We will begin shortly...

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Wednesday, May 27, 2026
Virtual Webinar

2026 Post CROI Apretude Conference Webinar

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Wednesday, May 27, 2026

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

Agenda

1

Real-World Effectiveness

- OPERA/TRIO
- PrEPFACTS/EBONI
- Ancillary Benefits

2

Safety & Tolerability

- CLARITY
- Use in Pregnancy and People of Child-bearing Potential

3

CAB LA PrEP Pipeline

- CAB 1600 mg (3x yearly)

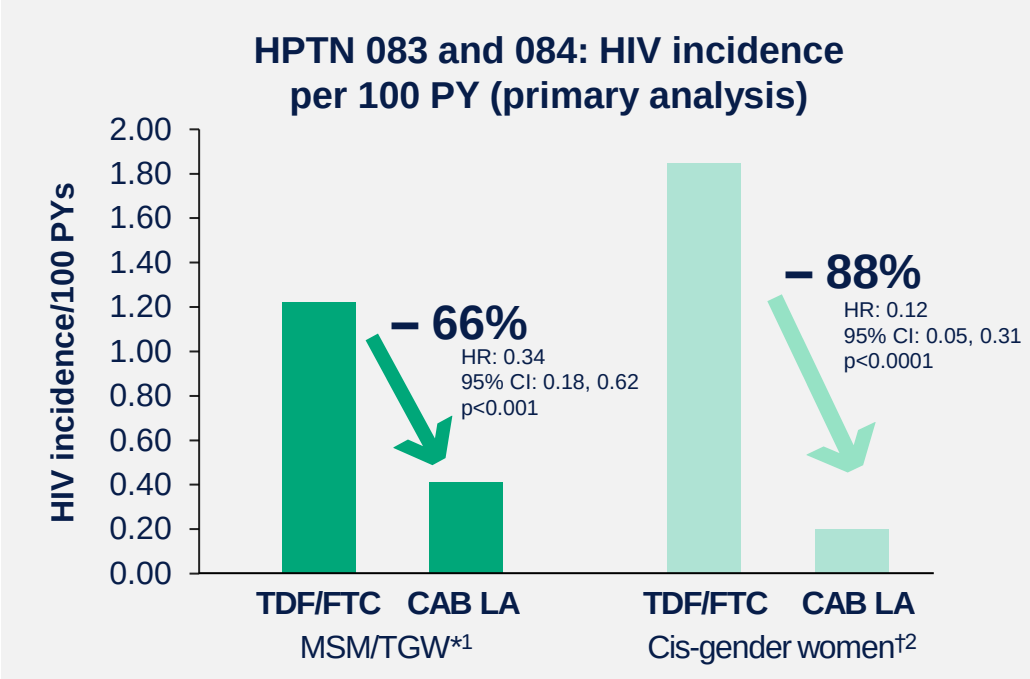
Please use the Q&A function to submit comments and questions throughout the Webinar

Kim Nezianya, PharmD, AAHIVE
US Medical Director, LAI for PrEP
ViiV Healthcare

CAB LA PrEP at CROI 2026

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]

CROI 2026

WELL TOLERATED

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

CROI 2026

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]

References and footnotes are available upon request

4+ Years of Real-World Effectiveness

OPERA, TRIO, PrEPFACTS, EBONI

CAB LA PrEP: Consistent effectiveness for HIV prevention in diverse real-world populations

	CROI 2026 OPERA[1]	CROI 2026 TRIO[2]	PrEPFACTS[3]	Howard Brown[4]	Eurosurveillance[5]	UC San Diego[6]	Kaiser Permanente[7]
Participants	N=1,748	N=1,696	N=1,202	N=270	N=265	N=187	N=180
Location	 **US** (Multicenter)	 **US** (Multicenter)	 **US** (Multicentre)	 **IL, US** (Single centre)	 **Italy** (Multicentre)	 **CA, US** (Single centre)	 **US** (Multicentre)
Population	Black: **27%** Hispanic: **29%**	Black: **28%** Hispanic: **23%**	Black: **22%** Hispanic: **18%** Asian: **3%**	Black: **25%** Hispanic: **24%**	Black: **NA** Hispanic: **NA**	Black: **3%** Hispanic: **40%**	Black: **19%** Asian: **9%** Hispanic: **34%**
Injections received	11,068	NA	5,941	Median (range): 4 (1–12)	≤6	≥1	868
Time on CAB LA PrEP	Median (IQR): 13 (9–19) months	Median (IQR): 12 (6–20) months	Median (IQR): 325 (242–423) days	NA	Median (IQR): 23 (20–28) weeks	NA	12 months
Incident sero-conversions	2[§]	2[‡]	2[†]	0[*]	0	0	0

