - OPERA/TRIO/ PrEPFACTS/EBONI
- CLARITY Day 190
- CAB 1600 (3x/year)

3

LA Treatment

- OPERA Comparative Analysis
- Use in Diverse Populations
  - IMPALA
  - LATA
  - Opioid Use Disorder

4

Oral ART

- VOGUE : Head 2 Head DOV vs. BIK among TN patients diagnosed with HIV in a rapid initiation setting

Please use the Q&A function to submit comments and questions throughout the Webinar

Buzz at AIDS 2026

Pediatrics and Adolescents

Implementation

Cabenuva RWE

Metabolics

LA PrEP

Voice of Patient

Access

bNAbs/Pipeline

New Oral 2DRs

AIDS 2026
26–31 July

ViiV PIPELINE

ViiV Healthcare's roadmap to the future of HIV care is LAIs, supporting an HIV-free generation

LAIs are transforming HIV treatment and prevention[1–4]

- 3x/year dosing[5]
- 2x/year dosing[5]
- Self-administration

Long-acting INSTIs at the core

- **VH-310**
  Phase I (H2, 2026)[6]
- **CAB 1600**
  Phase IIb[7] (PrEP)
  Phase Ia[8,9] (Tx)
- **VH-184**
  Phase IIa[10]

Classes of potential long-acting partners

- NNRTI
- bNAb
- Capsid inhibitor

H2, second half; LA, long-acting; LAI, long-acting injectable; NNRTI, non-nucleoside reverse transcriptase inhibitor; Tx, treatment

See slide notes for references

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APRETUDE

Advancing HIV prevention: Building on the established key benefits of CAB600 with CAB1600

	AIDS 2026 OPERA, PrEPFACTS, CAPTIVATE	AIDS 2026 CAPTIVATE	AIDS 2026 CLARITY	AIDS 2026 EXTEND 4M
SUPERIOR EFFICACY vs ORAL PrEP	/ Demonstrated in **two large international head-to-head Phase IIb/III studies***† [1,2]			
REAL-WORLD EVIDENCE		/ >98% effectiveness with **over 4 years of real-world data** in diverse populations [3–17]		
CONNECTED CARE			/ Multiple real-world studies of CAB600 report **ancillary benefits** from regular clinic visits [18–22]	
ESTABLISHED SAFETY PROFILE				/ Injections are **highly acceptable** [1,23–26]. **Few significant DDIs** have been established or predicted [27,28]
EXTENDING TO 3X A YEAR DOSING‡				/ Based on the established efficacy of CAB600 (6x a year), registrational trials are ongoing for CAB1600‖ (3x a year) [29,30]

***HPTN 083 study in cis-gender men/TGW: 4,566 participants (2,282 in the CAB LA PrEP group and 2,284 in the TDF/FTC group); 13 HIV acquisitions in 3,205 PY with CAB LA, 39 HIV acquisitions in 3,187 PY with TDF/FTC. Six (0.3%) participants acquired HIV whilst adherent to CAB LA injections across the blinded and unblinded phases. *Post-hoc* centralised testing of stored samples identified one additional incident HIV acquisition and reclassified one HIV acquisition as a BL acquisition in the CAB LA arm. Two additional incident acquisitions were identified in the TDF/FTC arm[1]

†HPTN 084 study in cis-gender women: 3,224 participants (1,614 in the CAB LA PrEP group and 1,610 in the TDF/FTC group); four HIV acquisitions in 1,956 PY with CAB LA, 36 HIV acquisitions in 1,942 PY with TDF/FTC. No participants acquired HIV whilst adherent to CAB LA injections across the blinded and unblinded phases. *Post-hoc* centralised testing of stored samples reclassified one incident HIV acquisition as a BL acquisition[2]

‡After an initiation dosing phase

§As per lexicon update, CAB Q4M and CAB ULA will now be referred to as CAB1600, which is administered 3 times a year

‖CAB LA, administered three times a year, refers to CAB1600. Previous terminology may include CAB LA PrEP, ultra-long acting (ULA) or CAB Q4M

Abbreviations:

CAB, cabotegravir; **DDI,** drug–drug interaction; **FTC,** emtricitabine; **ISR,** injection site reaction; **LA,** long acting; **PK,** pharmacokinetic; **PrEP;** pre-exposure prophylaxis; **Q2M** every 2 months; **Q4M,** every 4 months; **TDF,** tenofovir disoproxil fumarate

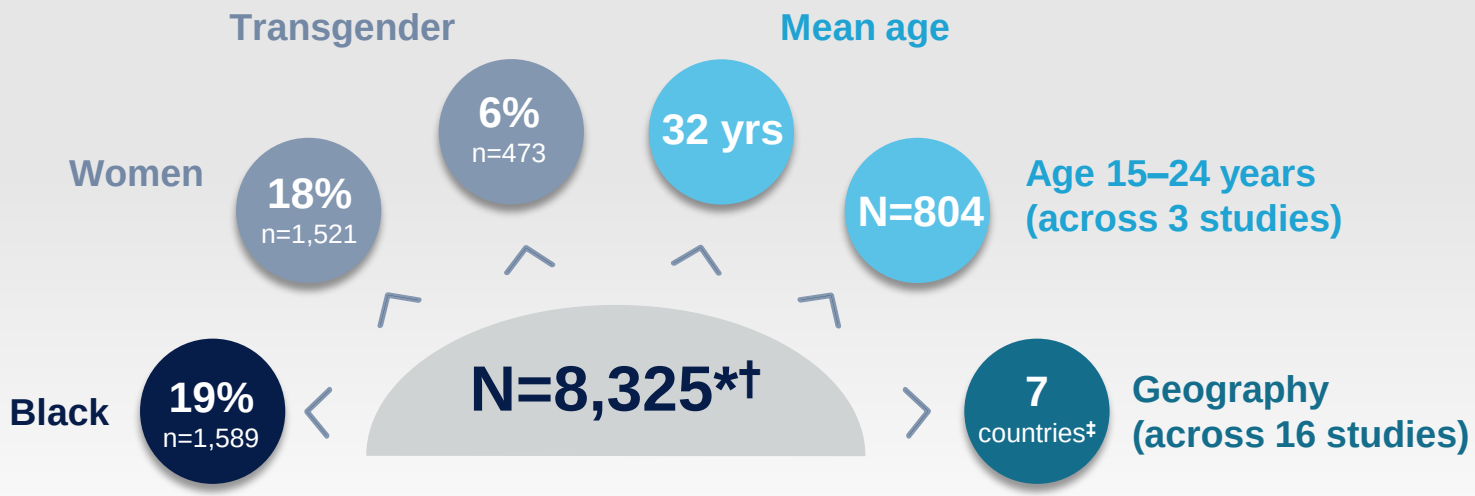
References available upon request

CAB LA for PrEP continues to demonstrate high effectiveness in real-world settings across diverse populations and geographic regions[1–56]

An ongoing SLR (December 2021 to present) identifies the number of participants receiving CAB LA for PrEP in the real world, and reviews the effectiveness of CAB LA for PrEP. As of 4 March 2026:

Among 8,325 participants receiving CAB LA for PrEP in selected studies that report effectiveness/seroconversion data…

CHARACTERISTICS



KEY OUTCOMES

98–100%

Effectiveness range
(no seroconversions)
reported in 16 studies
(N=8,325)

4.2–13 months

Median time on
CAB LA PrEP
reported in 10 studies
(N=7,005)

References available upon request

CAB600 continues to demonstrate consistent effectiveness in real-world studies, with adherence and persistence remaining high

OPERA and PrEPFACTS are ongoing, US-based RWE studies focused on the use, adherence and effectiveness of CAB600

RWE data

AIDS 2026

OPERA sub analysis: Cisgender or transgender adult women who received CAB600 (N=315)[1]

PrEPFACTS: Retrospective cohort study among individuals aged ≥12 years who received CAB600 (N=2,913)[2]

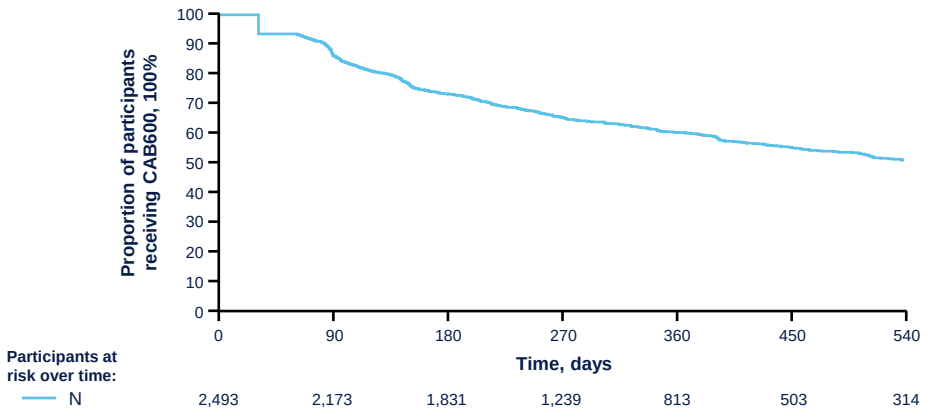
0 HIV acquisitions were observed among women receiving CAB600

87% (n=220/252) initiated CAB600 on time

56% (n=188/201) received all maintenance injections on time

Median (IQR) persistence among individuals who received ≥1 CAB600 injection was **577 (159–NR) days**

CAB600 persistence among individuals who received >1 injection



Overall adherence was high, with a median (IQR) PDC of 1.00 (0.96–1.00) and ≥89% achieving PDC ≥0.90

NR, not reached; **PDC,** proportion of days covered

1. Armas-Kolostroubis L, et al. AIDS 2026. Abstract OAC2805; **2.** Herman GF, et al. AIDS 2026. Poster TUPEC179

CAB600 continues to demonstrate high effectiveness including reports of ancillary benefits from regular clinic visits

CAPTIVATE is an ongoing, US-based RWE study which assesses CAB600 experience among users and HCPs using cross-sectional surveys and retrospective chart reviews

