Welcome to the 2026 Post CROI Conference Webinar

We will begin shortly...

Your audio has been muted upon entry.

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

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Wednesday, March 18, 2026
Virtual Webinar

2026 Post CROI Conference Webinar

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Wednesday, March 18, 2026

As the only pharmaceutical company solely focused on HIV, ViiV Healthcare's mission to leave no person living with HIV behind is resolute. We have an unwavering commitment to developing innovative medicines for the treatment and prevention of HIV in impacted communities. Clinical trial enrollment and real-world evidence generation that is representative of the populations most impacted by HIV is essential to delivering on our mission

Agenda

1

Pipeline

- VH-184
- Vh-499
- EMBRACE (N6LS)

2

LA Prevention

- CLARITY Day 190
- 4 years RWE
  - OPERA/TRIO/ PrEPFACTS/EBONI
- CAB ULA 4M

3

LA Treatment

- Data in Broad Populations
  - OPERA BMI, viremic
  - Adolescents
- VOLITION M11 Outcomes

4

Oral ART

- Meta-analysis: GEMINI-1/-2, D2ARLING, STAT and DOLCE
- PASO DOBLE
  - 96 weeks – SLD Sub study

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

Buzz at CROI 2026

Cure

Cabenuva RWE

Metabolics

Pediatrics and Adolescents

LA PrEP

DDIs

COVID 19

bNAbs/next gen INSTI

Weight Gain

Paula Teichner, PharmD, AAHIVP
Regional Medical Lead,
LAI for Treatment & Pipeline
ViiV Healthcare

PIPELINE

ViiV Portfolio

Pioneers in innovation of HIV treatment and prevention[1]

Search for remission and cure[1]

First long-acting injectable for PrEP[8]
Apretude: Cabotegravir

First complete long-acting treatment regimen[1]
Vocabria + Rekambys: Cabotegravir + rilpivirine
Cabenuva: Cabotegravir + rilpivirine

First attachment inhibitor for HTE[7]
Rukobia: Fostemsavir

First approved 2DRs[5,6]
Dovato: Dolutegravir/lamivudine
Juluca: Dolutegravir/rilpivirine

First second-generation INSTI[1,4]
Tivicay: Dolutegravir
Triumeq: Dolutegravir/abacavir/lamivudine

Legacy ART drug portfolio[2,3]
Zidovudine, abacavir, lamivudine, maraviroc

Paediatric formulations[1]
Tivicay PD: Dolutegravir
Triumeq PD: Dolutegravir/abacavir/lamivudine
Cabotegravir*

Shaping the future[9,10]

- Paving multiple pathways to **self-administration and LA/ULA,** with INSTI at the core
- Allowing for a shift from traditional reliance on daily oral medications by underscoring the broader **benefits of LAIs:** improved quality of life, better adherence and greater choice for people impacted by HIV

*Potential new medicines not currently approved for prescription
HTE, heavily treatment-experienced; **LA,** long acting; **LAI,** long-acting injectable; **INSTI,** integrase strand transfer inhibitor
PD, paediatric dose; **ULA,** ultra long acting

See slide notes for references

VH-184 demonstrated an enhanced resistance profile versus BIC, with a favourable PK profile supporting LA dosing

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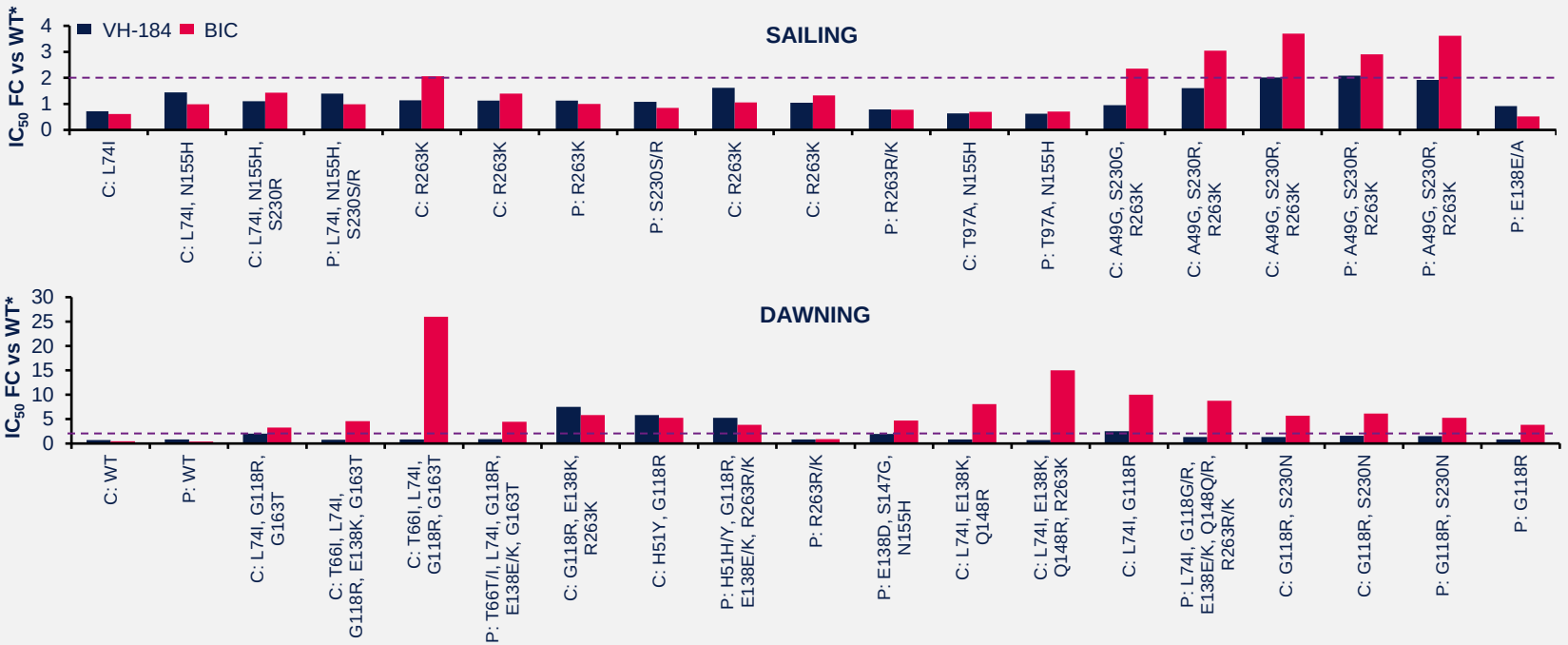
VH-184 resistance profile versus BIC[1]

The resistance profiles of **VH-184** and **BIC** were evaluated against a panel of **second-generation INSTI-resistant HIV-1 pseudotyped viruses** from participants who met CVW criteria in SAILING (n=7) and DAWNING (n=7)

Antiviral activity against INSTI-resistance pseudotyped clone variants*



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Phase I safety & PK analysis[2]

A Phase I double-blind, placebo-controlled RCT evaluated the safety, tolerability and PK of **injectable SC and IM VH-184** formulations (A and B) in 39 adults without HIV

Safety & tolerability: Both formulations of VH-184 were **well tolerated**; the majority of ISRs were Grade 1, with fewer Grade 2 and two Grade 3 ISRs

PK profile: Both formulations of VH-184 demonstrated a **favourable PK profile**, with an extended half-life **supporting LA dosing**, including Q6M dosing for formulation B

*Wild-type–level activity, defined as an IC_{50} fold change ≤2
C, clonal variants; **CVW,** confirmed virologic withdrawal; **FC,** fold change; **P,** virus populations; **SC,** subcutaneous; **WT,** wild type

1. Underwood M, et al. CROI 2026. Poster 554
2. Adapted from: Back H, et al. CROI 2026. Abstract 176

VH-499 is well tolerated, and PK safety analysis supports the potential for LA formulation

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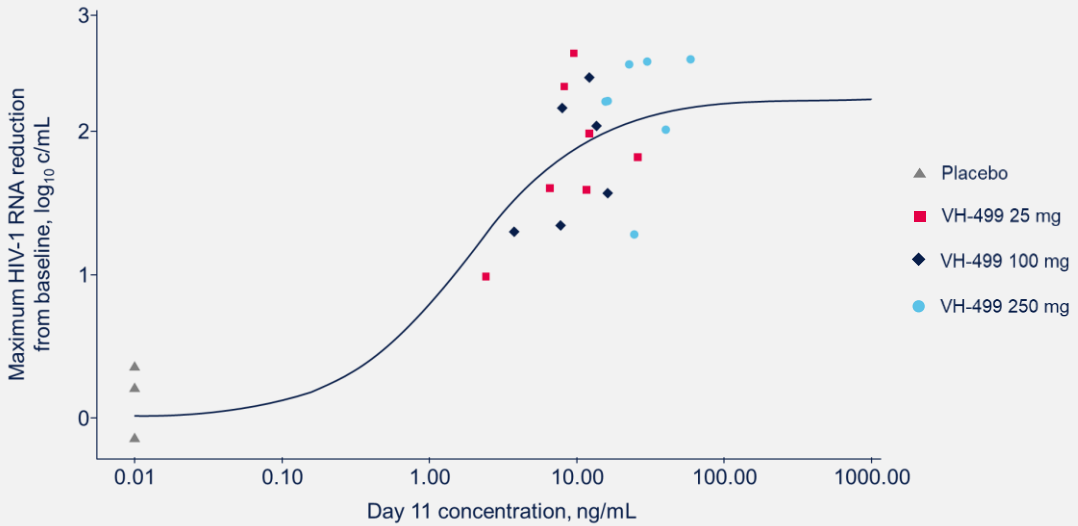
Population PK & exposure-response analysis[1]

