Welcome to the 2025 Post Fall Conference Webinar

We will begin shortly...

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Wednesday, November 12, 2025
Virtual Webinar: Zoom

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2025 Post Fall Conference Webinar

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Wednesday, November 12

Agenda

November 12 • 7:00 - 8:15 PM ET

1

Cabenuva

- OPERA and RELATIVITY: Large RW cohorts
- RWE Meta analysis
- Use in people with organ dysfunction
- PREFER LA: use in viremia

2

Apretude

- CLARITY: injection experience
- VOLITION: missed PrEP opportunities
- OPERA/EBONI: benefits of regular clinic visits

3

Dovato

- DOLCE: outcomes stratified by VL at initiation in naïve individuals

4

Pipeline

- bNAbs: N6LS

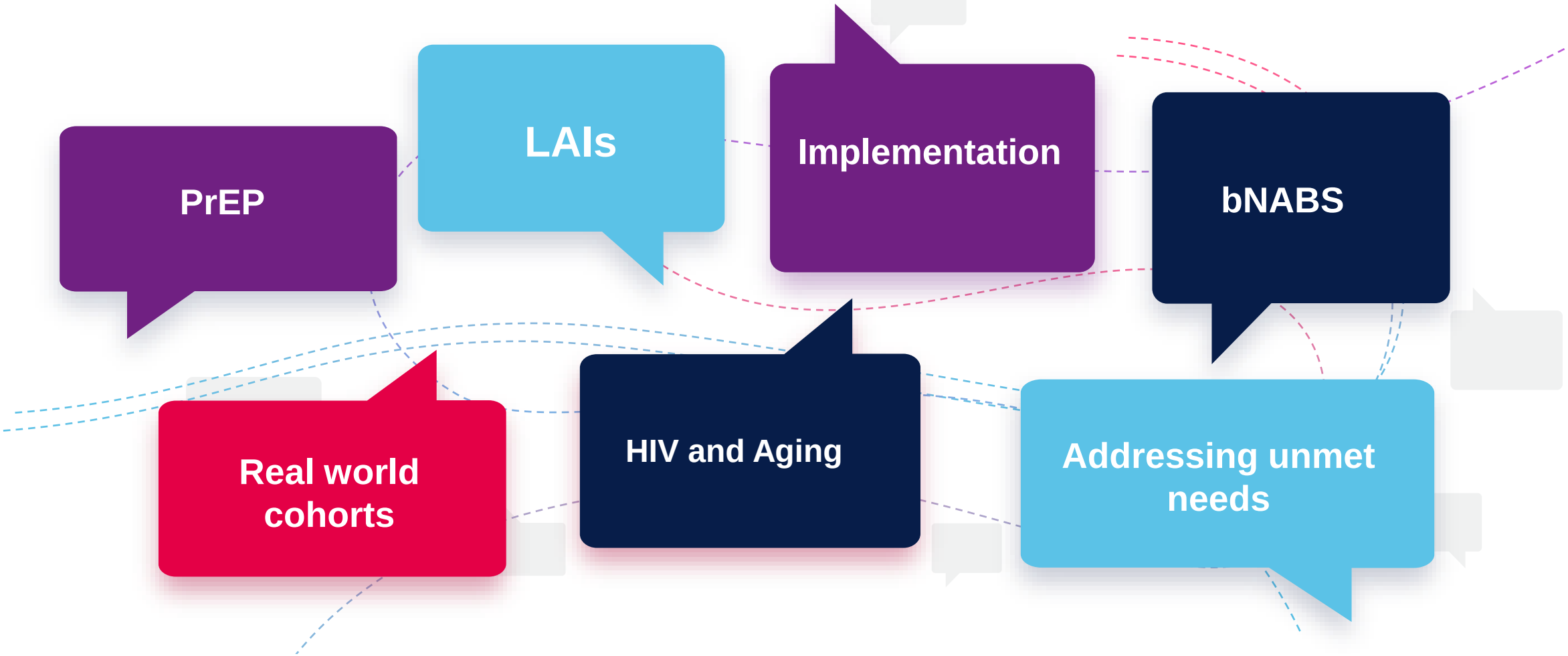
- **Please use the Q&A function to submit comments and questions throughout the Webinar**

ID Week 25

EACS 2025

The person depicted in this photo is a model, for illustrative purposes only.