RWE data

AIDS 2026

Users and HCP experience:
Study in HCPs and individuals using PrEP at each study site (from November 2024–April 2025)

User experience of CAB600 (N=241)[1]

Participants reported positive experiences with CAB LA PrEP

- 99% Satisfied with injections every 2 months vs oral PrEP
- 95% Found it easy to fit injection visits in their schedule
- 95% Able to return to daily activities after injection appointments

0 HIV acquisitions reported

Many users also reported **ancillary care received during injections visits,** including:

- STI screenings (**95%**)
- Blood pressure testing (**76%**)
- Vaccinations (**51%**)

HCP experience of CAB600 (N=18)[2]

Most (16/18) HCPs report positive experience delivering CAB LA PrEP, including advantages afforded by injection visits touchpoints

- 89% Assurance of adherence
- 72% More frequent STI testing
- 61% Opportunities to address other health needs
- 50% Enabled continued engagement with the PrEP care continuum

1. Brizzi M, et al. AIDS 2026. Poster TUPEC177; **2.** Visnyei K, et al. AIDS 2026. TUPEC200

DISCUSSION

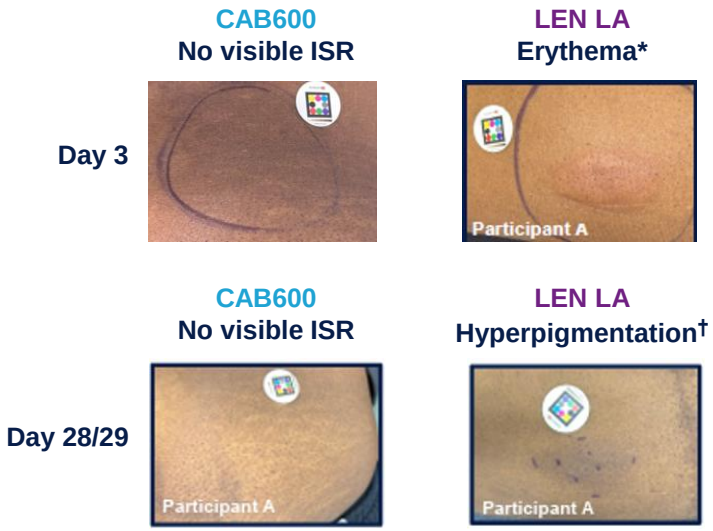
CAB600 continues to provide better injection, participant, and provider experience vs LEN LA six months after a single dose of each

CLARITY

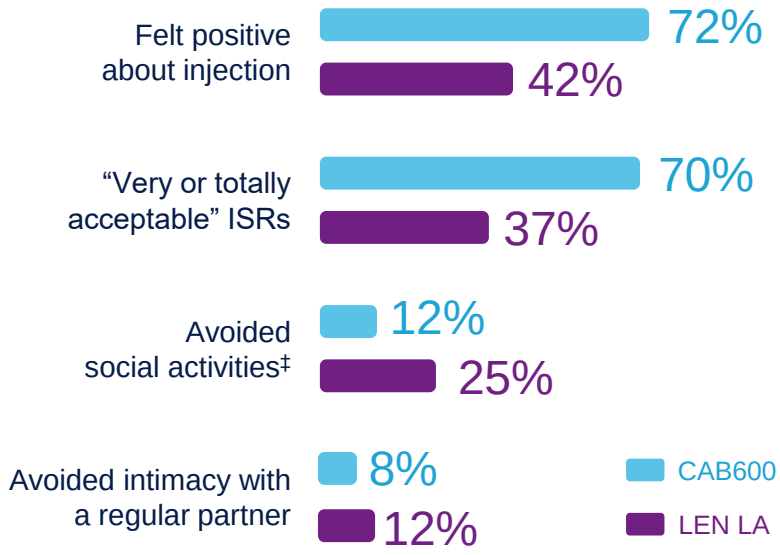
*CLARITY is an open-label, Phase 1 randomized crossover study (**CAB600** IM and **LEN SC**, one dose each). Previously, nodules and indurations were shown to be less frequent, visible, severe and bothersome, and were faster to resolve compared with LEN LA[1]*

Visible ISRs (erythema and hyperpigmentation) related to initial injection were shorter lasting and occurred less frequently for CAB600 vs LEN LA through up to 6 months of follow up, with impact on social activities and intimacy[2]

Representative images of post-injection erythema and hyperpigmentation events with LEN (single participant)[2]



Month 6 injection experience and impact of ISR on participants (n=60 in each group)[2]



Day 22 HCP injection experience (n=4)[2§]

Greater overall ease of administration **with CAB600 vs LEN LA**

(3/4 of HCPs reported less time to administer CAB vs. LEN; 0/4 HCPs reported difficulty administering or managing CAB, compared to 3/4 who had difficulty administering LEN and 2/4 managing it)

Less noticeable participant ISR **with CAB600 vs LEN LA**

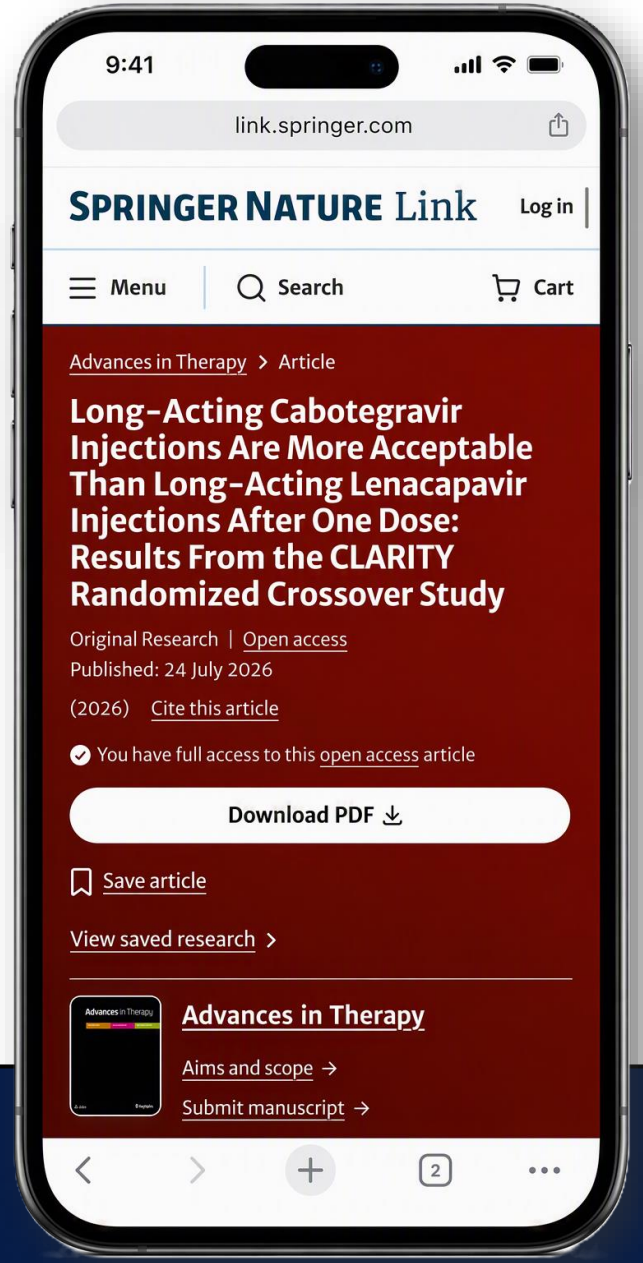
(CAB, n=2/4; LEN, n=4/4)

*Grade 1, with a surface area of 18.4 cm^2; †Grade 1, with a surface area of 19.0 cm^2; ‡Examples of social activities included swimming, wearing certain clothes and sex; §HCPs comprised one each of self-identified physician, nurse, medical assistant, and "other"

1. Fox D, et al. CROI 2026. Poster 998; **2.** Nelson KL, et al. AIDS 2026. Poster WEPEC177

CLARITY Study Publication Now Available in *Advances in Therapy*

Scan the QR code to view and download the open access article



Elliot, E.R., Boles, J., Fox, D. et al. Long-Acting Cabotegravir Injections Are More Acceptable Than Long-Acting Lenacapavir Injections After One Dose: Results From the CLARITY Randomized Crossover Study. Adv Ther (2026). https://doi.org/10.1007/s12325-026-03703-3

DISCUSSION

CAB 1600 is being developed to bring the known INSTI profile into a 3 times a year dosing schedule that better fits people's lives and helps create a connected care experience

EXTEND 4M

Phase IIb, open-label, single-arm, repeat-dose trial to evaluate PK, safety and tolerability of CAB1600‖ 3x a year for PrEP

AIDS 2026

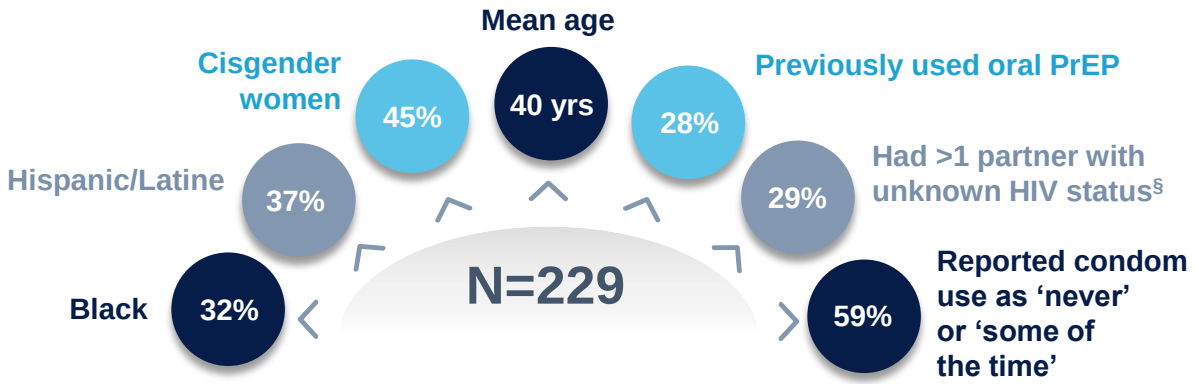
EXTEND 4M aims to demonstrate a PK, safety and tolerability profile for CAB1600 that is consistent with what is established for CAB600 *in adolescents and adults*

PK BRIDGING APPROACH

CAB 1600 builds on the **established efficacy and safety profile of CAB 600**, enabling an efficient pharmacokinetic (PK) bridging strategy rather than a new phase 3 efficacy program.