Data from two Phase I and a Phase IIa PoC study were used to create a **population PK model** following oral administration of VH-499

VH-499 Day 11 concentration vs maximum reduction from baseline HIV-1 RNA*



Exposure−response analysis using PoC data revealed a strong **relationship** between **VH-499 exposure and HIV-1 RNA decline**

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Phase I safety & PK analysis[2]

A Phase I double-blind (sponsor-unblinded), placebo-controlled RCT evaluated **injectable SC and IM VH-499** safety and PK in 48 adults without HIV

Safety & tolerability:

- The **most common VH-499-related AEs were ISRs**, with injection site pain most frequent (n=27/36, 75%) and most AEs a maximum Grade of 1 or 2 in severity
- There was a **higher frequency of ISRs with SC** (83–100%) **than IM** (33–83%) injections
- No participants withdrew for safety reasons; no serious AEs were reported

PK profile:

- Median t_{max} was ~7−18 days for IM and ~112 days for SC due to slower absorption

These results suggest that the LAI VH-499 formulation has the **potential to support ULA (i.e. ≥4 months) dosing intervals**, and either healthcare provider or self-administration could be feasible

***Mode-predicted individual participant exposures to VH-499 are presented when a Day 11 concentration was not available. Placebo data were assigned a concentration of 0.01 ng/mL to allow visualisation on a log-transformed x-axis. Dosing was done on Day 1 and Day 6
PoC, proof of concept; **t_{max},** time to maximum concentration;

1. Thakkar N, et al. CROI 2026. Poster 492
2. Adapted from: Thakkar N, et al. CROI 2026. Abstract 175

EMBRACE: Lotivibart (N6LS) Q4M maintained viral suppression and was well tolerated through 12 months

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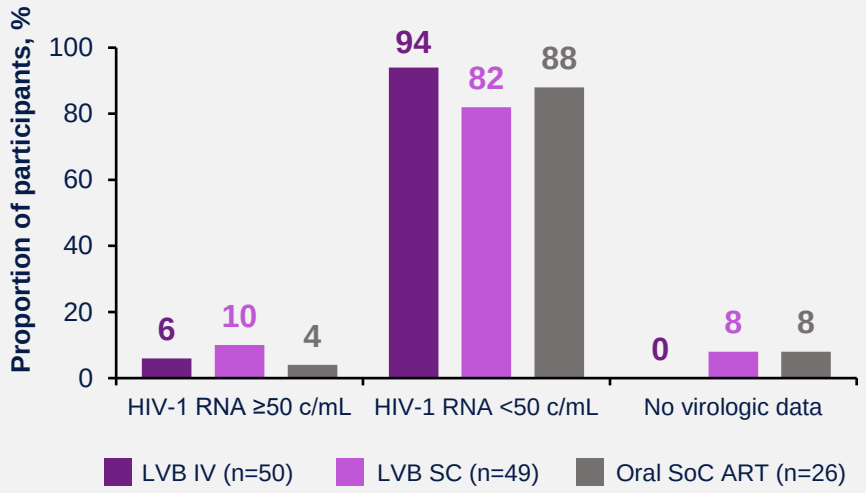
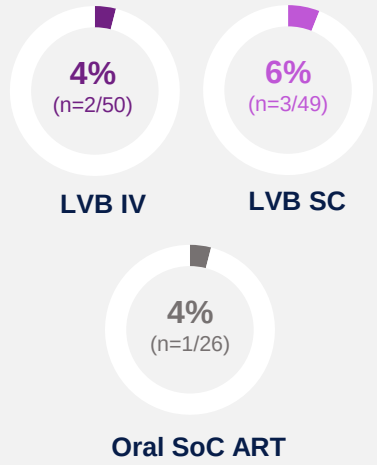
LVB (N6LS) Q4M VS through 12 months

In the EMBRACE Phase IIb study, adults (N=125) with HIV-1 RNA <50 c/mL and phenotypic sensitivity to LVB (N6LS)* were randomised 2:2:1 to **LVB** 60 mg/kg **IV** Q4M + CAB LA IM Q1M, **LVB** 3,000 mg + rHuPH20 **SC** Q4M + CAB LA IM Q1M, or to continue their pre-baseline **SoC regimen**

Virologic suppression at Month 12 (FDA Snapshot)



Confirmed virologic failure at Month 12



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Safety & acceptability

Participants in both LVB groups reported **high tolerability** and **acceptability** through Month 12

Safety through Month 12

n (%)	LVB IV (n=50)	LVB SC (n=49)	Oral SoC ART (n=26)
Any AE	46 (92)	45 (92)	18 (69)
Any AE leading to discontinuation	1 (2)	5 (10)	0
LVB-related AE	12 (24)	26 (53)	—
Grade 3–4 LVB-related AE	0	8 (16)	—
LVB-related ISR	4 (8)	25 (51)	—

LVB IV Q4M demonstrated a **better tolerability profile** than **SC Q4M** through 12 months of coadministration with CAB LA

*IC_{90} ≤2 µg/mL, maximum percent inhibition >98%
FDA, US Food and Drug Administration; **IV,** intravenous; **Q1M,** every 1 month; **rHuPH20,** recombinant human hyaluronidase PH20
SoC, standard of care; **VS,** virologic suppression

Adapted from: Rolle CP, et al. CROI 2026. Abstract 178

Robert Morris, PharmD

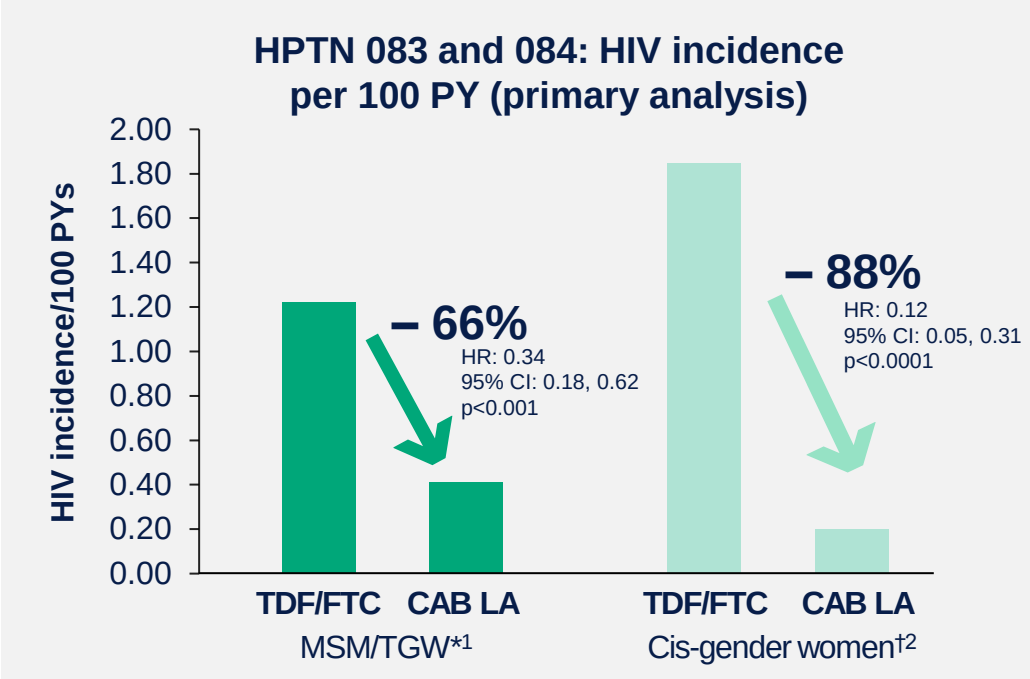
Medical Director,
Long-acting Injectables for PrEP

ViiV Healthcare

APRETUDE

Advancing CAB LA PrEP: Building on proven benefits of CAB LA Q2M with Q4M dosing

CAB LA PrEP Q2M has shown superior efficacy vs oral TDF/FTC; in two large international head-to-head Phase IIb/III studies, 0.2% of cisgender men/TGW* and 0% of cisgender women† experienced seroconversion with on-time injections[1–5]