§ Two additional HIV acquisitions were observed 4 and 6 months after CAB LA discontinuation, respectively ‡ Three total HIV seroconversions identified: 1 individual with nonreactive HIV Ab at first injection (no HIV RNA test performed); HIV RNA detected with second injection (no HIV Ab test done); two incident seroconversions †Three total HIV seroconversions identified: 1 individual started on CAB LA 5 days prior to evidence of HIV diagnosis; 2 individuals discontinued CAB LA >2 months before first evidence of HIV-1 diagnosis *One individual was identified as having HIV infection at the time of CAB LA PrEP initiation

CA, California; IL, Illinois; NA, not available; UC, University of California; US, United States

1. Hsu RK, et al. CROI 2026. Poster 979; **2.** Elion R, et al. CROI 2026. Poster 981
3. Metzner AA, et al. IDWeek 2025. Oral 574; **4.** Hazra A, et al. CROI 2024. Poster 1241
5. Moschese D, et al. Euro Surveill 2025;30:2500739
6. Turner C, et al. HIVR4P 2024. Poster 01725; **7.** Traeger M, et al. CROI 2025. Oral 191

CAB LA PrEP: Consistent effectiveness for HIV prevention across international implementation studies

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	ImPrEP[1]	SEARCH[2]	PILLAR[3]	EBONI[4]
Participants	N=1,200	N=274	N=201	N=163
Location	 **Brazil** (Multicenter)	 **Kenya, Uganda** (Multicenter)	 **CA, US** (Multicenter)	 **US** (Multicenter)
Population	Non-White: **61%**	African: **100%**	Black: **26%** Hispanic: **38%**	Black: **100%**
Injections received	5,041	NA	NA	NA
Time on CAB LA PrEP	Median (IQR): **7** (5–10) months	Median (IQR): **11** (6–11) months	**12 months**	**12 months**
Incident sero-conversions	3†	0	0	0

Additional ongoing implementation studies[4]

N=9,795*

African, Latin American, US (incl. Black and Hispanic)

Sub-Saharan Africa, Brazil, US

† Four total seroconversions identified: 1 participant had HIV-1 RNA retrospectively detected at initiation of CAB for PrEP; a second seroconversion was identified 407 days after first injection with no additional injections or HIV tests performed.
*Planned total N number for PrEP 1519, CATALYST, PrEPared to Choose, Project PrEP, LAPIS, AXIS and Mobile Men

1. Grinsztejn B, et al. CROI 2025. Oral 192; **2.** Kamya MR, et al. Lancet HIV 2024;11:e736–45
3. Khan T, et al. CROI 2025. Oral 196; **4.** Tims-Cook Z, et al. CROI 2026. Poster 1081

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

DISCUSSION

Acceptability and Tolerability of ISRs with LA Prevention

Injection-Site Reactions More Common and Bothersome With Single Doses of Lenacapavir vs Cabotegravir (CLARITY)