Buzz at Fall Conferences 2025



Cabenuva

Elizabeth Moore, PhD, FNP-BC, ACRN
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High effectiveness and low rates of VF with resistance in virally suppressed people with HIV across real-world cohorts

	IDW 2025	EACS 2025	EACS 2025	EACS 2025	EACS 2025
	OPERA[1]	**Hospital Clínic**[2]	**ATHENA**[3]	**Fofana et al**[4]	**Dat'AIDS**[5]
	N=4,000 Median follow-up: 14 months (IQR: 7–23) On-treatment analysis	N=461 52 Weeks On-treatment analysis	N=585 1.9 years (IQR: 1.5 – 2.4)	N=1,441 At least 6 months	N=2,196 Month 13 (IQR: 7 – 19)
Virologically suppressed†	**95%**	**99%**	**NR**	**NR**	**NR**
VF‡	**1%** (n=43)	**1.7%** (n=8)*	**2.4%** (n=11)	**2.6%** (n=37)**	**1.9%** (n=42)
VF with resistance	**NR**	**NR**	**1.7%** (n=10)	**0.9%** (n=13)	**0.6%** (n=13)¶

Real-world cohorts presented at EACS, reporting both virologic suppression and VF, and with the highest number of people with HIV (majority virally suppressed at initiation). See slide notes for footnotes and abbreviations

1. Sension M, et al. IDW 2025. P-371; **2.** González-Cordón A, et al. EACS 2025. eP102
3. Wit F, et al. EACS 2025. eP072**; 4.** Fofana D, et al. EACS 2025. eP159; **5.** Deschanvres C, et al. EACS 2025. eP124

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

Study population and design[1]

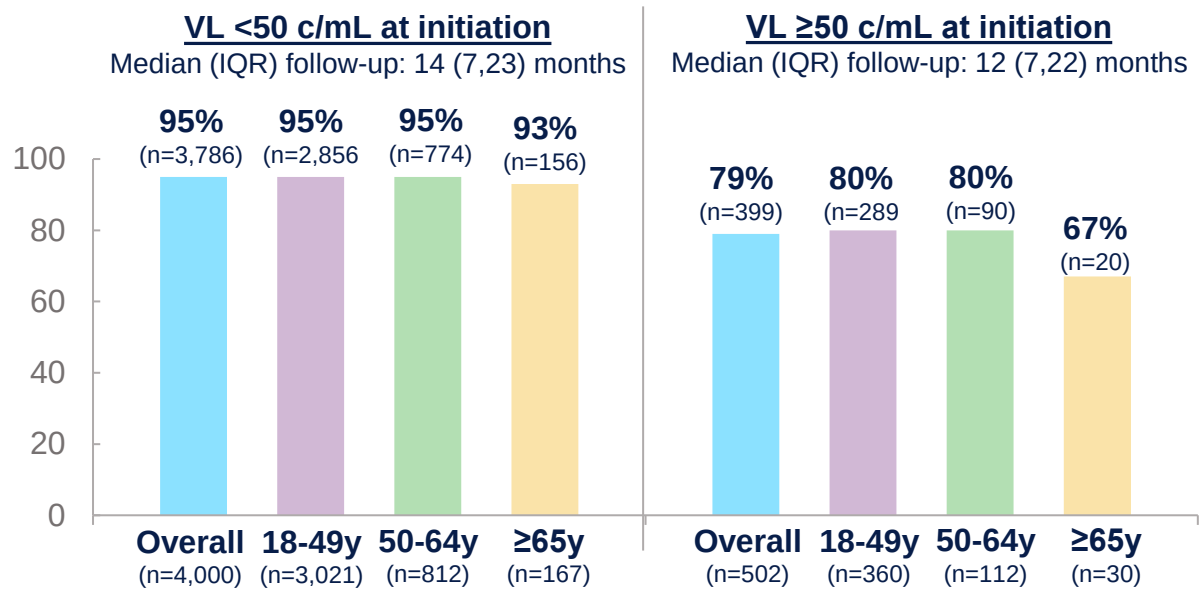
Demographic and clinical characteristics at CAB+RPV LA initiation (N=5,264)*