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REAL-WORLD EFFECTIVENESS

Demonstrated >99% effectiveness in **over 4 years of real-world data** in diverse populations,[6–16] with multiple studies reporting ancillary benefits from regular clinic visits[17–21]

LOW POTENTIAL FOR CLINICALLY RELEVANT DDIS[22,23]

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WELL TOLERATED

Injections were highly acceptable and discontinuations due to ISRs were rare in clinical trials[1,24–26]

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DATA IN PREGNANCY

Data on outcomes and PK of CAB LA PrEP use during pregnancy are expanding[6,27–29]

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Clinical trials are ongoing for Q4M CAB ULA for PrEP, which will build on the established benefits of Q2M dosing[30]

See slide notes for footnotes and abbreviations

See slide notes for references

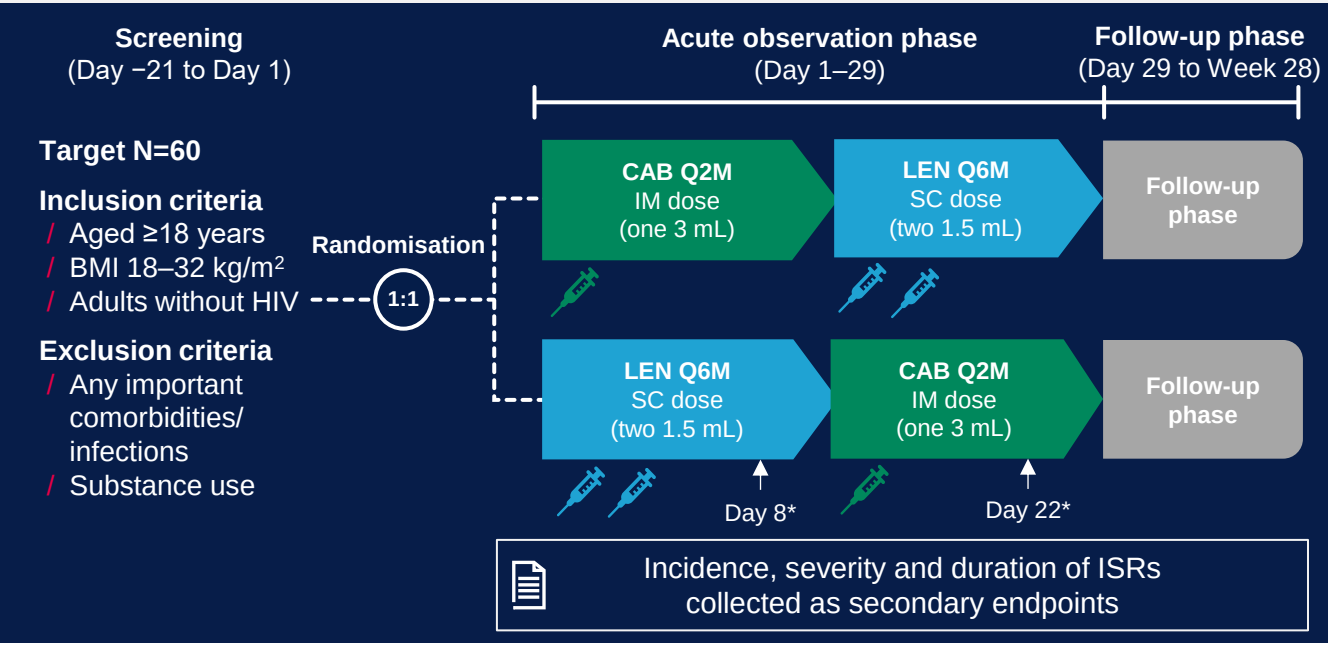
CAB LA PrEP injections were more acceptable and preferable to participants than LEN LA injections after one dose of each medicine

CLARITY study

EACS 2025

Open-label, randomised crossover study (CAB IM and LEN SC, one dose each) in 63 adults without HIV (single-centre in the US)

Primary endpoint was local reaction acceptability 7 days after each initial injection using the 21-item PIN questionnaire*



Participant acceptability

Proportion of participants reporting that local reactions were "totally or very acceptable" (PIN) 7 days post injection

CAB LA†

69%

"totally or very acceptable" (42/61)‡

LEN LA†

48%

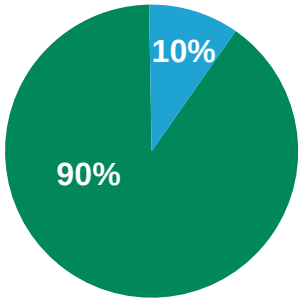
"totally or very acceptable" (29/60)‡

Participant preference

Day 22 (N=60)§¶

CAB LA preference (90%; n=54)

- Less pain during injection administration (n=40)
- Less pain or soreness after injection administration (n=33)
- Duration of injection nodules or swelling (n=31)
- Size of injection nodules or swelling (n=30)



LEN LA preference (10%; n=6)

- Less pain or soreness after injection administration (n=5)
- Duration of injection nodules or swelling (n=3)
- Size of injection nodules or swelling (n=3)
- Fewer side effects (n=3)

*Primary endpoint: PIN acceptability domain (assessed 7 days post injection on Day 8 and Day 22); †Seven days post injection (data from Days 8 and 22 are combined); ‡Participants with available data §The question 'Which medication regimen do you prefer' from the Study Medication Preference Questionnaire was used to assess preference on Day 22; ¶Participant preferences were assessed only at Day 22, after all participants had received both CAB LA and LEN LA injections; participants were allowed to select multiple reasons for their stated preference, the top four reasons for preference are listed

IM, intramuscular; **LEN**, lenacapavir; **PIN**, Perception of Injection; **Q6M,** every 6 months; **SC,** subcutaneous

Boles J, et al. EACS 2025. Poster MeP20.4.LB

CLARITY: Education arond CAB and LEN ISRs may facilitate informed shared decision-making

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Study details

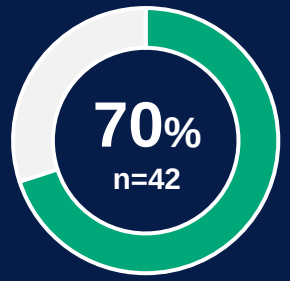
Open-label, randomized crossover study comparing one dose of either CAB LA PrEP or LEN PrEP in adult participants (N=63)

CAB LA PrEP
n=61

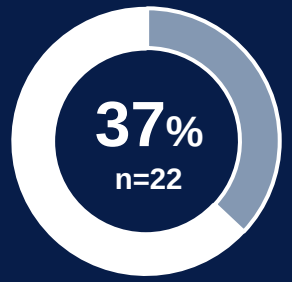
LEN PrEP
n=62

- **Primary endpoint:** ISR acceptability 7 days after injection using the PIN questionnaire
  - Data were reported for visible and palpable ISR events up to **190 days** after administration of each study drug

Participants reporting ‘very’ or ‘totally’ acceptable local reactions and pain with CAB LA PrEP vs LEN PrEP at Day 190



CAB LA PrEP (n=60)



LEN PrEP (n=60)

Summary of nodules and indurations*

	CAB LA PrEP (n=61)†	LEN PrEP (n=62)†
Nodules, n	35	124
Nodules unresolved by Day 190, n (%)	**4 (11)**	**120 (97)**
Duration of nodules, median (range), days‡	64.0 (7–128)	196.5 (2–224)
Nodules visible at anytime, n (%)	5 (14)	78 (63)
Indurations, n	12	94
Indurations unresolved by Day 190, n (%)	0 (0)	0 (0)
Duration of indurations, median (range), days‡	12.0 (2–42)	14.0 (2–59)
Indurations visible at anytime, n (%)	10 (83)	84 (89)

At Day 190, the proportion of patients reporting “very or totally acceptable” local reactions to initial injections and pain were 70% for CAB LA and 37% for LEN LA

*In participants who received ≥1 injection; †One participant received CAB LA PrEP at Day 1 but did not receive LEN PrEP at Day 15
‡Includes both resolved and unresolved ISRs (up to data cut-off date of Dec 29, 2025). **LEN**, lenacapavir; **PIN**, perception of injection

Fox D, et al. CROI 2026. Poster 998

EBONI and PrEPFACTS: CAB LA PrEP use is associated with ancillary benefits in real-world settings

Existing ancillary benefits data

Broader sexual health care utilization[1]

- Improved engagement in PrEP services and broader sexual health care utilization were observed in OPERA

Additional screening for STIs and comorbidities[2,3]

- Previous data from EBONI have shown that CAB LA PrEP is highly suitable for Black women, with 2-monthly visits offering ancillary benefits such as additional screening for STIs and comorbidities

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PrEPFACTS: Participants (≥12 years) who received ≥1 CAB LA PrEP injection or oral PrEP between December 2020 and September 2024 (N=2,913)*[4]

Rates of several preventive care measures were higher during CAB LA PrEP use vs baseline:

STI screening: +287.6/100PYs
(IRR: 1.31 [95% CI: 1.26, 1.36]; p<0.05)