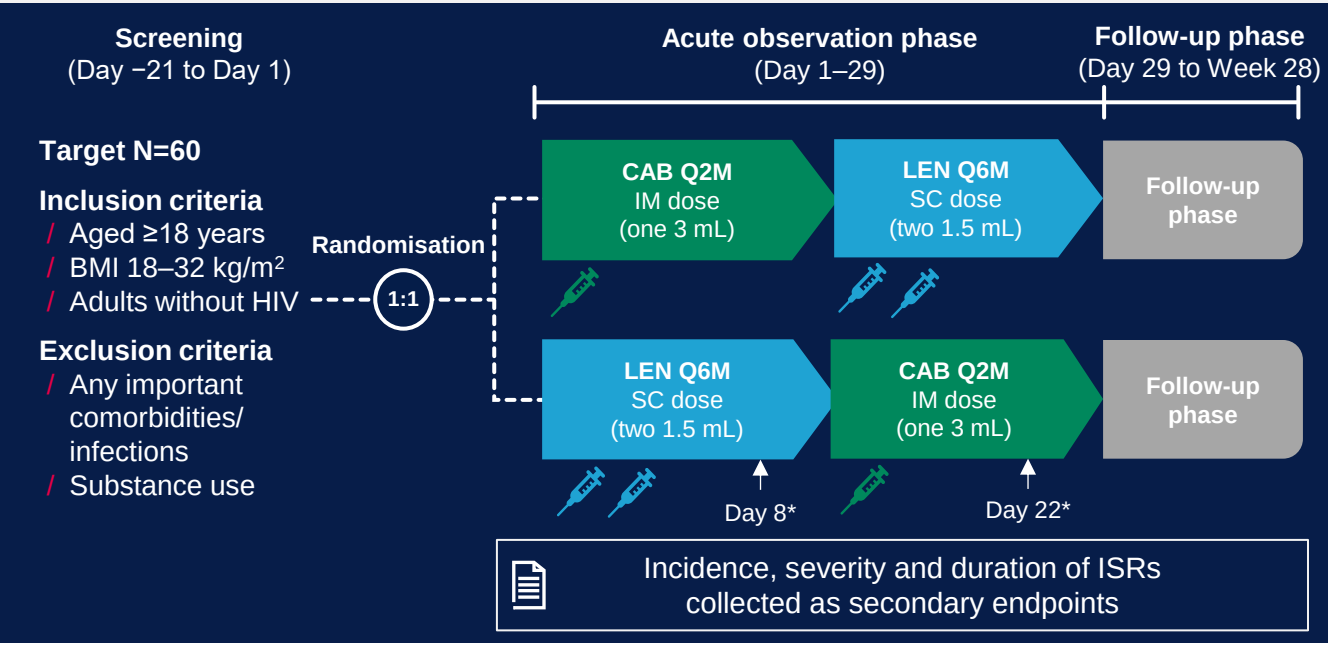
CAB LA PrEP injections were more acceptable and preferable to participants than LEN LA injections after one dose of each medicine

CLARITY study

EACS 2025

Phase I, open-label, randomized crossover study (CAB IM and LEN SC, one dose each) in 63 adults without HIV (single-center 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%

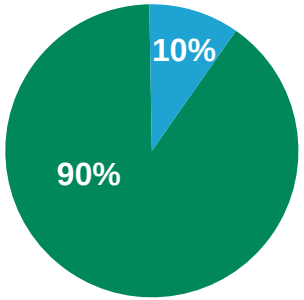
"totally or very acceptable" (29/60)‡

Participant-reported Preference for Injections

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

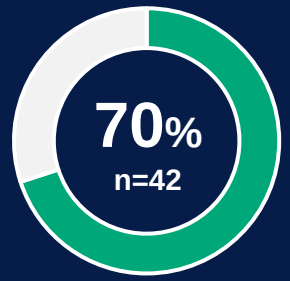
Open-label, randomized crossover study comparing one dose of either CAB LA PrEP or LEN PrEP in adult participants (N=63)

CAB LA PrEP
n=61

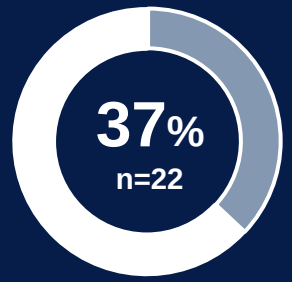
LEN PrEP
n=62

- **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, Indurations, and Swelling Events*