EXTEND 4M, a registrational phase 2b PK study, **is designed to confirm that CAB 1600 achieves trough concentrations** comparable to CAB 600

EXTEND 4M is being conducted in a population (N=229) representative of those receiving PrEP in the real-world



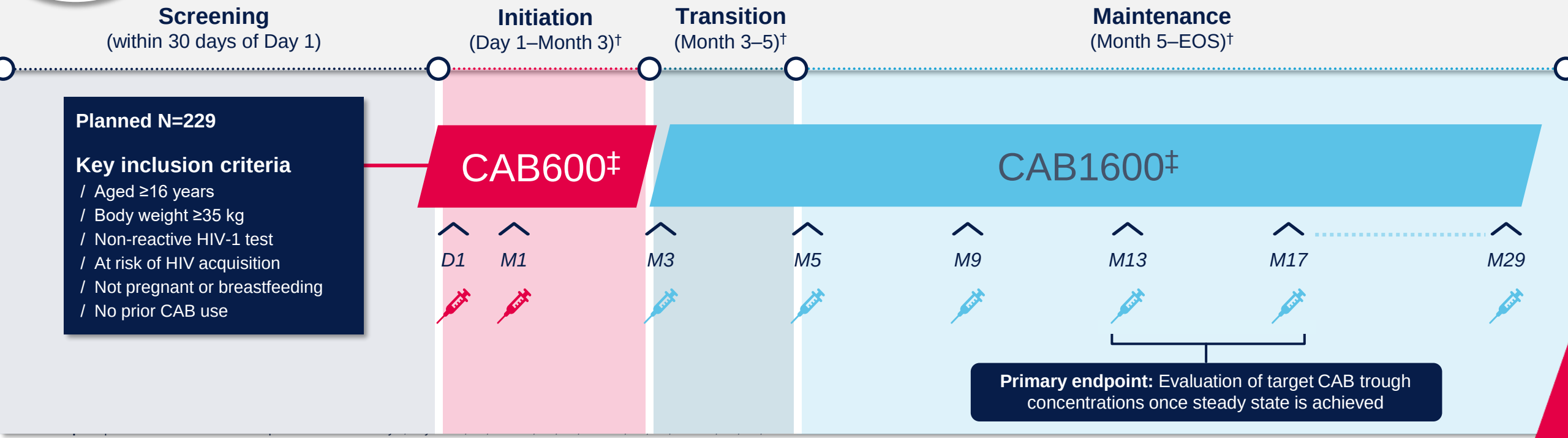
*After an initiation dosing phase; †Percentages may equal less than 100% due to rounding
‡N=228; §N=66; ‖CAB LA, administered three times a year, refers to CAB1600. Previous terminology may include CAB LA PrEP, ultra-long acting (ULA) or CAB Q4M

Acuipil C, et al. AIDS 2026. Poster WEPEB096

EXTEND 4M: Study design[1,2]

Phase IIb open-label, single-arm, repeat-dose study to evaluate the PK profile, safety and tolerability of CAB1600*

- **Primary objective:** To confirm that the plasma trough concentration of CAB1600 IM gluteal injections are equal to or higher than those observed in CAB600 registrational studies (HPTN 083 and HPTN 084), separately by sex-at-birth subgroups



M8, M9, M9+1W, M10, M11, M13, M13+1W, M17, M17+1W, M21, M25, M29, and M33; ‡Administered via gluteal injection. **CAB,** cabotegravir; **EOS,** end of study

IM, intramuscular; **LA,** long acting; **M,** Month; **PK,** pharmacokinetic; **PrEP,** pre-exposure prophylaxis; **Q4M,** every 4 months; **ULA,** ultra long acting; **W,** Week

1. NCT06741397. Available at: https://clinicaltrials.gov/study/NCT06741397. Accessed July 2026

2. Acuipil C, et al. AIDS 2026. Poster WEPEB096

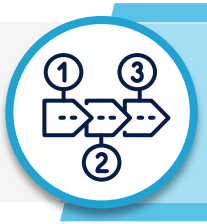
Extensive real-world effectiveness data and positive injection experience with CAB LA PrEP enables a 3 times a year future

REAL-WORLD EFFECTIVENESS

/ CAB600 continues to demonstrate **high effectiveness in diverse real-world settings**[1–4]

INJECTION EXPERIENCE

/ In the CLARITY study, **ISRs** were **more frequent, visible, severe, and slower to resolve** in those receiving **LEN SC vs CAB600.** Providers reported **fewer** administration and management **difficulties** with **CAB600 vs LEN SC**[5]



3X A YEAR DOSING

/ **EXTEND 4M** is evaluating the **PK, safety and tolerability of CAB1600*** in participants who benefit from PrEP. **Baseline demographics** were **representative** of those receiving PrEP in the **real-world**[6]

SC, subcutaneous

*CAB LA, administered three times a year, refers to CAB1600. Previous terminology may include CAB LA PrEP, ultra-long acting (ULA) or CAB Q4M

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CABENUVA

CAB + RPV LA: Highly efficacious with long-term durability in people with HIV, including under-represented populations

ROBUST CLINICAL DEVELOPMENT AND PH III/IV PROGRAM

VOLITION 11M

CROI 2026

High efficacy in early switch, with low rates of CVF with resistance[1]

SOLAR 12M, CARES 96W

Non-inferiority vs oral ART, including BIC/FTC/TAF[2,3]

ATLAS-2M 152W, LATTE-2 256W

Long-term durability up to 5 years, with high rates of virologic suppression[4,5]

IMPALA 48W

Non-inferiority vs INSTI-based ART in people with suboptimal HIV control[6]

LATITUDE 48W

Superiority vs oral ART in people with barriers to adherence[7]

MOCHA 96W

CROI 2026

High virologic suppression and strong preference among adolescents with HIV[8]

CONSISTENT EFFECTIVENESS IN REAL-WORLD EVIDENCE

Meta-analysis of published RWE at Month 12*[9]

27 studies, encompassing 7,687 virologically suppressed (VL <50 c/mL) people with HIV receiving CAB + RPV LA for 12 months

93% virologic suppression
maintained after switching to CAB + RPV LA
(N=1,708 people with HIV across six studies; 95% CI: 88.7, 96.9)

0.3% resistance at failure
with overall low virologic failure rate
(N=1,003 people with HIV across five studies; 95% CI: 0.0, 1.2)

*Results presented in the meta-analysis reflect estimates calculated using a random-effects model, and number of studies included for each endpoint varied due to differing timepoints and endpoint definitions. **BIC,** bictegravir; **CAB,** cabotegravir; **CI,** confidence interval; **CVF,** confirmed virologic failure; **FTC,** emtricitabine; **M,** month; **RPV,** rilpivirine; **RWE,** real-world evidence; **TAF,** tenofovir alafenamide; **VL,** viral load; **W,** week

1. Rolle CP, et al. CROI 2026. Poster 525; **2.** Ramgopal MN, et al. Lancet HIV 2023;10:e566–77
3. Kityo C, et al. Nat Med 2026;32:168–77; **4.** Overton ET, et al. Clin Infect Dis 2023;76:1646–54
5. Smith G, et al. Open Forum Infect Dis 2021;8:ofab439; **6.** Cresswell FV, et al. IAS 2025. Oral OAB0106LB
7. Rana AI, et al. N Engl J Med 2026 Feb 26;394(9):858-871; **8.** Gaur A, et al. CROI 2026. Oral 155
9. Orkin C, et al. EACS 2025. Poster eP103

CAB + RPV LA advances individualized HIV care beyond daily oral ART

AIDS 2026 IMPALA

NON-INFERIORITY vs ORAL ART

- **Non-inferior efficacy vs oral ART**, including BIC/FTC/TAF, with **high virologic suppression rates** and a favourable safety and tolerability profile[1–5]

AIDS 2026 OPERA

REAL-WORLD EFFECTIVENESS

- **High effectiveness**, **comparable with INSTI-based oral ART**, across **diverse populations** in large real-world studies with up to **3 years of follow-up**[6–13]

AIDS 2026 IMPALA, LATA

OBSERVED ADHERENCE

- **High, directly observed adherence to injections**, **higher adherence vs daily oral ART** (including BIC/FTC/TAF) and **superior efficacy vs oral ART in people with barriers to adherence**[1–3,14,15]

AIDS 2026 IMPALA, LATA

HIGH QoL AND PREFERENCE

- **Strong preference** vs prior oral ART, with **high and improved QoL**, including alleviation of psychological challenges and stigma[1,2,16–31]

BENEFITS BEYOND SUPPRESSION

- **High retention and engagement in care,**[24,32–34] low risk of DDIs,[35] neutral impact on metabolic syndrome, renal and bone biomarkers and **increased CD4/CD8 ratio** after switching from oral ART[36–45]

AIDS 2026 LATA

SUPERIORITY vs ORAL ART IN KEY POPULATIONS

CAB + RPV LA demonstrated **superior efficacy vs daily oral ART** in people with barriers to adherence to oral ART at 48 weeks[14] and in adolescents with HIV at 96 weeks, with no new safety signals observed[46]

QoL, quality of life

References available upon request

CAB + RPV LA: Comparable efficacy and real-world effectiveness vs BIC/FTC/TAF, with low rates of virologic failure

Head-to-head RCT: Non-inferior efficacy vs BIC/FTC/TAF*[1]

SOLAR Protocol 213500

14 countries, N=454

High virologic suppression at Month 12†

90% (n=403/447) CAB + RPV LA

(vs 93% [n=207/223] BIC/FTC/TAF)