Wellness exams: +5.9/100PYs
(IRR: 1.09 [95% CI: 0.99, 1.19])

Preventive counselling: +8.8/100PYs
(IRR: 1.51 [95% CI: 1.24, 1.84]; p<0.05)

Cancer screening: +5.0/100PYs
(IRR: 1.10 [95% CI: 0.99, 1.23])

These findings indicate that **HIV-related preventive care**, such as **counselling and STI screening**, occurred more frequently during CAB LA PrEP use[4]

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EBONI: Phase IV hybrid IS study that assessed the integration of CAB LA PrEP at 20 sites for Black CGW and TGW (N=163)[5]

Ancillary benefits reported at M12 (N=99):

- **71%** — **Had more opportunities** to discuss **concerns or manage side effects**
- **55%** — Could discuss other **sexual healthcare issues,** such as **STIs or contraception**
- **44%** — Had a **better relationship with HCPs**
- **35%** — Had **more opportunities** to receive **additional health screenings**
- **32%** — Had more opportunities to **discuss health concerns** when the arise

Regular visits offered multiple ancillary benefits[5]

*Individuals with an HIV-1 or HIV-2 diagnosis, receiving any PrEP, or ≥60 days of non-PrEP ART at baseline were excluded
CGW, cis-gender women; **IRR,** incidence rate ratio; **IS,** implementation science; **STI,** sexually transmitted infection

1. Barnett S, et al. IDWeek 2025. Poster P-332; **2.** Tims-Cook Z, et al. IAS 2025. Poster THPEE096
3. Nelson KL, et al. IDWeek 2025. Poster P-313; **4.** Metzner A, et al. CROI 2026. Poster 985
5. Tims-Cook Z, et al. CROI 2026. Poster 1081

CAB ULA 012: Simulations of CAB ULA 1,600 mg Q4M demonstrated consistent plasma concentrations, safety and tolerability profile with the established CAB LA Q2M dosing

Study details

Adults without HIV-1 received a single IM CAB Q4M dose ranging from 800–3,200 mg in a Phase I study;* CAB plasma concentrations and safety were assessed over 52 weeks (N=48)

CAB Q4M concentrations

800 mg	1,200 mg	1,600 mg	2,400 mg	3,200 mg
n=8	n=8	n=16	n=9	n=7

- CAB PK profiles were simulated following virtual dosing of CAB ULA PrEP Q4M and were compared with two doses of CAB LA PrEP 2 months apart
- A previously established CAB LA PopPK model was leveraged to develop a CAB Q4M PopPK model based on these new data

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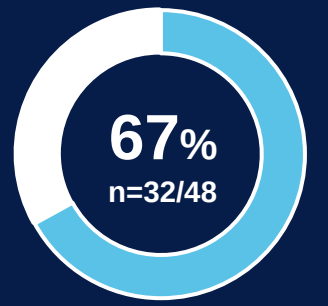
Comparison of predicted exposures after CAB ULA 1,600 mg Q4M vs CAB LA 600 mg Q2M through 16 weeks

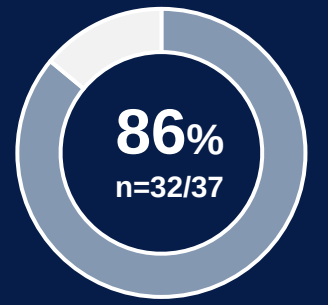
Plasma concentrations observed from a single dose of CAB ULA Q4M (1,600 mg) were:

- Consistent with plasma concentrations predicted by the CAB ULA Q4M PopPK model
- Lower than plasma concentrations that would arise from the second CAB LA 600 mg Q2M dose (but maintained above therapeutic levels)

ISRs occurred in 77% (n=37/48) of participants:



ISRs were the most common AE



of participants had a maximum Grade 1 ISR

Simulations based on CAB ULA Q4M PopPK model support the 1,600 mg maintenance dose currently in Phase IIb registrational trials

*NCT05418868
AE, adverse event; **IM**, intramuscular

Summary: CAB LA PrEP

Real-world effectiveness

CAB LA PrEP continues to demonstrate **high effectiveness in real-world settings**, and individuals benefit from **regular clinic visits**, as demonstrated by **increased sexual healthcare utilization**[1–12]

Injection site reactions

In CLARITY, **9 out of 10 patients preferred CAB LA** over LEN LA, mainly driven by **less severe ISRs** (nodules, swelling).
At day 190, **70% of CAB LA participants reported** local reactions and pain as **"very or totally acceptable"** versus 37% for LEN LA [13]

Use in pregnancy

Unbound CAB PK and PK modelling data **support** the use of CAB LA for PrEP **maintenance and initiation during pregnancy**[14,15]

Evolution to Q4M dosing

Q4M demonstrated **consistent plasma concentrations, safety and tolerability profile** with the established **CAB LA Q2M** dosing[16]

See slide notes for references

DISCUSSION

Mark Lewandowski, PharmD

Medical Director, LAI for Treatment
ViiV Healthcare

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

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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. Abstract 155
9. Orkin C, et al. EACS 2025. Poster eP103

OPERA: High effectiveness and persistence on CAB+RPV LA in >5,000 people, including people with viremia

Study population and design

CAB + RPV LA in people with VL <50 c/mL at initiation (N=4,587)

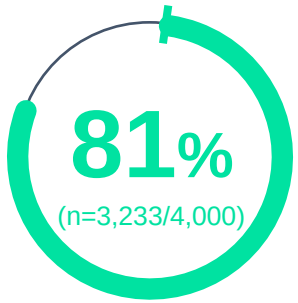
- **Median (IQR) age:** 38 (32, 50) years
- **Aged ≥50 years:** 25%
- **Black:** 43%
- **Hispanic:** 31%
- **BMI ≥30 kg/m²:** 30%

Effectiveness* and Persistence

Median (IQR) follow-up: 16 (9, 26) months†

(n=3,786/4,000)

of people with HIV had **last VL <50 c/mL**



(n=3,233/4,000)

of people with HIV had **all VL <50 c/mL**

1%

(n=43/4,000)

of people with HIV experienced CVF‡

- **High persistence on CAB+RPV LA throughout follow-up time**
  3,279 (78%) individuals were on CAB + RPV LA at the end of analysis period §

CAB + RPV LA in people with viremia

VL ≥ 50 c/mL at initiation (N=582)

- **VL ≥1,000 c/mL at BL:** 27%
- **Black:** 54%
- **Median (IQR) age:** 40 (32–51) years
- **Hispanic:** 21%
- **BMI ≥30 kg/m²:** 29%

Effectiveness*

Median (IQR) follow-up: 15 (8–26) months†

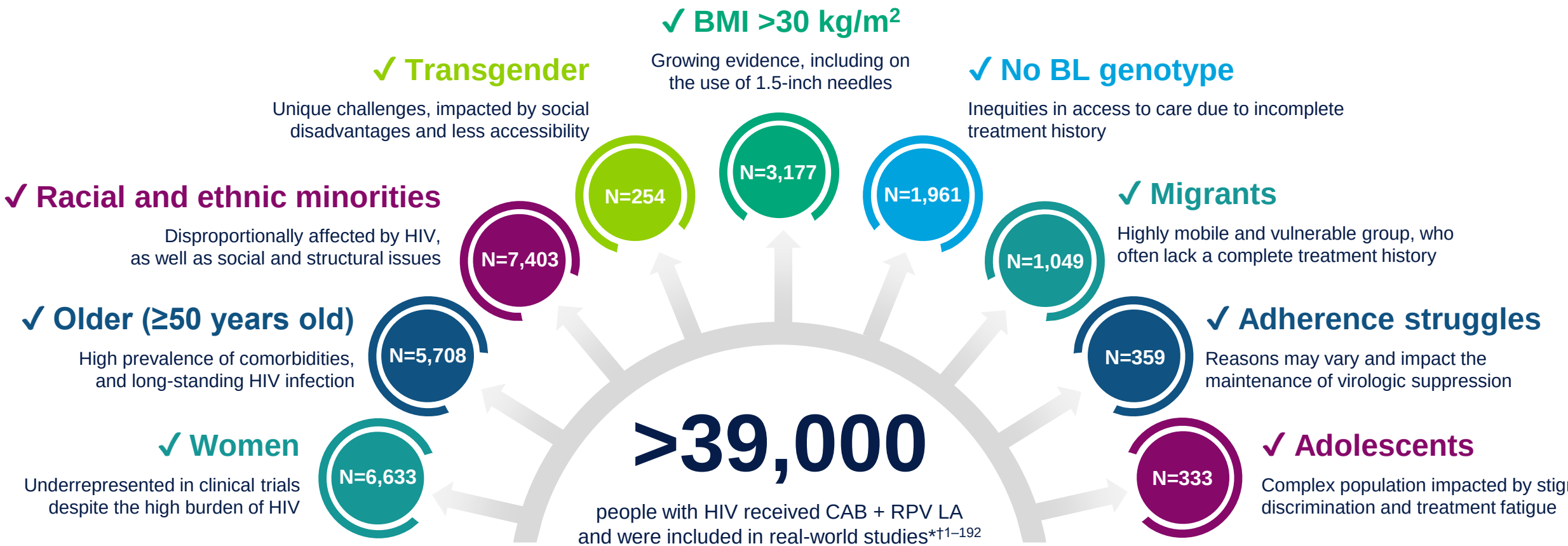
n=399/502 had **last VL <50 c/mL**

n=439/502 achieved **VL <50 c/mL**

N=7/439 experienced **CVF‡**

RWE supports the use of CAB + RPV LA in broad and diverse groups of people with HIV