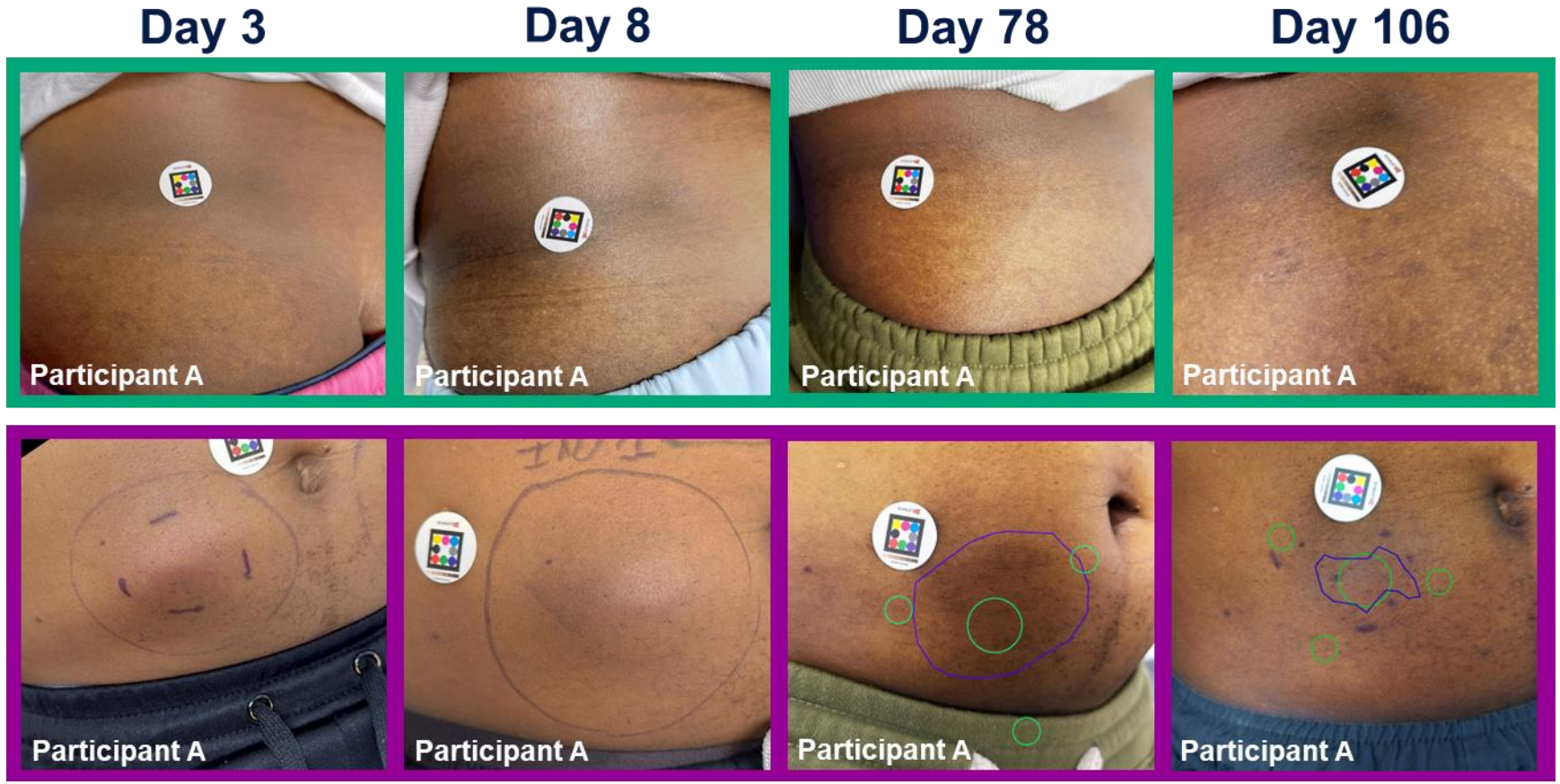
	CAB LA (n=61)†	LEN LA (n=62)†
Nodules, n	**35**	**124**
Nodules unresolved by Day 190, n (%)	4 (11)	120 (97)
Duration of nodules, median (range), days‡	64.0 (7–128)	196.5 (2–224)
Nodules visible at anytime, n (%)	5 (14)	78 (63)
Indurations, n	**12**	**94**
Indurations unresolved by Day 190, n (%)	0 (0)	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)
Swelling, n	**22**	**68**
Swelling unresolved by Day 190, n (%)	0 (0)	0 (0)
Duration of swelling, median (range) days	5.0 (2-36)	7.0 (2-202)
Swelling visible at any time, n (%)	17 (77)	59 (87)

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

Injection site reactions from one participant following a single injection of CAB LA (IM) and LEN LA (SC)



The nodules reported in Participant A correspond to the median nodule diameters observed for CAB LA (2.0 cm) and LEN LA (4.1 cm).