Low rate of CVF (ITT-E)‡

0.7% (n=3/454) CAB + RPV LA

(vs 0% [n=0/227] BIC/FTC/TAF)

Well tolerated

A similar proportion of participants reported AEs (excluding ISRs) across both groups

After adjusting for baseline characteristics, CVF risk difference was not statistically significant[2]

*Primary endpoint: VL ≥50 c/mL at Month 11–12: 1.1% (n=5/447) with CAB + RPV LA vs 0.4% (n=1/223) with BIC/FTC/TAF; †VL <50 c/mL (mITT-E for SOLAR)

‡Two consecutive HIV-1 RNA measurements of ≥200 c/mL. Two participants in the mITT-E population and one in the ITT-E population met the CVF criterion

§Two consecutive VLs ≥200 c/mL or one VL ≥200 c/mL followed by discontinuation within 4 months

CVF, confirmed virologic failure; **ISR,** injection site reaction; **ITT-E,** intention-to-treat exposed; **mITT-E,** modified ITT-E; **RCT,** randomised controlled trial; **US,** United States

RWE: High and comparable effectiveness when switching to CAB + RPV LA vs BIC/FTC/TAF[2]

AIDS 2026

OPERA

OPERA US, N=4,090

High virologic suppression at last VL†

Median (IQR) follow-up: 15 (8–25) vs 22 (14–31) months

89% (n=3,655/4,090) CAB + RPV LA

(vs 83% [n=2,239/2,699] BIC/FTC/TAF)

Low and comparable rate of CVF§

1.1% (n=46/4,090) CAB + RPV LA

(vs 1.7% [n=46/2,699] BIC/FTC/TAF)

1. Ramgopal MN, et al. Lancet HIV 2023;10:e566–77; **2.** Hsu R, et al. AIDS 2026. Poster WEPEB099

OPERA: High, comparable effectiveness of CAB + RPV LA vs BIC/FTC/TAF

ART-experienced, virologically suppressed adults switching to CAB + RPV LA or BIC/FTC/TAF in the US between February 2022 and March 2025

/ Baseline characteristics, persistence and virologic effectiveness were compared across regimens

BL characteristics (N=4,090)

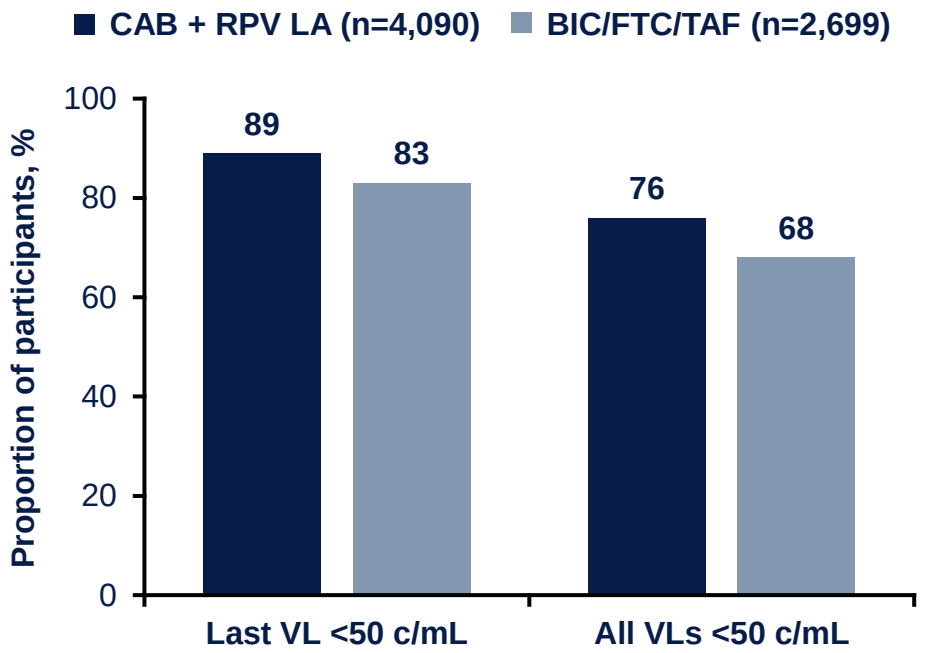
Age
Median: 38 years (IQR 32,49)

Female
14%

Black
42%*

IDU
6%

Virologic outcomes†



CVF‡

1% (n=46/4,090) CAB + RPV LA
(vs 2% [n=46/2,699] BIC/FTC/TAF)

Resuppression to <50 c/mL following CVF§

68% (n=15/22) CAB + RPV LA
(vs 69% [n=20/29] BIC/FTC/TAF)

*Data missing for 322 individuals; †Median follow-up: 15 months (CAB + RPV LA) vs 22 months (BIC/FTC/TAF); ‡Two consecutive VLs ≥200 c/mL or one VL ≥200 c/mL followed by discontinuation within 4 months. After adjusting for baseline characteristics, difference was not statistically significant; §In participants with post-CVF VL available. **ART,** antiretroviral therapy; **BIC,** bictegravir
BL, baseline; **CAB,** cabotegravir; **CVF,** confirmed virologic failure; **FTC,** emtricitabine; **IDU,** intravenous drug user; **LA,** long acting; **RPV,** rilpivirine; **TAF,** tenofovir alafenamide; **VL,** viral load

Hsu R, et al. AIDS 2026. Poster WEPEB099

DISCUSSION

CAB + RPV LA: Real-world use in broad and diverse populations with unmet needs

Hi-Vis
SHINING A SPOTLIGHT ON REAL-WORLD EVIDENCE
Click for more RWE data

✓ BMI ≥30 kg/m²

Growing evidence, including on the use of 1.5-inch needles

N=3,819

✓ Transgender

Unique challenges, impacted by social disadvantages and less accessibility

N=285

✓ No BL genotype

Inequities in access to care due to incomplete treatment history

N=2,256

✓ Racial and ethnic minorities

Disproportionally affected by HIV, as well as social and structural issues

N=7,738

✓ Migrants

Highly mobile and vulnerable group, who often lack a complete treatment history

N=1,049

✓ Older (≥50 years old)

High prevalence of comorbidities, and long-standing HIV infection

N=6,856

✓ Adherence struggles

Reasons may vary and impact the maintenance of virologic suppression

N=368

>45,000

people with HIV received CAB + RPV LA and were included in real-world studies*†[1–213]

✓ Women

Underrepresented in clinical trials despite the high burden of HIV

N=8,076

✓ Adolescents

Complex population impacted by stigma, discrimination and treatment fatigue

N=503

N=1,749 **Detectable viraemia (off-label use)‡**

*N=45,596. Supporting references for subgroup population N numbers can be found in the slide notes; †Potential overlap between real-world cohorts cannot be ruled out; ‡Use of CAB + RPV LA in people with detectable viraemia is outside of the labelled indication
BMI, body mass index

References available upon request

IMPALA: High, non-inferior efficacy of CAB + RPV LA vs DTG-based ART at Week 96

Multicenter, open-label, randomized study of CAB + RPV LA vs DTG-based ART in Uganda, Kenya and South Africa (CAB + RPV LA, N=271; DTG-based ART, N=269)[1,2]

- Primary endpoint was proportion of participants with VL <50 c/mL in ITT-E population (−10% non-inferiority margin)
- Secondary endpoints included CVF* and proportion of participants with any VL >1,000 c/mL (pre-specified sensitivity analysis)

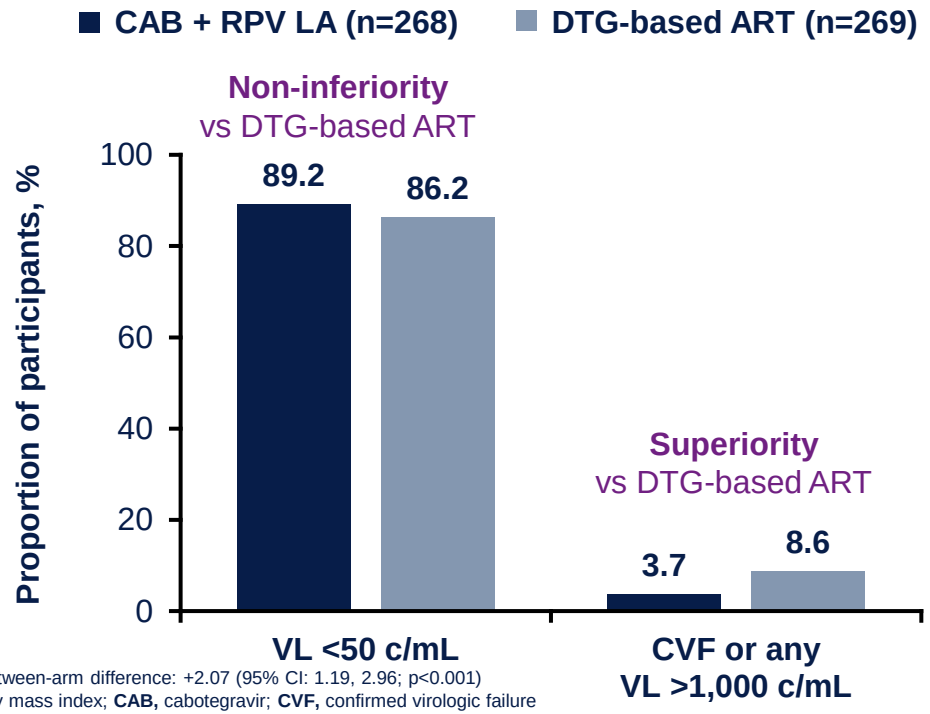
BL characteristics[2] (N=540)

Age
Median: 40 years (IQR 33, 48)

Female
60%

Black
99.6%

Virologic outcomes (Week 96)[2]



CVF with resistance[1,2]
1.9% (n=5/268) CAB + RPV LA
Overall, 2.6% [n=7/268] on CAB + RPV LA
vs 0.7% [n=2/269] on DTG-based ART experienced CVF