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



See Clinical Benefits deck for additional subgroup data

*N=39,434. 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 viremia is outside of the labelled indication

See slide notes for references

OPERA: High effectiveness, persistence and low CVF rates on CAB+RPV LA, regardless of BMI at initiation

Study population

Demographic and clinical characteristics at CAB+RPV LA initiation (N=4,405)*

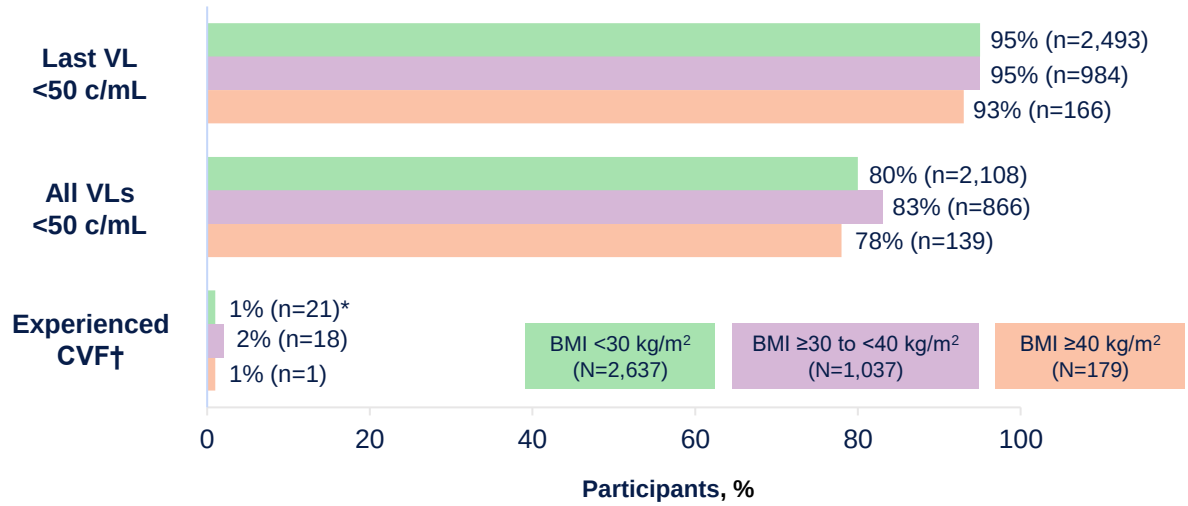
- **BMI ≥30 to <40 kg/m²:** 27% (N=1,179)
- **BMI ≥40 kg/m² :** 5% (N=201)
- **≥50 years:** 25%
- **Female:** 14%
- **Black race:** 42%
- **Hispanic:** 32%
- **Any comorbidity:** 79%

Effectiveness* and Persistence

- **High persistence on CAB+RPV LA throughout follow-up**
  3,279 (78%) of complete initiators were on CAB + RPV LA at the end of the analysis period, similar across BMI subgroups‡
  - Median follow up (IQR) was 14 (7, 23), 14 (8, 22) and 13 (7, 23) for individuals with BMI <30, 30 to <40 and ≥40 kg/m², respectively

- **High and consistent effectiveness of CAB+RPV LA across BMI groups**
  93-95% of complete initiators maintained virologic suppression (VL<50 c/mL) over follow-up §, and rates of CVF were low (1-2%)

Virologic outcomes among complete initiators with ≥1 VL during follow-up by BMI at initiation



Conference on Retroviruses and Opportunistic Infections; March 9-12, 2025; San Francisco, CA
See slide notes for footnotes

Sension M, et al. CROI 2026; Denver, CO. Poster 534

OPERA: High effectiveness and persistence on CAB+RPV LA in >5,000 people, including people with viremia

Study population and design

CAB + RPV LA in people with VL <50 c/mL at initiation (N=4,587)

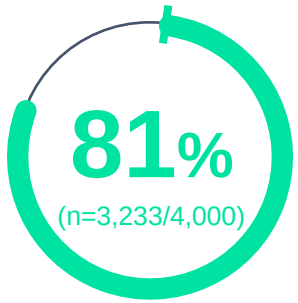
- **Median (IQR) age:** 38 (32, 50) years
- **Aged ≥50 years:** 25%
- **Black:** 43%
- **Hispanic:** 31%
- **BMI ≥30 kg/m²:** 30%

Effectiveness* and Persistence

Median (IQR) follow-up: 16 (9, 26) months†

(n=3,786/4,000)

of people with HIV had **last VL <50 c/mL**



(n=3,233/4,000)

of people with HIV had **all VL <50 c/mL**

1%

(n=43/4,000)

of people with HIV experienced CVF‡

- **High persistence on CAB+RPV LA throughout follow-up time**
  3,279 (78%) individuals were on CAB + RPV LA at the end of analysis period §

CAB + RPV LA in people with viremia

VL ≥ 50 c/mL at initiation (N=582)

- **VL ≥1,000 c/mL at BL:** 27%
- **Black:** 54%
- **Median (IQR) age:** 40 (32–51) years
- **Hispanic:** 21%
- **BMI ≥30 kg/m²:** 29%

Effectiveness*

Median (IQR) follow-up: 15 (8–26) months†

n=399/502 had **last VL <50 c/mL**

n=439/502 achieved **VL <50 c/mL**

N=7/439 experienced **CVF‡**

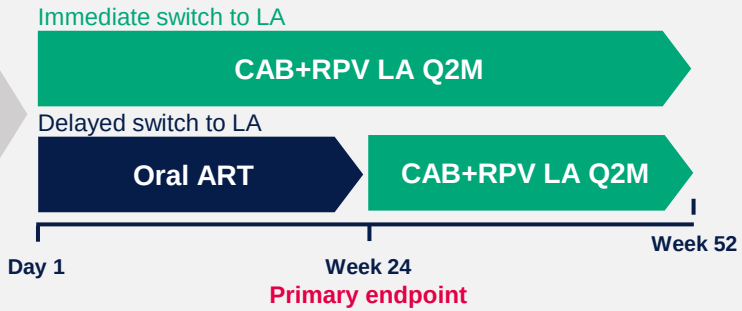
SUPLA

Switching to CAB+RPV LA showed superior efficacy vs oral ART in achieving virologic suppression among people with adherence challenges

Study design and population

Phase 3, multicenter, randomized, open-label, superiority study in adult ART-experienced PWH with suboptimal HIV suppression with oral ART

Eligibility criteria
- ART-experienced
- ≥18 years and ≥35 kg
- HIV diagnosis >12 months
- HIV-1 RNA ≥200 c/mL
- No RAMs to CAB or RPV

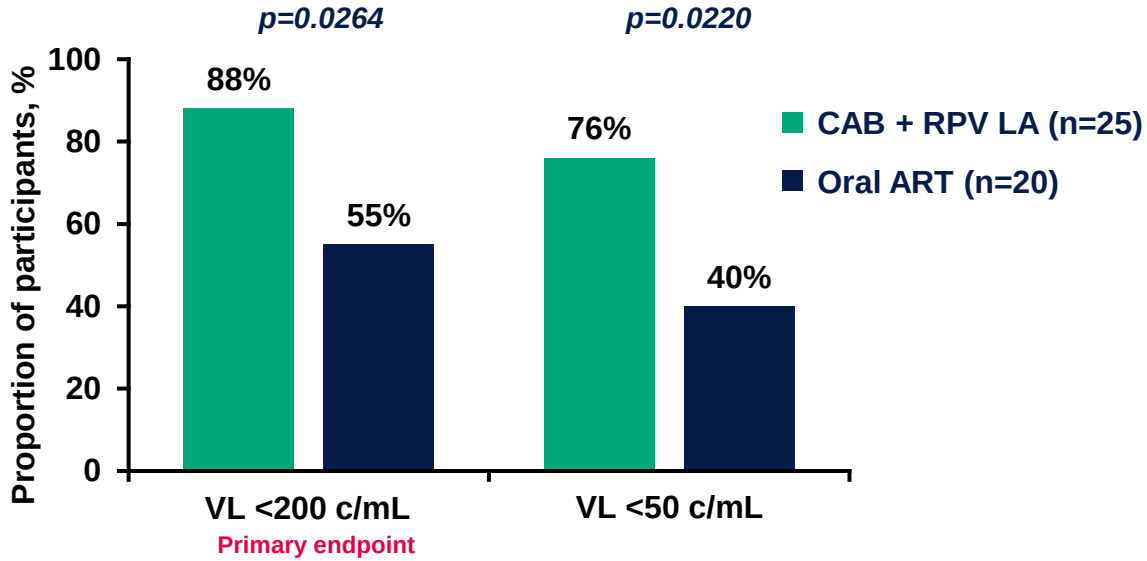


Primary endpoint

Proportion of participants achieving VL <200 c/mL, evaluated via a superiority analysis