Fox D, et al. CROI 2026. Poster 988

DISCUSSION

Use of CAB LA PrEP in Pregnancy

HPTN 084 OLE, Antiretroviral Pregnancy Registry, CAB PK/PopPK

Cabotegravir LA Pregnancy Safety

- There are insufficient human data on the use of APRETUDE during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage. Discuss the benefit-risk of using APRETUDE with individuals of childbearing potential or during pregnancy.
- Cabotegravir use in pregnant individuals has not been evaluated. APRETUDE should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus..
- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to APRETUDE during pregnancy. Healthcare providers are encouraged to register individuals by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

The dataset of pregnancy outcomes in people using CAB LA PrEP is expanding

Existing pregnancy data in HPTN 084[1]

- During the HPTN 084 OLE phase, 325 pregnancies were included in the safety analysis (212 with active CAB LA use)
- Maternal and infant outcomes were aligned with background rates during pregnancy

New pregnancy data from the ARV Pregnancy Registry (APR)[2]

Prospective, international exposure-registration cohort study

42 reported pregnancies with exposure to CAB†

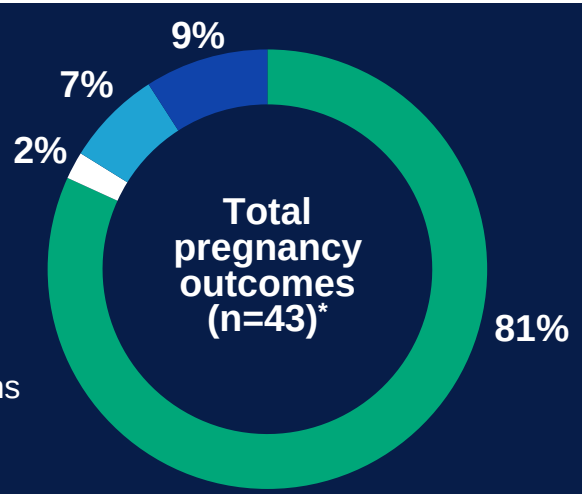
- **CAB LA PrEP, n=14**
- **CAB Treatment, n=28**

31 July 2024

- APR data were analysed to determine pregnancy and neonatal outcomes after being exposed to CAB
- Evaluates early warning signs of major teratogenic effects of ARV treatment during pregnancy

Outcomes[2]

- Live births
- Stillbirths
- Spontaneous abortions
- Induced abortions



1 birth defect reported among live births (congenital ptosis)

5 preterm births‡

6 with low birth weight‡§

No significant safety concerns were observed

Healthcare providers should discuss the benefit-risk of using APRETUDE with individuals of childbearing potential or during pregnancy. CAB LA should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus[3]

*Including one twin birth; †N=41 for pregnancies where route of administration was known; 7.3% exposed to oral CAB and 92.7% exposed to CAB LA
‡Singleton births only (n=33); §Low birth weight defined as <2,500 grams
APR, the antiretroviral pregnancy registry; **ARV,** antiretroviral

1. Delany-Moretlwe S, et al. AIDS 2024. Oral SY2503
2. Vannappagari V, et al. IAS 2025. Abstract OAB0402
3. Apretude US PI. April 20254;

HPTN 084: Unbound CAB PK and PopPK data support the use of CAB LA maintenance and initiation during pregnancy

Existing pregnancy data

Maternal and infant outcomes[1,2]

- Maternal and infant outcomes for **325 pregnancies** aligned with background rates in HPTN 084
- An additional **42 pregnancies** were reported in the ARV Pregnancy Registry (n=32 CAB treatment; n=10 CAB LA PrEP)
  - No significant safety concerns were observed