Viral suppression (BMI ≥30 kg/m²)[2]
89.7% (n=61/68) CAB + RPV LA
(vs 78.4% [n=40/51] DTG-based ART)

Treatment preference[2]
93% (n=237/255) CAB + RPV LA vs oral ART

Treatment satisfaction[2]
Mean score increased in both arms; the difference was **higher for CAB + RPV LA†**

Comparable safety profile (serious AEs)[2]
7.7% (n=21/271) CAB + RPV LA
(vs 6.7% [n=18/269] DTG-based ART)

*Two consecutive VLs ≥200 c/mL, 4% non-inferiority margin; †Mean between-arm difference: +2.07 (95% CI: 1.19, 2.96; p<0.001)
AE, adverse event; **ART,** antiretroviral therapy; **BL,** baseline; **BMI,** body mass index; **CAB,** cabotegravir; **CVF,** confirmed virologic failure **DTG,** dolutegravir; **ITT-E,** intention-to-treat exposed; **LA,** long acting; **RPV,** rilpivirine; **VL,** viral load

1. Cresswell FV, et al. IAS 2025. Oral OAB0106LB
2. Ruzagira E, et al. AIDS 2026. Poster LB24

AIDS 2026

26–31 July • Rio de Janeiro, Brazil

aids2026.org

Session: Co-chairs' Choice

Abstract code: OAX1105LB

Every-8-weeks injectable cabotegravir and rilpivirine is superior to daily oral tenofovir disoproxil fumarate/ lamivudine/ dolutegravir in adolescents living with HIV in sub-Saharan Africa: LATA 96-week results

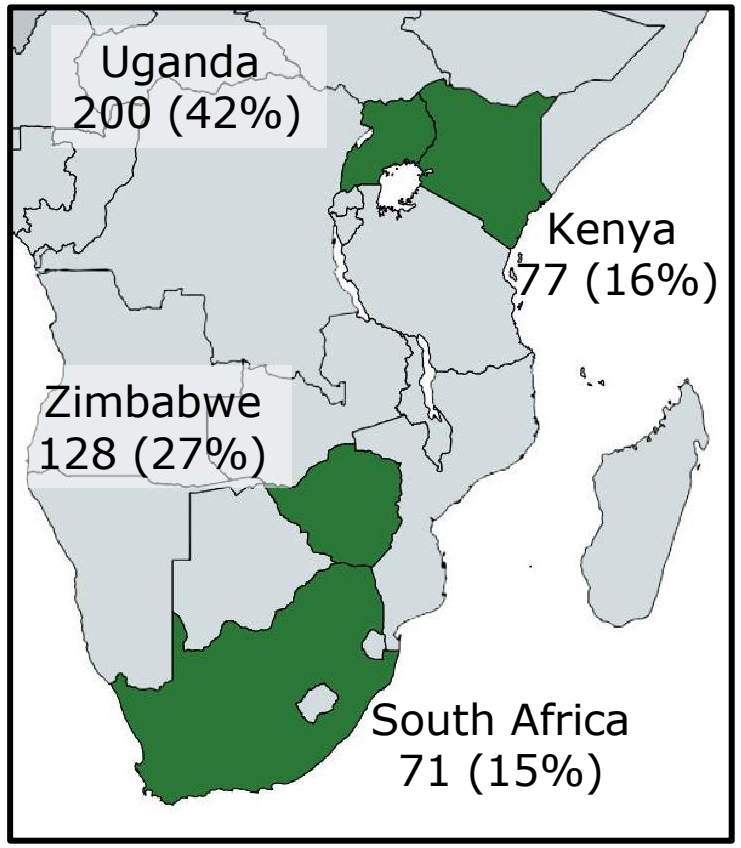
Mutsa Bwakura-Dangarembizi*, Elizabeth Chappell, Adeodata R. Kekitiinwa, Cissy Kityo, Abraham Siika, Mo Archary, Lungile Jafta, Hilda A Mujuru, Louis Diana Anena, Shamim Nakabuye, Cecilia Kiilu, Rosie Mngqibisa, George Akabwai, Henry Mugerwa, Simon Walker, Janet Seeley, David Burger, Anas Omar, Alasdair Bamford, Annabelle South, Hanh Nguyen, Carlo Giaquinto, Ben Spittle, Deborah Ford, Sarah Pett, on behalf of the LATA trial team

*University of Zimbabwe Clinical Research Centre, Harare, Zimbabwe

LATA

Baseline characteristics

476 participants enrolled: 235 **LAI**, 241 **control**



At baseline, % or median (range):

- **Age:** 16.5 years (12.0, 19.99)
- **Sex:** 54% female
- **Mode of HIV acquisition:** 98% vertical
- **BMI:** 19.6 kg/m^2 (14.2, 39.9)
- **Years on ART:** 11.7 years (1.4, 18.9)
- **Previous ART:** 99.6% DTG, 83% NNRTI
- 40% chose **optional CAB/RPV Oral Lead In** (LAI arm only)

All characteristics were well balanced across arms

LATA: Superior efficacy of CAB + RPV LA vs DTG/3TC/TDF at Week 96

Non-inferiority study of CAB + RPV LA vs DTG/3TC/TDF in virologically suppressed adolescents with no prior treatment failure in Uganda, Kenya and Zimbabwe

- Primary endpoint was confirmed virologic rebound (2 confirmed VL ≥50 copies/ml) by Week 96 (VL measured every 24 weeks)
- Non-inferiority margin and significance level were dependent on the control event rate (8.9% margin, 99% CI for 6% event rate)

BL characteristics (N=476)

Age
Median: 17 years (12-20)

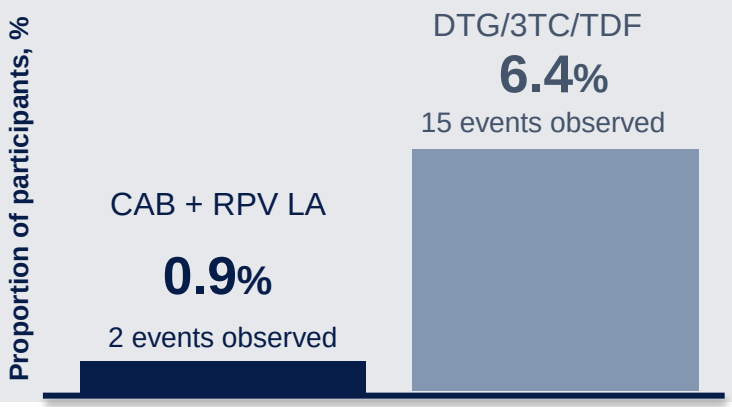
Female
54%

BMI
Median: 20 kg/m^2

Duration of prior ART
Median: 12 years (1-19)

94% of participants receiving CAB + RPV LA reported that **taking LAIs was a lot easier** than taking daily treatment

Virologic outcomes (Week 96)



Safety results through Week 96

n (%)	CAB + RPV LA (N=235)	DTG/3TC/TDF (N=241)
Any serious AE	**14 (6)**	**12 (5)**
Any ISR	**213 (91)**	**–**
Any Grade ≥3 ISR	4 (2)	–
Permanent discontinuation∓	**7 (3)**	**0 (0)**
AE	3 (1)	–
Planning pregnancy	2 (<1)	–
VL ≥200 c/mL	1 (<1)	–

Outcomes of 12 who became pregnant and opted to stay on LAI: live birth (4)†, miscarriage (4), induced abortion (1), ongoing (3)

* ITT-adjusted Kaplan-Meier estimated proportion, Difference: −5.5% (99% CI: −10.3, −1.5) p=0.001; † negative HIV tests reported for all live-born infants. 2 live infants born to participants who opted to return to oral ART once pregnant and 2 live births in participants who previously returned to oral ART; ∓ one additional participant discontinued due to patient choice

3TC, lamivudine; **AE,** adverse event; **ART,** antiretroviral therapy; **BL,** baseline; **BMI,** body mass index; **CAB,** cabotegravir; **CI,** confidence interval
DTG, dolutegravir; **ISR,** injection site reaction;**LA,** long acting; **RPV,** rilpivirine; **TDF,** tenofovir disoproxil fumarate; **VL,** viral load

Dangarembizi M, et al. AIDS 2026. Abstract OAX1105LB

CAB + RPV LA advances individualised HIV care beyond daily oral ART

AIDS 2026 IMPALA

NON-INFERIORITY vs ORAL ART

- **Non-inferior efficacy vs oral ART**, including BIC/FTC/TAF, with **high virologic suppression rates** and a favourable safety and tolerability profile[1–5]

AIDS 2026 OPERA

REAL-WORLD EFFECTIVENESS

- **High effectiveness**, **comparable with INSTI-based oral ART**, across **diverse populations** in large real-world studies with up to **3 years of follow-up**[6–13]

AIDS 2026 IMPALA, LATA

OBSERVED ADHERENCE

- **High, directly observed adherence to injections**, **higher adherence vs daily oral ART** (including BIC/FTC/TAF) and **superior efficacy vs oral ART in people with barriers to adherence**[1–3,14,15]

AIDS 2026 IMPALA, LATA

HIGH QoL AND PREFERENCE

- **Strong preference** vs prior oral ART, with **high and improved QoL**, including alleviation of psychological challenges and stigma[1,2,16–31]

BENEFITS BEYOND SUPPRESSION

- **High retention and engagement in care,**[24,32–34] low risk of DDIs,[35] neutral impact on metabolic syndrome, renal and bone biomarkers and **increased CD4/CD8 ratio** after switching from oral ART[36–45]

AIDS 2026 LATA

SUPERIORITY vs ORAL ART IN KEY POPULATIONS

CAB + RPV LA demonstrated **superior efficacy vs daily oral ART** in people with barriers to adherence to oral ART at 48 weeks[14] and in adolescents with HIV at 96 weeks, with no new safety signals observed[46]

QoL, quality of life

References available upon request

Sana Clinic
CAB+RPV LA use in people with history of IDU at a harm reduction clinic