- Of 45 participants enrolled, 25 were randomized to immediately switch to CAB+RPV LA Q2M and 20 to continue oral ART until W24 when they were switched to CAB+RPV LA up to W52
  - Median age 40 (IQR 33-49) years, 9% female, 60% substance use
  - Median BL VL 35,000 (3,630-225,000) c/mL and 27% had CD4+ <200 cells/µL
  - 33% had VL 100,000-1,000,000 and 7% had ≥ 1,000,000 c/mL at initiation
  - Most (58%) switched from BIC/FTC/TAF; 56% and 44% experienced an interrupted or irregular pattern of adherence to the last oral ART, respectively

Efficacy and Tolerability



- At W24, a significantly higher proportion of participants in the immediate LA group achieved viral suppression <200 c/mL: 88% vs 55%, p=0,026 (mITT-E)
  - Median VL at W24 was also significantly lower in the immediate LA group vs oral ART group (21.6 [0-46] vs 62 [22-21,760], p=0071)
- 2 individuals discontinued LA treatment for any reasons, and no individuals discontinued in the oral ART group

Conference on Retroviruses and Opportunistic Infections; February 22-25, 2026; Denver, CO

*mITT-E, modified intention to treat: individuals with missing data at W24 were classified as virally non-suppressed

Chen NY, et al. CROI 2026; Denver, CO. Poster 530

IMPAACT 2017 (MOCHA): High and sustained virologic suppression over 96W and strong preference for CAB+RPV LA among adolescents

Study population and demographics

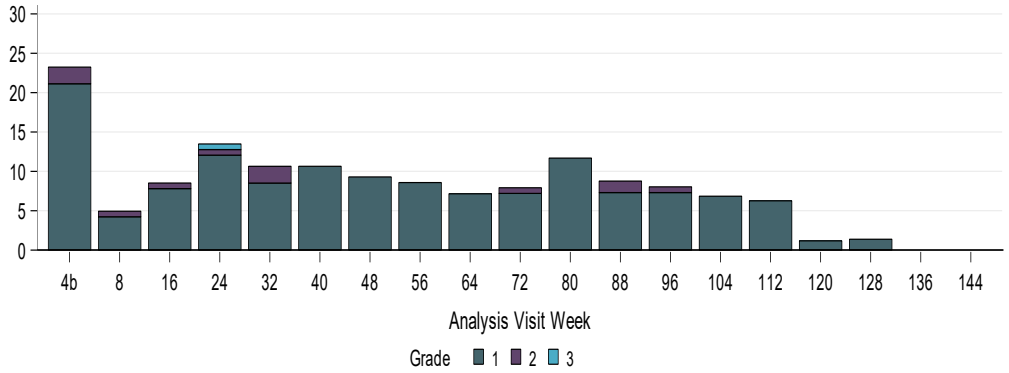
Adolescents living with HIV receiving CAB+RPV LA Q2M and stopping their oral ART (N=144)

- **Median (range) age:** 15 (12, 17) years
- **Female:** 51%
- **Black/African American:** 74%
- **Acquired HIV vertically:** 92%
- **Median (range) BMI:** 19.5 (16, 34) kg/m^2

Effectiveness, Adherence, Preference and Safety

- **Majority (94%) of participants maintained virologic suppression at W96**
- **No CVF* occurred through 96 weeks**
  11 participants experienced viral blips with at least one VL >50 c/mL during the injection phase, two of whom were >200 c/mL
- **97% of injections occurred within 8 days of the target injection date**
- **97% of participants preferred CAB+RPV LA to daily oral ART**
- **60 (42%) participants experienced a drug-related adverse event**
  2 Grade 3 AEs, and 1 Grade 4 AE†
- **52/142 (37%) participants with ≥1 injection reported ISRs**
  Majority (92%) were injection site pain assessed as Grade 1 and lasting ≤7 days

Injection site reactions by visit through end of study



Conference on Retroviruses and Opportunistic Infections; February 22-25, 2026; Denver, CO

*CVF defined as 2 consecutive VL ≥200 c/mL

†2 Grade 3 AEs: pain and abscess; 1 Grade 4 AE: anaphylaxis per site, post-injection reaction per protocol team, resolved but led to study drug discontinuation

Gaur A, et al. CROI 2026; Denver, CO. Oral presentation 155

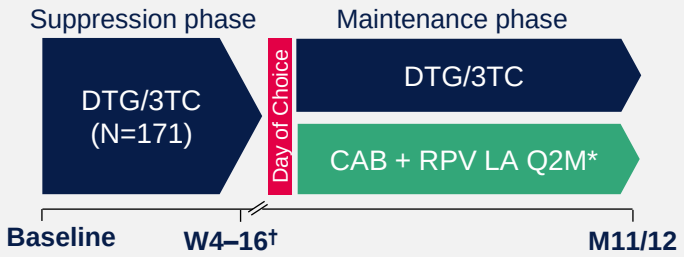
DISCUSSION

VOLITION: High efficacy in early switch to CAB + RPV LA, empowering ART-naïve people with HIV to choose their preferred treatment

CROI 2026

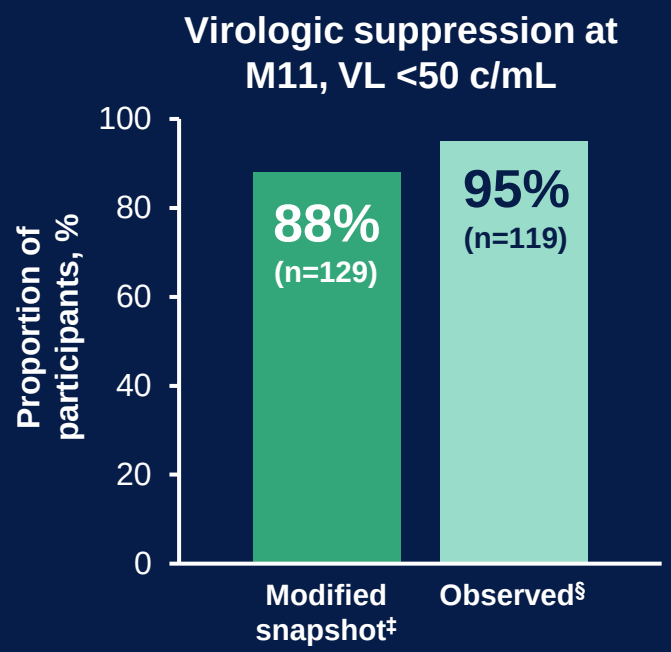
Importance of choice

Phase IIIb, multicenter, non-randomized, parallel-group, open-label study



At Day of Choice,
85% (n=129/151)
of eligible participants **chose to switch to CAB + RPV LA** vs continuing daily oral ART

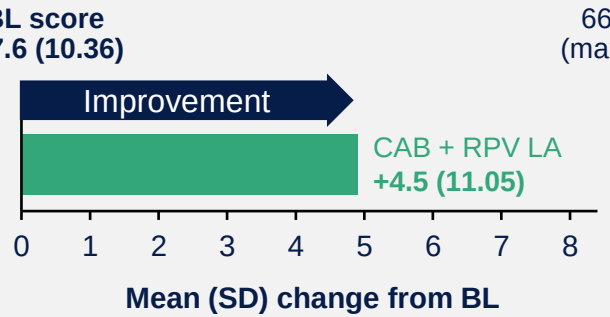
High efficacy and rare CVF with resistance

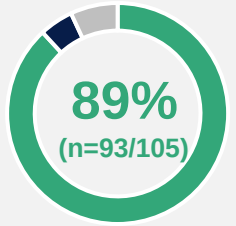


0.8% (n=1/129)
participants experienced CVF with resistance‖

High treatment satisfaction

Treatment satisfaction¶
HIVTSQs





of participants preferred to continue on CAB + RPV LA vs daily oral ART (5%)#

CAB + RPV LA was well tolerated through Month 11, with most DRAEs being ISRs. No new safety signals were identified and no AEs led to withdrawal