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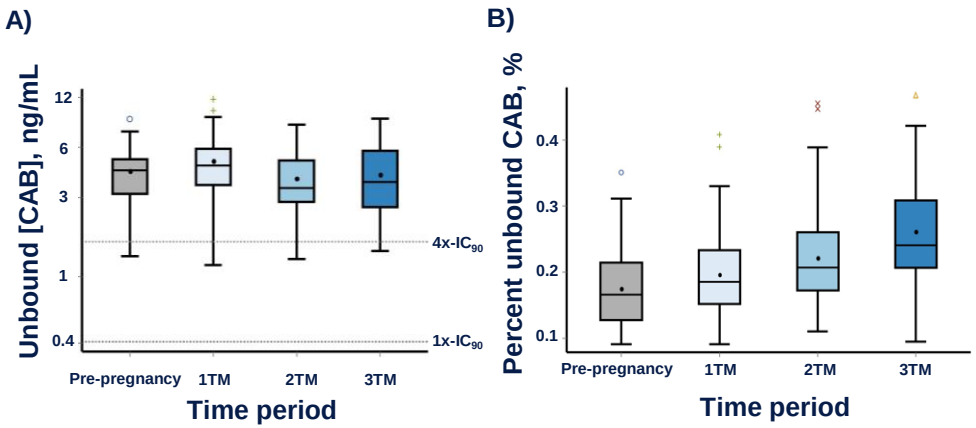
75 individuals without HIV who received ≥4 CAB LA injections both in the year prior to and during pregnancy were evaluated (May 17,2022-Sept 13, 2023)[3]

(A) Geometric mean unbound Cτ CAB concentrations*† and (B) arithmetic mean percent unbound CAB during pre-pregnancy, 1TM, 2TM and 3TM.† 1x-IC_{90}: 0.407 ng/mL; 4x-IC_{90}: 1.627 ng/mL



While declines in total CAB concentrations throughout pregnancy were observed, **the percent unbound CAB increased through the third trimester,** indicating an **increase in bioavailable drug**

CROI 2026

An established CAB PopPK model was adapted to describe total CAB concentrations (N=2,679) in 75 women from HPTN 084 who continued CAB LA PrEP during pregnancy[4]

Using conservative simulation criteria, **pregnancy reduced** total **CAB exposures** relative to the pre-pregnancy period

However, unbound CAB **concentrations increased** with **subsequent dosing** following initiation during pregnancy

Estimated unbound CAB Cτ remained **>4x IC_{90} in >90%** of women **throughout pregnancy** when **continuing** CAB LA and remained >IC_{90} following **initiation during pregnancy**

These PopPK data **further support that CAB LA PrEP** can be **initiated or continued** during **pregnancy** at the standard regimen

*Assay lower limit of quantification (0.05 ng/mL) and the 4x PA-IC_{90} (1.627 ng/mL) are noted by dashed lines
†Black dots indicate the overall mean of geometric (A) and arithmetic mean (B)
Cτ, trough concentration; **IC_{90},** 90% maximal inhibitory concentration; **OLE,** open-label extension; **PA- IC_{90},** protein-adjusted IC_{90}
PopPK, population pharmacokinetics; **TM,** trimester

1. Delany-Moretlwe S, et al. AIDS 2024. Oral SY2503; **2.** Vannappagari V, et al. IAS 2025. Oral OAB0402
3. Marzinke MA, et al. CROI 2026. Poster 789; **4.** Ford SL, et al. CROI 2026. Poster 790

DISCUSSION

CAB LA Prevention Pipeline

CAB 1600 mg (3x yearly)