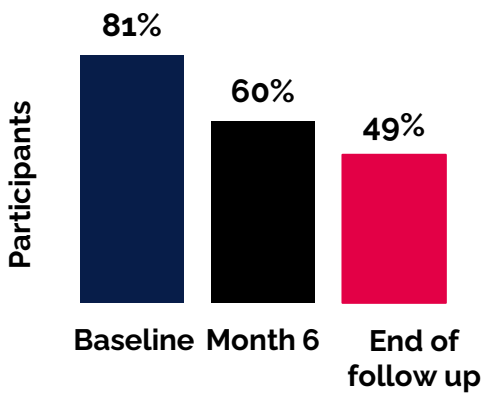
Setting
Sana Clinic, a harm-reduction clinic at Prevention Point in Philadelphia, PA

Study and population
Retrospective cohort of **40 PWH with history of IDU** who initiated CAB+RPV LA between Feb 2022 and June 2025 with at least 6 months of follow up

Patient Characteristics
- 65% male; 95% cisgender;
- 57.5% White; 25% Black; 17.5% Latinx
- 57.5% Unstably house
- 92.5% reported history of OUD

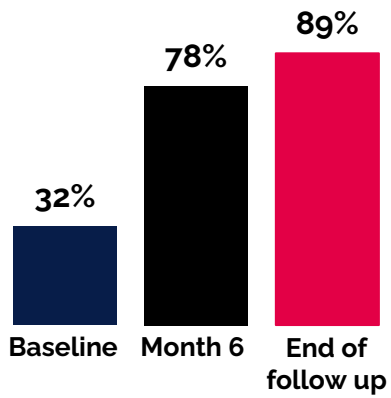
Opioid Use Disorder Outcomes

Self-reported opioid use



Opioid use declined over study period

MOUD uptake and retention

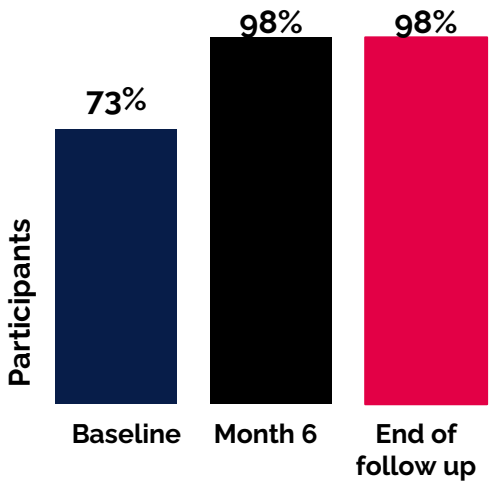


MOUD uptake increased over study period

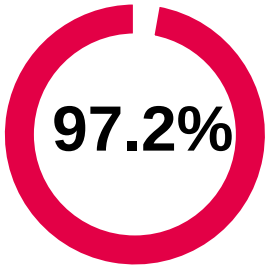
✓ 40% of MOUD initiations were within first 2mths of switch and 91% remained on treatment

HIV Outcomes

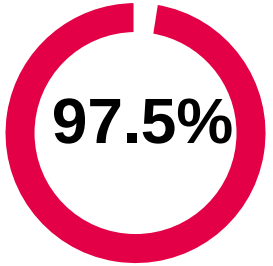
HIV-1 RNA <200 copies/mL



Retention among survivors



Participants adherent to dosing schedule



✓ **32.5%** received doses at alternative sites
✓ **22.5%** received doses incarcerated

Switching to CAB+RPV LA improves viral suppression and engagement in Opioid Use Disorder Treatment among PWH with a history of IDU

MOUD, medication for opioid use disorder; OUD, opioid use disorder; IDU, injection dr

Whidden et al AIDS 2026 Poster TUPEE558

DISCUSSION

Gustavo Verdier

Regional Medical Lead, Oral Treatments Team
ViiV Healthcare

DOVATO

Please scan the QR code for a copy of the presentation

In VOGUE: DTG/3TC Demonstrates Non-Inferior Efficacy to BIC/FTC/TAF as First-Line Treatment

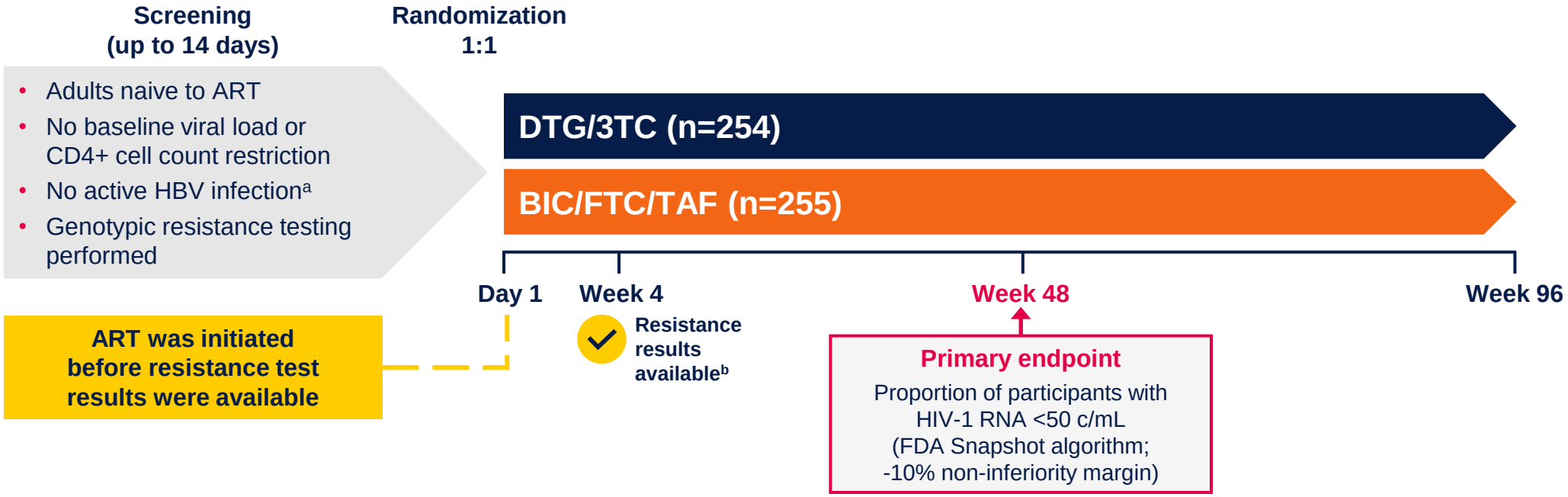
Jade Ghosn,[1,2] Federico Pulido,[3] Gustavo D. Lopardo,[4] Anita Olczak,[5] Diego Ripamonti,[6] Charlotte Martin,[7] Orlando Paredes Ceballos,[8] Hartmut Stocker,[9,10] Maria Josefina Mendez Vasquez,[11] Hiroyuki Gatanaga,[12] Simeon Metallidis,[13] Daniel Elbirt,[14] Gary Whitlock,[15] José Ignacio Mateo González,[16] Perry Mohammed,[17] Kehui Wang,[18] Ruolan Wang,[19] Adelaide Jewell,[17] Emilie Elliot,[20] Riya Moodley,[17] Bryn Jones,[17] Michelle Kisare,[17] Piotr Budnik,[17] Jean van Wyk,[17] for the VOGUE study group

[1]Université Paris Cité, INSERM, IAME, Paris, France; [2]Assistance Publique - Hôpitaux de Paris Nord, Hôpital Bichat-Claude Bernard, Paris, France; [3]Hospital Universitario 12 de Octubre, imas12, UCM, Madrid, Spain; [4]Fundacion Centro de Estudios Infectologicos, Buenos Aires, Argentina; [5]Nicolaus Copernicus University Ludwik Rydygier Collegium, Bydgoszcz, Poland; [6]Infectious Diseases Unit, ASST Papa Giovanni XXIII, Bergamo, Italy; [7]Centre Hospitalier Universitaire Saint-Pierre, Brussels, Belgium; [8]Unidad de Atención Médica e Investigación en Salud, Mérida, Yucatán, México; [9]Department of Infectious Diseases, St Joseph Hospital, Berlin-Tempelhof, Berlin, Germany; [10]EPIMED GmbH, Berlin, Germany; [11]Porto University Hospital Centre, Lisboa, Portugal; [12]AIDS Clinical Center, National Center for Global Health and Medicine, Tokyo, Japan; [13]AHEPA Hospital, Aristotle University of Thessaloniki, Thessaloniki, Greece; [14]Allergy, Immunology and HIV Unit, Kaplan Medical Center, Rehovot, Israel; [15]Department of HIV/GUM, Chelsea and Westminster Hospital NHS Foundation Trust, London, UK; [16]Consorcio Hospital General Universitario de Valencia, Valencia, Spain; [17]ViiV Healthcare, London, UK; [18]GSK, Collegeville, PA, USA; [19]ViiV Healthcare, Durham, NC, USA; [20]ViiV Healthcare, Madrid, Spain

26th International AIDS Conference; July 26-31, 2026; Rio de Janeiro, Brazil

VOGUE Study Design

Phase 3b, randomized, open-label, non-inferiority study (NCT05979311)



- Randomization was stratified by plasma HIV-1 RNA (< vs ≥100,000 c/mL) and CD4+ cell count (< vs ≥200 cells/mm^3)

Countries: Argentina, Belgium, Denmark, France, Germany, Greece, Ireland, Israel, Italy, Japan, Mexico, Poland, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

ART, antiretroviral therapy; FDA, US Food and Drug Administration; HBV, hepatitis B virus; INSTI, integrase strand transfer inhibitor.

[a]Participants with immunity to HBV, including those with isolated hepatitis B core antibody positivity without detectable HBV DNA, were not excluded. [b]Participants with major resistance-associated mutations to INSTIs, 3TC, FTC, or TAF were required to discontinue study treatment.

Ghosn et al. AIDS 2026; Rio de Janeiro, Brazil. Oral presentation OAB0106LB.