- **VL <50 c/mL:** 87%
- **VL ≥50 c/mL:** 11%
- **Median (IQR) age:** 38 (32, 50) years
- **Female:** 16%
- **Black race:** 44%
- **Switch from INSTI:** 76%

Effectiveness & Persistence

- The **majority** (**79%**, 3,731/4,748) of complete initiators alive and in care at time of analysis **remained on CAB+RPV LA**, and those aged ≥50 years had slightly longer cumulative months on CAB+RPV LA than those aged 18-49‡
- **VL <50 c/mL at initiation: most (93-95%) remained suppressed at last VL across age groups and CVF was rare (1%)**, with no individuals aged ≥65 years experiencing CVF
- **VL ≥50 c/mL at initiation: virologic suppression at last measure ranged from 67-80%**. Among those who suppressed (n=355), **CVF was rare (2%)**, with no individuals aged 50-64 years experiencing CVF

Virologic suppression (VL <50 c/mL) among complete initiators with ≥1 follow-up VL



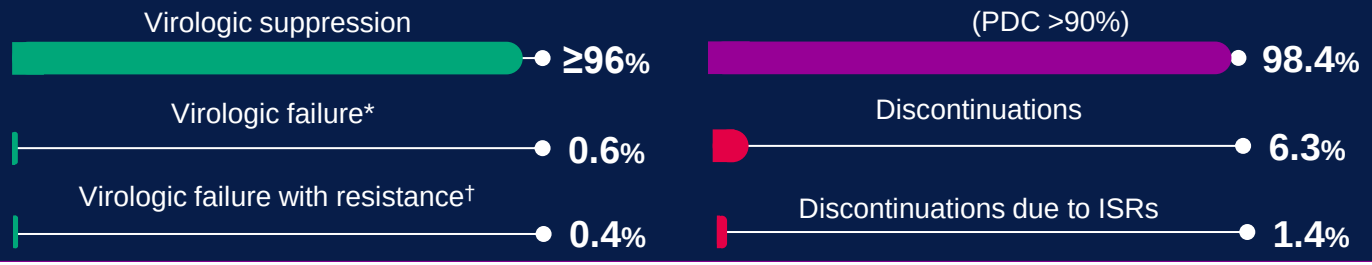
RELATIVITY: Large real-world cohort shows CAB + RPV LA is highly effective in diverse groups of people with HIV

RELATIVITY (N=3,146)[1]

Multicenter, retrospective and prospective study in virologically suppressed people with HIV (Spain)

- **Median (IQR) age:** 45 (37–54) years
- **Median (IQR) time on ART:** 9 (5–15) years
- **Previous VF:** 3.5%

Median (IQR) follow-up: 13.8 (8.8–19.1) months



RELATIVITY (subgroups)[2–8‡]

	Virologic suppression	Virologic failure	D/C due to ISRs	Adherence (PDC ≥90%)
Women (N=477)[2]		1.3%	2.1%	
Transgender women (N=18)[3]	100%	0%	5.6%	
Migrants (N=967)[4]		1.1%	2.0%	98.6%
Older (≥60 years old) (N=370)[5]	≥95%	0.3%	1.4%	99.4%
BMI ≥30 kg/m^2 (N=362)[6]		1.1%	1.9%	≥95%
Perinatally acquired HIV (N=28)[7]		3.6%	0%	
Pre-existing K103N (N=44)[8]	91%	2.3%		

*Virologic failure defined as two HIV RNA >200 c/mL or one >500 c/mL leading to discontinuation
†NNRTI RAMs: 7/3,146 (0.2%); INSTI RAMs: 8/3,146 (0.3%); ‡Some outcomes data were not available for all subgroups
PDC, proportion of days covered

1. Buzón-Martín L, et al. J Antimicrob Chemother. 2025:dkaf389; **2.** Galindo Puerto MJ, et al. EACS 2025. Oral RO3.7l **3.** Díaz-de Santiago A, et al. EACS 2025. Poster eP480; **4.** Llenas-García J, et al. EACS 2025. Poster MeP21.6; **5.** Buzón Martín L. IDWeek 2025. Oral 393 **6.**Troya J, et al. IDWeek 2025. Poster 358; **7.** Bernardino J, et al. EACS 2025. Oral 2.2; **8.** Martín Carbonero L, et al. EACS 2025. Poster eP078