ViiV PIPELINE

CAB-ULA

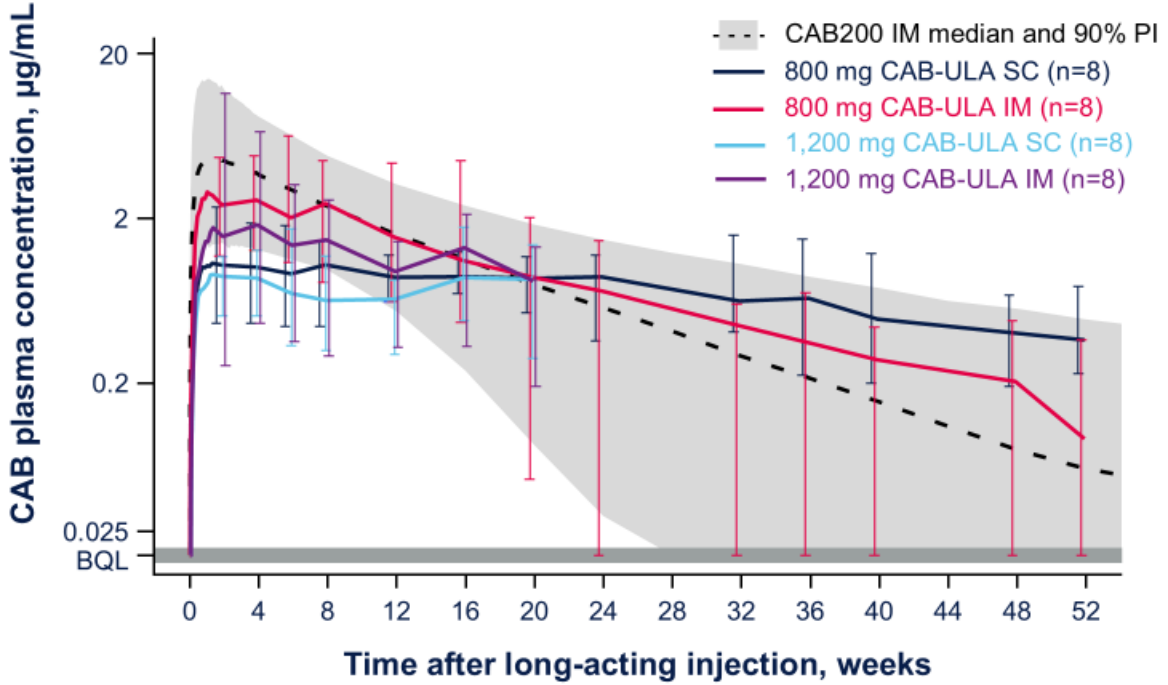
INSTIs at the core

CAB-ULA exhibits a PK profile that supports dosing 3 times a year and demonstrates favourable tolerability and safety[1]

A new CAB-ULA formulation was administered SC or IM in an open-label, single-dose, dose-escalation Phase I study[1]

- CAB-ULA exhibited **slower absorption and longer $t_{1/2}$** than the CAB200 IM (currently approved CAB formulation),[2] with **flatter PK profiles**[1]
- **CAB-ULA $t_{1/2}$** for **SC** and **IM** was predicted to **be >6x and >2x the $t_{1/2}$ of CAB200 IM**, respectively*[1,2]
- **CAB-ULA IM was better tolerated than SC** and was **comparable to the currently approved CAB200 IM ISR** profile,[2] despite higher single doses of CAB-ULA[1]

Observed median and range (error bar) dose-normalised to 1,600 mg†[1]



*Current follow-up time is insufficient to calculate final $t_{1/2}$ value for CAB-ULA[1]
†Error bars before Week 2 are not displayed for visibility[1]
BQL, below quantification limit of 0.025 µg/mL; **IM**, intramuscular; **ISR**, injection-site reaction
PI, prediction interval; **PK**, pharmacokinetics; **SC**, subcutaneous; $t_{1/2}$, terminal half-life

1. Han K, et al. CROI 2024. Oral presentation 130
2. Vocabria EU SmPC, April 2025

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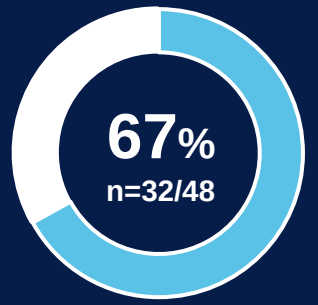
Comparison of predicted exposures after CAB ULA 1,600 mg Q4M vs CAB LA 600 mg Q2M through 16 weeks