VOGUE Study Population

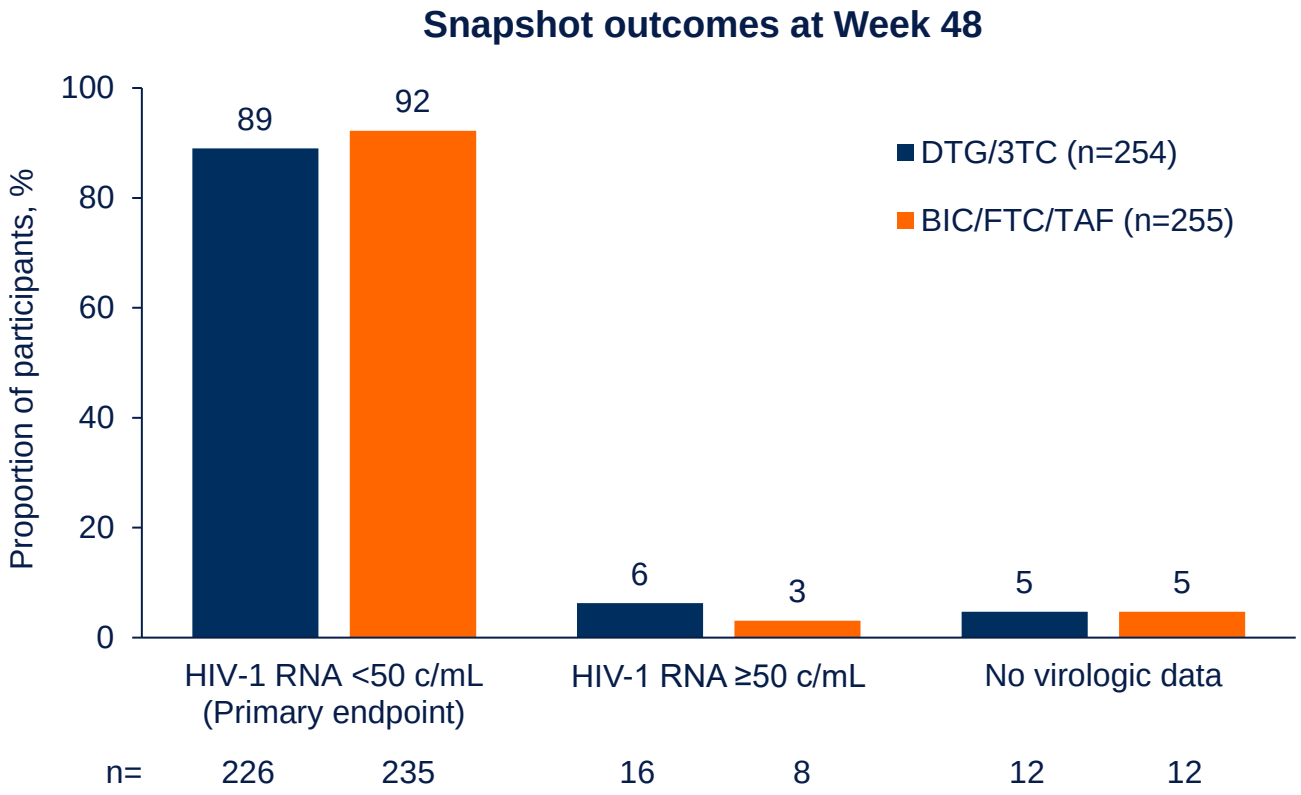
See Poster WEPEB094 for additional data

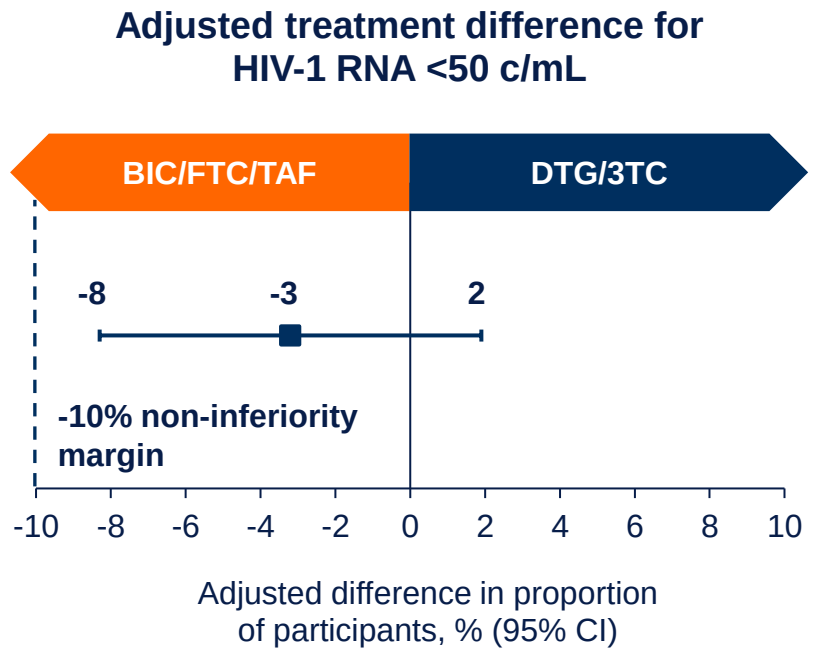
Parameter	DTG/3TC (n=254)	BIC/FTC/TAF (n=255)	Total (N=509)
Age, median (range), y	33 (18-73)	33 (18-84)	33 (18-84)
Sex assigned at birth, female, n (%)	41 (16)	38 (15)	79 (16)
Race (self-reported), n (%)			
White	211 (83)	212 (83)	423 (83)
Black or African American	24 (9)	20 (8)	44 (9)
Asian	14 (6)	12 (5)	26 (5)
Other[a]	5 (2)	11 (4)	16 (3)
Ethnicity (self-reported), Hispanic or Latino, n (%)	100 (39)	97 (38)	197 (39)
Plasma HIV-1 RNA, median (IQR), log_{10} c/mL	4.98 (4.40-5.56)	4.92 (4.39-5.45)	4.94 (4.40-5.46)
≥100,000 c/mL, n (%)	126 (50)	113 (44)	239 (47)
≥500,000 c/mL, n (%)	45 (18)	38 (15)	83 (16)
CD4+ cell count, median (IQR), cells/mm^3	375 (267-548)	372 (257-529)	373 (264-535)
<200 cells/mm^3, n (%)	40 (16)	39 (15)	79 (16)
Time from screening to treatment initiation, median (IQR), d	10 (8-14)	10 (8-14)	10 (8-14)

- 0.4% (2/548) of screened individuals were excluded due to active hepatitis B virus infection
- 1 participant in each treatment group with baseline M184V achieved HIV-1 RNA <50 c/mL at Week 4 and discontinued study treatment per protocol

[a]American Indian or Alaska Native (DTG/3TC, n=1; BIC/FTC/TAF, n=4), Native Hawaiian or other Pacific Islander (DTG/3TC, n=3; BIC/FTC/TAF, n=5), or unknown race (DTG/3TC, n=1; BIC/FTC/TAF, n=2).

DTG/3TC Demonstrates High and Non-Inferior Efficacy to BIC/FTC/TAF at Week 48

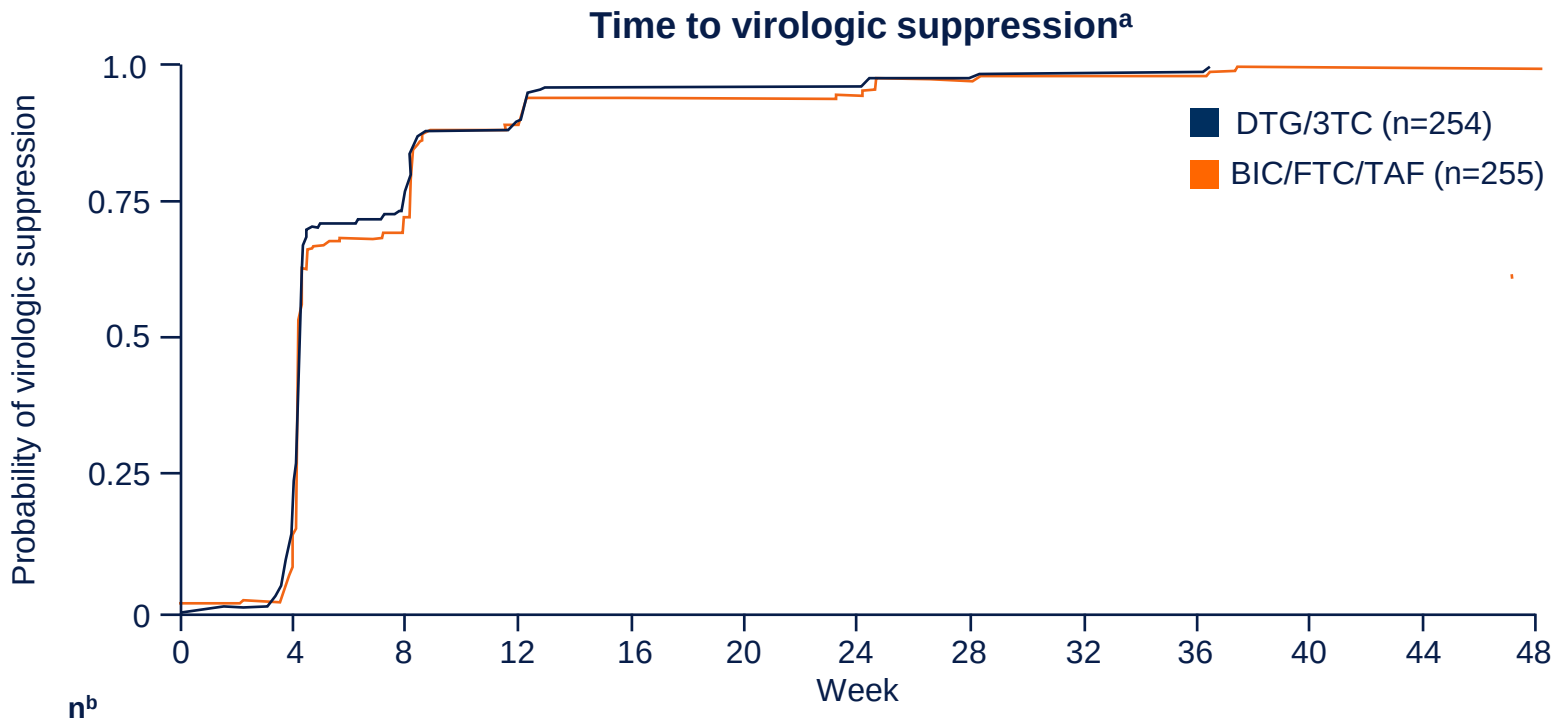




- Most instances of Snapshot HIV-1 RNA ≥50 c/mL were viral load blips <200 c/mL after prior suppression to <50 c/mL, and participants continued on study[a]

[a]DTG/3TC: Of 16 participants with Snapshot HIV-1 RNA ≥50 c/mL at Week 48, 9/12 with available data at the next visit resuppressed to <50 c/mL. BIC/FTC/TAF: Of 8 participants with Snapshot HIV-1 RNA ≥50 c/mL at Week 48, 2/3 with available data at the next visit resuppressed to <50 c/mL.