CAB+RPV LA RWE Meta-analysis: High effectiveness and adherence to injections, and low rates of VF with resistance and discontinuation (1/2)

Study design, population and results

- The meta-analysis included 27 studies, with 7,687 virologically suppressed (HIV-1 RNA <50 copies/mL) individuals receiving CAB+RPV LA across 9 countries
  - Studies were identified through a systematic literature review of congress abstracts and articles published between January 2020 and March 2025
  - Due to differences in endpoint definitions and time points used, the number of studies included for each endpoint varied

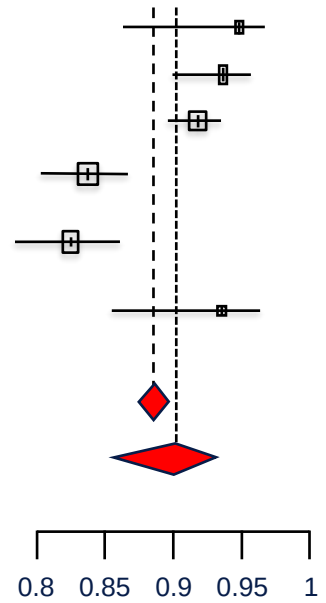
Results

- At Month 12, the **estimated proportion of people with HIV with virological suppression, and adherence to injections was high:**
  - **Virologic suppression**: estimated **93.4%** (95% CI 88.7–96.9)
  - **Adherence to injections:** estimated **95.1%** (95% CI 89.3–98.7). N=4,292 injections across 4 studies

Virologic suppression* at M12

Study	Time point	Events, n	Total, N	Viral suppression at M12*	95% CI	Weight, fixed (%)	Weight, random (%)
Spampinato et al. 2024	Week 48	50	51	0.980	[0.896; 1.000]	3.0	12.7
Schneider et al. 2024	Month 12	181	187	0.968	[0.931; 0.988]	11.0	17.3
Sension et al. 2025	Month 12	511	538	0.950	[0.928; 0.967]	31.5	19.0
Sax et al. 2025	Month 12	452	520	0.869	[0.837; 0.897]	30.4	19.0
Jonsson–Oldenbüttel et al. 2024	Month 12	301	351	0.858	[0.817; 0.892]	20.5	18.5
Haser et al. 2024	Month 12	59	61	0.967	[0.887; 0.996]	3.6	13.5
Fixed effects model				**0.918**	**[0.904; 0.930]**	**100.0**	–
Random effects model				**0.934**	**[0.887; 0.969]**	–	**100.0**

Heterogeneity: I^2=89.6%, τ^2=0.0084, p<0.0001



*Virologic suppression defined as VL <50 c/mL in these 6 studies.

20th European AIDS Conference; October 15-18, 2025; Paris, France

Results presented reflect estimates calculated using a random-effects model where the model allowedd for variation between studies

CAB+RPV LA RWE Meta-analysis: High effectiveness and adherence to injections, and low rates of VF with resistance and discontinuation (2/2)

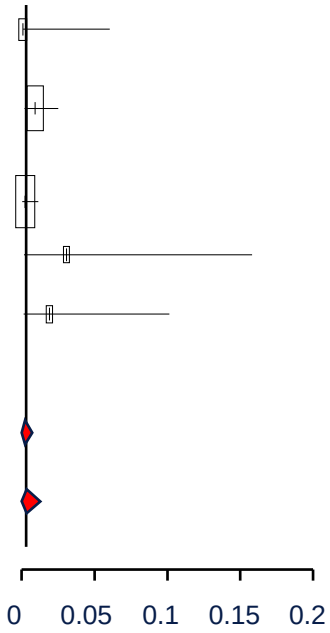
Results (cont.)