*A diverse population of participants was represented (n=129): 26% women, 33% Black or African American, 51% Hispanic/Latine, 21% with BMI ≥30 kg/m^2, 22% with CD4$^+$ <350 cells/mm^3; †Median time to virologic suppression (<50 c/mL) on DTG/3TC: 4.1 weeks (95% CI: 4.1, 4.3); ‡Modified snapshot: RealTime HIV-1 RNA results were prioritised over the cobas® 6800 assay when available and within the Snapshot window; §Includes only participants with available virologic data in-window; ‖Three additional participants met CVF criteria and were withdrawn, however retrospective retesting did not confirm CVF, and no RAMs were detected; ¶Mean (SD) BL HIVTSQs total score (n=127), mean (SD) change from BL to Month 11 HIVTSQs total score (n=114); #Includes 105 participants who responded to the preference questionnaire, with remaining 7% unsure. After rounding proportions total 101%

3TC, lamivudine; **BL,** baseline; **BMI,** body mass index; **DoC**, Day of Choice **DRAE,** drug-related adverse event; **DTG,** dolutegravir; **HIVTSQs,** HIV Treatment Satisfaction Questionnaire status version; **M,** Month; **Q2M,** every 2 months

RAM, resistance-associated mutation; **SD,** standard deviation; **W,** Week

Rolle CP, et al. CROI 2026. Poster 525

DISCUSSION

Kyana D. Stewart, MS, PharmD

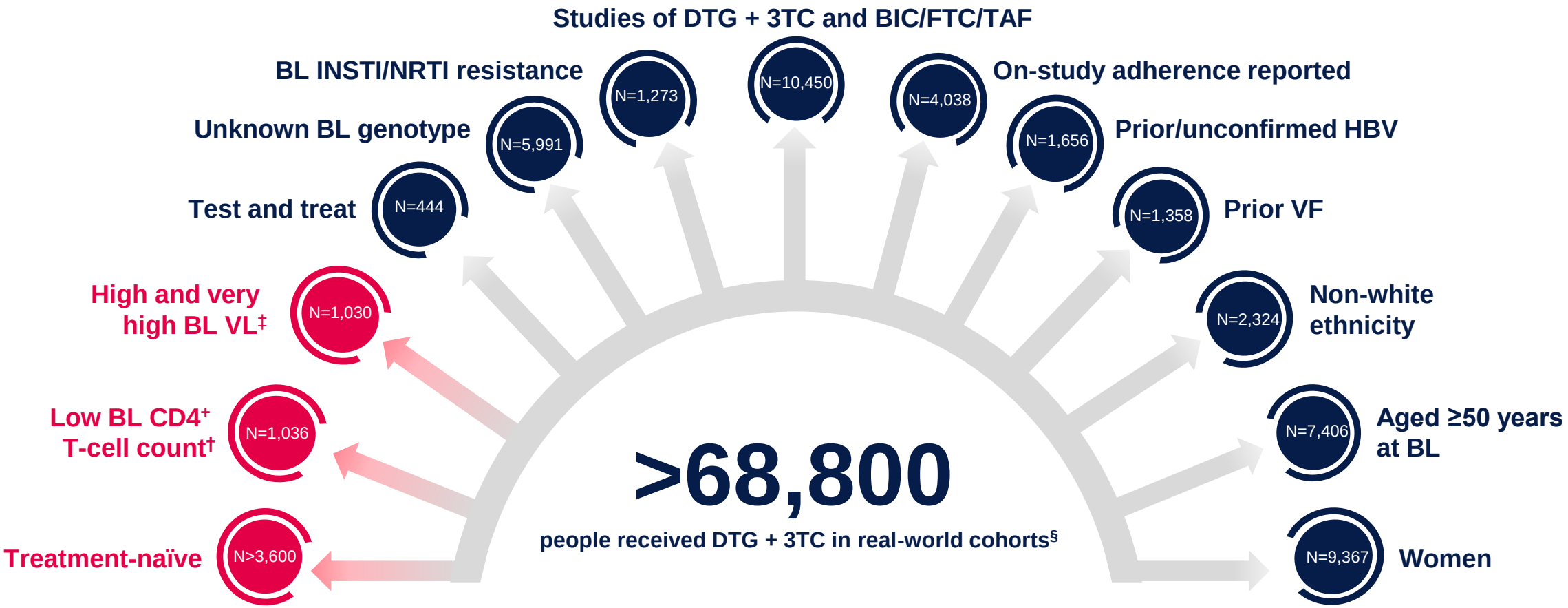
U.S. Medical Director, Oral Treatments Team
ViiV Healthcare

DOVATO

Broad and diverse populations have been included in real-world studies of DTG + 3TC*

Hi-Vis
SHINING A SPOTLIGHT ON REAL-WORLD EVIDENCE

Click for more RWE data



*Real-world studies are often not clear in reporting use of separates or FDCs. For this purpose, we refer to DTG + 3TC; †Defined as <200 cells/mL for most studies; however, some individual studies use ≤200, <350, <400 or <500 cells/mL; ‡High and very high VL defined as >100,000 and >500,000 c/mL, respectively; §Population categories are non-exhaustive and non-mutually exclusive
FDC, fixed-dose combination; **HBV,** hepatitis B virus; **NRTI,** nucleoside reverse transcriptase inhibitor

See slide notes for references

Meta-analysis: Robust efficacy for participants naïve to ART with very high VL and low CD4⁺ at baseline in Phase III/IV clinical trials

Very High VL at BL

Meta-analysis of 1,861 ART-naïve participants comparing DTG/3TC vs DTG-based 3DRs using data from **GEMINI-1/-2**, **STAT**, **DOLCE** and **D2ARLING** Phase III/IV clinical trials

Baseline demographics

n, (%)	Total participants (N=1,861)
VL ≥500,000 c/mL	114 (6)
VL ≥1,000,000 c/mL	42 (2)
CD4⁺ T-cell count <200 cells/mm³	368 (20)

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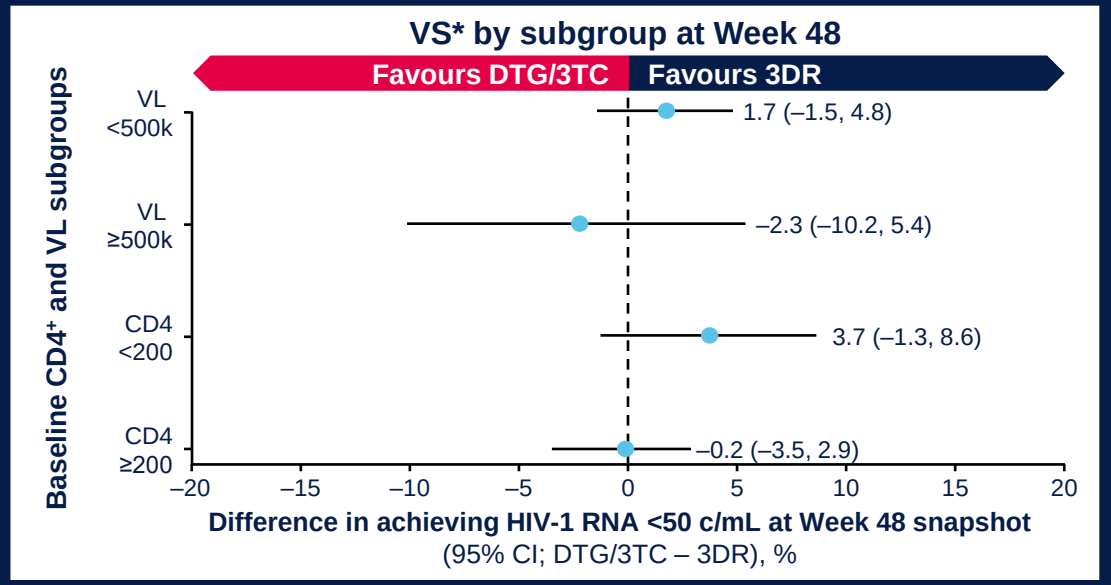
Robust efficacy through 48 weeks

DTG/3TC achieved **comparable VS rates*** to DTG-based 3DRs across baseline subgroups, including those with **very high VL** (≥500,000 c/mL; 86.7% vs 84.4%, respectively), and **low CD4⁺ T-cell count** (<200 cells/mm³; 86.3% vs 90.1%, respectively)



Safety and resistance

Both regimens were **well tolerated** with no notable differences between groups

No treatment-emergent resistance occurred through Week 48 in any study

*Proportion of participants with VL <50 c/mL at Week 48

Cahn P, et al. CROI 2026. Poster 536

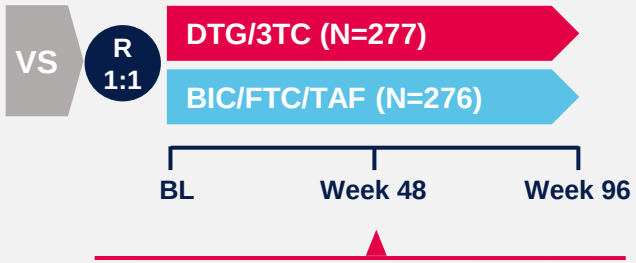
PASO DOBLE: Less weight gain and lower incidence of steatotic liver disease with DTG/3TC vs BIC/FTC/TAF