Virologic Suppression Was Rapid in Both Treatment Groups



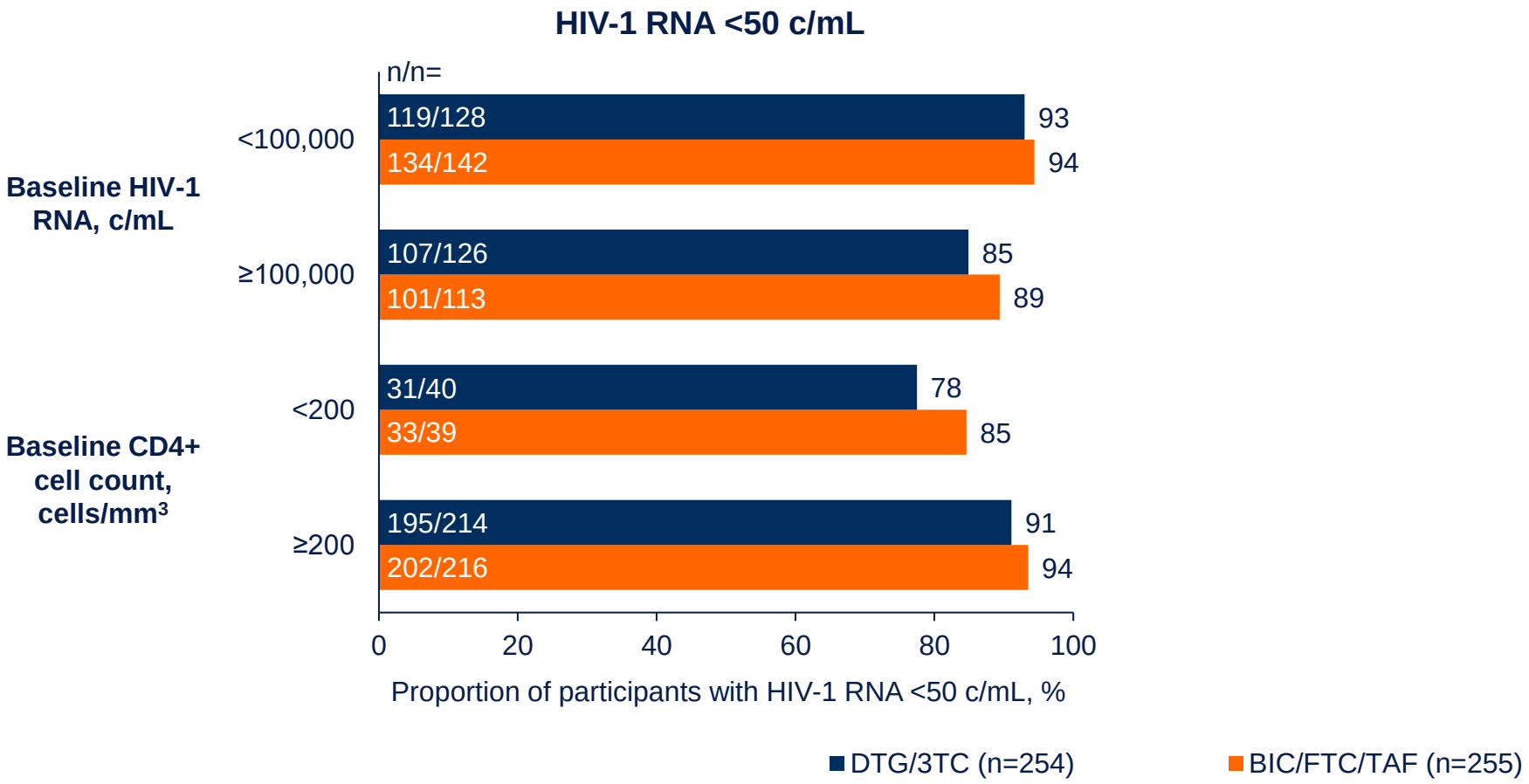
n[b]													
DTG/3TC	254	221	63	27	11	11	11	7	5	5	0	0	0
BIC/FTC/TAF	255	232	72	29	16	16	15	8	6	6	2	2	2

- Participants receiving DTG/3TC had a 23% higher hazard of achieving virologic suppression than those receiving BIC/FTC/TAF (adjusted hazard ratio, 1.23 [95% CI, 1.03, 1.47]; *P*=0.0357)[c]
- Median (95% CI) time to virologic suppression was 4.1 (4.1, 4.1) weeks for DTG/3TC and 4.1 (4.1, 4.3) weeks for BIC/FTC/TAF

[a]First viral load <50 c/mL. [b]Number of participants at risk and remaining on study at the start of each study visit window. Participants who withdrew from the study without achieving virologic suppression were censored. [c]Estimated using a Cox proportional-hazards model, with treatment as a covariate and controlled for randomization strata.

Ghosn et al. AIDS 2026; Rio de Janeiro, Brazil. Oral presentation OAB0106LB.

High Virologic Suppression Observed Across Randomization Strata



Efficacy was consistent across clinically important baseline subgroups

No Treatment-Emergent Resistance Was Identified Through Week 48

- CVW was defined as 2 consecutive plasma HIV-1 RNA measurements meeting protocol-defined criteria for either virologic non-response or virologic rebound (≥200 c/mL)

Outcome, n (%)	DTG/3TC (n=254)	BIC/FTC/TAF (n=255)
CVW by Week 48	**7 (3)**	**7 (3)**
Virologic non-response	0	1
Virologic rebound	7	6
Treatment-emergent resistance[a,b]	**0**	**0**

CVW, confirmed virologic withdrawal; INSTI, integrase strand transfer inhibitor; NRTI, nucleoside reverse transcriptase inhibitor.

[a]Baseline and virologic withdrawal samples (including available suspected virologic withdrawal and/or confirmatory samples meeting HIV-1 RNA thresholds ≥200 c/mL) were analyzed for resistance using next-generation sequencing by Cerba Laboratory (3% detection threshold) for participants in the European Union or Monogram Biosciences (10% detection threshold) for participants outside of the European Union.

[b]Among 14 participants meeting CVW criteria, resistance data were obtained for 6 individuals (DTG/3TC, n=2; BIC/FTC/TAF, n=4), and no treatment-emergent resistance to INSTIs or NRTIs was identified. For the remaining 8 participants (DTG/3TC, n=5; BIC/FTC/TAF, n=3), resistance testing failed due to viral load of samples being below the assay cutoff.

Safety Profiles Were Comparable Between Treatment Groups

- No drug-related SAEs or fatal SAEs occurred in the study
- No new HBV infections or reactivations were observed
- Mean change in weight from baseline to Week 48 was +3.6 kg for DTG/3TC and +4.0 kg for BIC/FTC/TAF

Parameter, n (%)	DTG/3TC (n=254)	BIC/FTC/TAF (n=255)
Any AE	224 (88)	237 (93)
Grade 3-4 AE[a]	26 (10)	27 (11)
Drug-related AE	44 (17)	49 (19)
Grade 3-4 drug-related AE[a]	1 (<1)	1 (<1)
SAE	23 (9)	20 (8)
AE leading to discontinuation	3 (1)	3 (1)
Drug-related AE leading to discontinuation	0	2 (<1)[b]

AE, adverse event; HBV, hepatitis B virus; SAE, serious adverse event.

[a]There were no grade 5 AEs. [b]Alopecia and increased weight (n=1 each).

Overall incidence of AEs was similar, and AEs leading to discontinuation were uncommon in both treatment groups. No drug-related discontinuations occurred with DTG/3TC.

VOGUE: Publication in *Open Forum Infectious Diseases*

Please scan the QR code for a copy of the publication

Open Forum Infectious Diseases

MAJOR ARTICLE

VOGUE: Non-Inferior Efficacy of Dolutegravir/Lamivudine Versus Bictegravir/Emtricitabine/Tenofovir Alafenamide in Adults With HIV-1 Naive to Treatment

Jade Ghosn,[1,2] Federico Pulido,[3] Gustavo D. Lopardo,[4] Anita Olczak,[5] Diego Ripamonti,[6] Charlotte Martin,[7] Orlando Paredes Ceballos,[8] Hartmut Stocker,[9,10] Maria Josefina Mendez Vazquez,[11] Hiroyuki Gatanaga,[12] Simeon Metallidis,[13] Daniel Elbirt,[14] Gary Whitlock,[15] José Ignacio Mateo González,[16] Perry Mohammed,[17] Kehui Wang,[18] Richard Grove,[19] Ruolan Wang,[20] Adelaide Jewell,[17] Kenneth Sutton,[20] Emilie Elliot,[21] Riya Moodley,[17] Rebecca Borsi,[20] Bryn Jones,[17] Michelle Kisare,[17*] Piotr Budnik,[17] Jean van Wyk,[17] for the VOGUE study group

DISCUSSION