- **The estimated proportion of virologic failure and virologic failure with resistance was low**:
  - **Virologic failure:** estimated **1.2%** (95% CI 0.6–2.0); N=1,269 across 8 studies
  - **Virologic failure with resistance:** estimated **0.3%** (95% CI 0.0–1.2)
- **For CAB+RPV LA, the estimated proportion of discontinuation due to any reason was infrequent and the discontinuation due to ISR was low:**
  - **Discontinuation due to any reason:** estimated **7.3%** (95% CI 4.4–10.9); N=1,361 across 10 studies
  - **Discontinuation due to ISR:** estimated **2.6%** (95% CI 1.5–3.9); N=758 across 4 studies

Virologic failure with resistance at M12

Study	Time point	Events, n	Total, N	VF at M12	95% CI	Weight, fixed (%)	Weight, random (%)
John et al. 2024	Month 12	0	60	0.000	[0.000; 0.060]	6.0	10.1
Jonsson–Oldenbüttel et al. 2024	Month 12	3	351	0.009	[0.002; 0.025]	35.0	34.3
Gagliardini et al. 2024	Year 1	1	506	0.002	[0.000; 0.011]	50.4	40.5
Kirk et al. 2024	Month 12	1	33	0.030	[0.001; 0.158]	3.3	6.0
Iannone et al. 2025	Month 12	1	53	0.019	[0.000; 0.101]	5.3	9.1
Fixed effects model				**0.001**	**[0.000; 0.007]**	**100.0**	–
Random effects model				**0.003**	**[0.000; 0.012]**	–	**100.0**

Heterogeneity: I^2=30.7%, t^2=0.0007, p=0.2171



- Sensitivity analyses showed the estimated proportions were consistent for all endpoints when pooling studies reporting outcomes between Months 9 and 15 with consistent outcome definitions and/or pooling all studies between Months 9 and 15 regardless of outcome definition

CAB + RPV LA: RWE supports the consistent high effectiveness and low rates of virologic failure with resistance

Meta-analysis of published RWE[1]

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

0.3% resistance at failure†
with overall low virologic failure rate (1.2%)

95% injections administered on time‡
within the ±7-day dosing window

7% discontinuations for any reason§
with 2.6% ISR-related

Results presented in the meta-analysis reflect estimates calculated using a random-effects model.
Number of studies included for each endpoint varied due to differing timepoints and endpoint definitions.
Please see slide notes for additional details, footnotes and references.

High effectiveness in large real-world studies‖ of up to 2 years[2,3]

IDW 2025

OPERA[2]
N=4,000
Median follow-up:
16 months (IQR 9, 26)¥

RELATIVITY[3]
N=3,146
Median follow-up:
13.8 months (IQR 8.8-19.1)

Virologic suppression¶	**95%**	**≥96%** through month 23
VF#	**1%** (n=43)	**0.6%** (n=20)
VF with resistance	**NR**	**0.4%** (n=10)

1. Orkin et al. EACS 2025. Poster eP103
2. Sension M, et al. IDWeek 2025. Poster P-371; 3. Buzón-Martín L, et al. J Antimicrob Chemother. 2025:dkaf389

CAB+RPV LA: Real-world use in people with organ dysfunction

People with severe renal impairment

CAPRI[1]

US, 48 Weeks

Study Design: Phase IV clinical study (2 centers)

- 12 individuals with CKD stage 4/5 (CrCl <30 mL/min), of which 6 were on hemodialysis

Key results

- **All participants remained virologically suppressed at W48***
- **Renal function remained stable overall, and increased among renal transplantations**
  - eGFR BL vs W48: 15±7 vs 25±16, p=0.065
- **Consistent PK**
- **ISRs reported were mostly mild in severity and short in duration; pain was most commonly reported ISR**

➔ High effectiveness and good safety profile in people with severe renal impairment

Midway Specialty Care Center[2]

US

Study Design: Retrospective case series of those with ESRD who initiated CAB+RPV LA between 01/2021 and 11/2024

- 9 individuals: 1 receiving PD, 8 receiving HD

Key results

- **All remained virologically suppressed with no missed injections**
- **Duration on CAB+RPV LA ranged from 0.7-2.8 years** (4 with >114W and 4 with ≤55W)
- **No VFs, emergent RAMs, adverse events, or treatment discontinuations reported**