CROI 2026

Study design[1]

Phase IV study comparing **switch to DTG/3TC** or **BIC/FTC/TAF** in virologically suppressed people with HIV-1

Study design



Primary endpoint: HIV-1 RNA ≥50 c/mL
Key secondary endpoint: Weight change
Sub-studies: Omics, senescence, fat biopsies and liver steatosis

Weight gain[2]

Following switch to DTG/3TC versus BIC/FTC/TAF through 96 weeks:

Statistically significantly less weight gain (BIC/FTC/TAF had greater mean adjusted* weight gain vs DTG/3TC [95% CI]: +1.52 kg [0.74, 2.29])

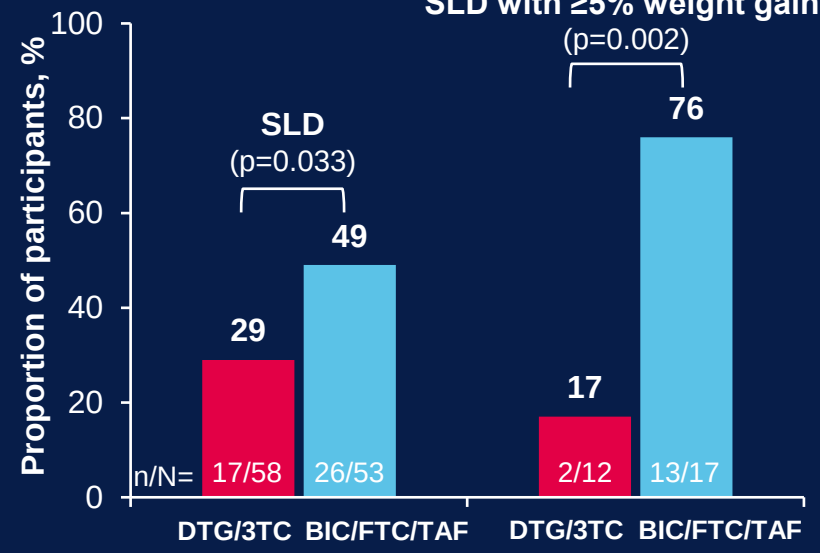
Lower odds of clinically meaningful† weight gain (>5%) (aOR* [95% CI]: 2.05 [1.37, 3.07]; p=0.001)

Steatotic liver disease‡ at Week 96[3]

Switching to DTG/3TC was associated with a **lower frequency of SLD** compared with BIC/FTC/TAF§

This difference was **more pronounced** in participants with **≥5% weight gain**

SLD at Week 96



*Adjusted by BL weight, sex, presence of TAF in previous ART, age and ethnicity; †Weight gain >5% from BL to Week 96 (>5% is a widely recognised metric for clinically meaningful weight change in adults);[4–11] ‡CAP value ≥248 dB/m
§BL characteristics were similar between treatment arms
aOR, adjusted odds ratio; **CAP,** controlled attenuation parameter; **R**, randomised; **SLD,** steatotic liver disease

1. Ryan P, et al. Lancet HIV 2025;12:e473–84; **2**. Martinez E. EACS 2025. Oral RO3.8.LB; **3.** Pineda JA, et al. CROI 2026. Poster 598
4. Williamson DA, et al. Obesity (Silver Spring) 2015;23:2319–20; **5.** Apovian CM, et al. J Clin Endocrinol Metab 2015;100:342–62
6. Magkos F, et al. Cell Metab 2016;23:591–601; **7.** Wing RR, et al. Diabetes Care 2011;34:1481–6
8. Brown JD, et al. Transl Behav Med 2016;6:339–46; **9.** Ryan DH and Yockey SR. Curr Obes Rep 2017;6:187–94
10. Milic J, et al. AIDS 2022;36:1643–53; **11.** Verkouter I, et al. J Clin Med 2019;8:1559

PASO DOBLE: Association between CAP increases and other factors

Association between SLD increase and other factors in a multivariate analysis

Variable	β (95% CI)	p-value
Age	–0.083 (–1.173, 1.006)	0.880
Sex	16.592 (–7.786, 40.969)	0.180
Assigned treatment	23.026 (–0.024, 46.075)	0.050
Baseline plasma TG	–0.181 (–360, –0.002)	0.047
Weight gain	0.940 (–1.297, 3.178)	0.406
First NRTI in prior regimen	–4.908 (–15.866, 6.049)	0.376
Second NRTI in prior regimen	–9.534 (–27.695, 8.626)	0.300

CI, confidence interval; **NRTI,** nucleoside reverse transcriptase inhibitor; **SLD,** steatotic liver disease; **TG,** triglycerides

Summary

Treatment naïve

DTG/3TC has demonstrated **robust efficacy and a high barrier to resistance across a diverse population of people who are naïve to ART**, including those with high VL and low $CD4^+$ T-cell counts

Diverse populations

The proven and durable efficacy of DTG/3TC across RCTs is supported by a large body of RWE across **>68,800 treatment-naïve and treatment-experienced people with HIV**

Differentiation

DTG/3TC demonstrated **statistically significantly less weight gain and a lower incidence of SLD** versus BIC/FTC/TAF after suppressed switch, through 96 weeks

See slide notes for references

DISCUSSION

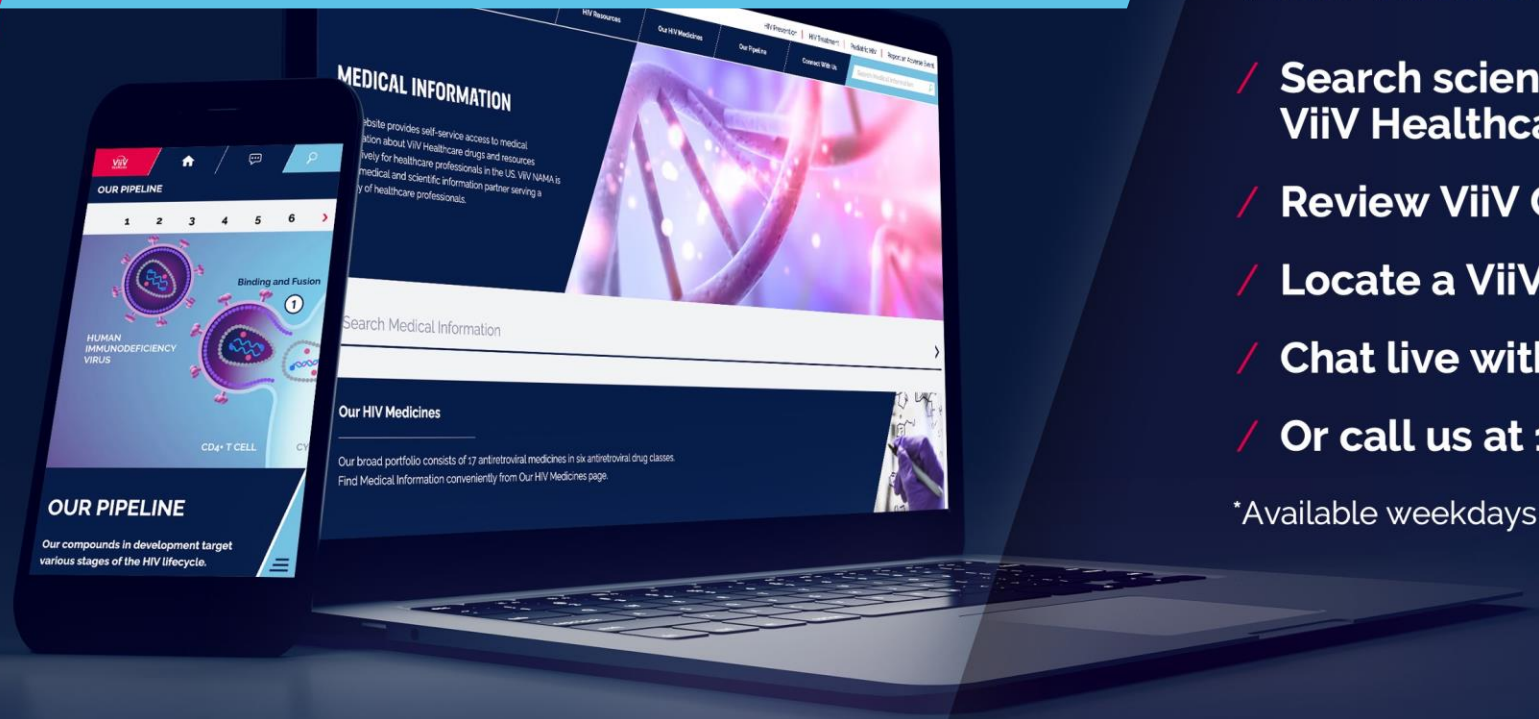
Q & A

- **Please use the Q&A function to submit comments and questions**
- **If we are unable to get to your question, we will ensure to follow up with you!**

FEEDBACK

Tell us what you think of today's program

Thank You!



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