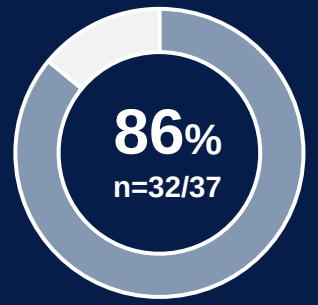
Plasma concentrations observed from a single dose of CAB ULA Q4M (1,600 mg) were:

- 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

DISCUSSION

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

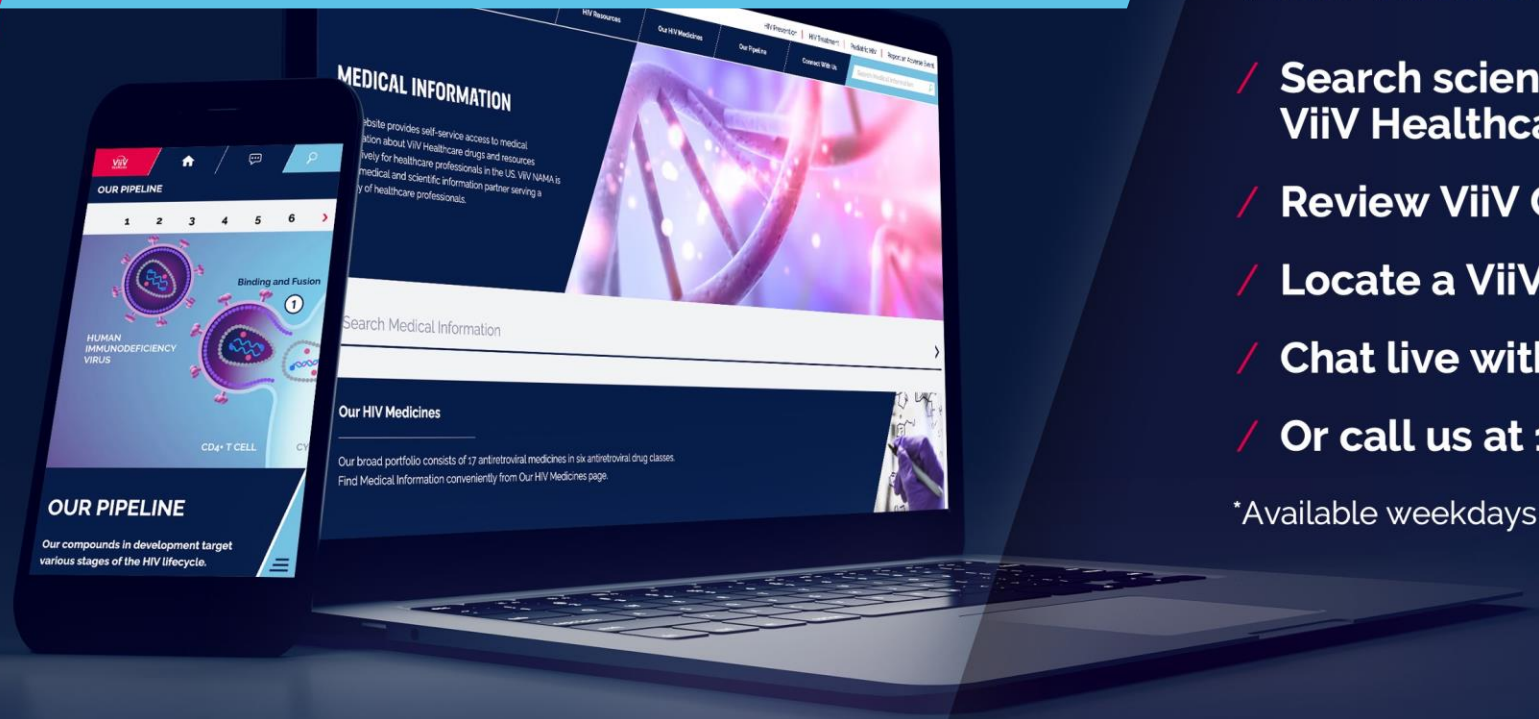
Q & A

- **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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