➔ High effectiveness and good tolerability observed in people with HIV on dialysis treated with CAB+RPV LA

People with liver fibrosis

San Raffaele hospital[3]

Italy, follow-up time NR

Study Design: Observational, single center, real-world cohort study

- 371 individuals, 545 CAB+RPV concentrations¥

Key results

- **CAB concentrations did not vary by FIB-4 category, and RPV concentrations were higher in people with FIB-4 ≥1.30 vs <1.30**
  - Both CAB and RPV concentrations were positively related to total bilirubin
- **No clinical events or hepatic toxicity occurred, and among people with FIB-4 ≥1.30, 4 (2.2%) discontinued therapy vs 17 (4.8%) among those with FIB-4 <1.30**

➔ Supports the potential use of CAB+RPV LA in people with mild-to-moderate liver fibrosis

PD, peritoneal dialysis; HD, hemodialysis; ESRD, end stage renal disease; VF: virologic failure; RAMS, resistance associated mutations

*11 people had VL<50 c/mL, one deceased due to NSTEMI

1. Shon et al. IDWeek 2025 Oral 394;
2. Bolivar et al. LAAI 2025 Poster 28
3.Candela et al. EACS 2025 Poster MeP21.3;

DISCUSSION

PREFER LA: High virologic suppression and adherence to CAB+RPV LA injections in people with prior adherence challenges to oral ART

Study population and design

PREFER-LA is an observational, cross sectional US study of people with HIV on CAB+RPV LA for ≥6 to ≤18 months (N=159)

Inclusion criteria: People with HIV aged ≥18 years with documented adherence challenges* on prior oral ART as identified by their HCP, and who had been on CAB + RPV LA for 6-18 months, excluding those who discontinued treatment

/ **Median age (IQR):** 39 (32,53) / **Ciswoman:** 17% / **Black:** 57% / **~70% had received ≥2 prior regimens** / **59% switch from BIC/FTC/TAF†**

Effectiveness

Effectiveness & Adherence

98% achieved or maintained viral suppression </=200 c/mL after CAB+RPV LA initiation

At BL, 89% had VL <200 c/mL

87% had no missed CAB+RPV LA dose in last 6 months

Driven by CAB+RPV LA fitting with their lifestyle, convenience of clinic visits and in person support

13% missed/skipped/delayed a dose of CAB+RPV LA in last 6 months

Due to forgetting appointments or those not fitting with work/social/travel plans, insurance coverage or transport issues

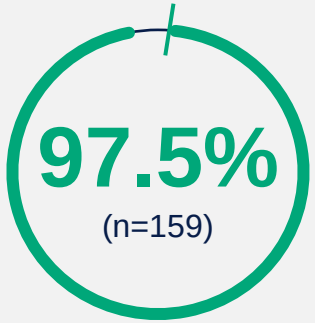
IDWeek 2025; October 19-22, 2025; Atlanta, GA

*See slide notes for footnotes

Short W et al. IDWeek 2025; Atlanta, GA. Oral presentation 575

PREFER LA: High preference for CAB+RPV LA among people with HIV with prior adherence challenges to oral ART

Preference and benefits for people with HIV



preferred CAB + RPV LA vs daily oral ART

mainly due to believing injections are more reliable than daily oral ART to keep VL undetectable (71%), and not having to worry about others seeing/finding their HIV pills (71%)

Impact that switching to CAB+RPV LA from daily oral ART has had on people with HIV (n=159):

- **Positive impact on overall health (67%)**
- **Positive impact on quality of life (79%)**
- **Helped control HIV better (79%)**
- **Fits better with daily life/ everyday activities (83%)**

→ **90% (n=159) of people with HIV were very likely to recommend CAB+RPV LA to other people with adherence challenges,** and most people reported overall positive feelings toward CAB+RPV LA and more positive feelings towards themselves since switching

HCP perspectives on persistence and benefits for adherence challenged people with HIV

The **most common reason** among both HCPs and people with HIV for switching to CAB+RPV LA was to **improve treatment adherence**.

95% (n=151) of HCPs reported that they foresee PWH remaining on CAB+RPV LA long term, mainly driven by the regimen fitting with people's lifestyle, people being more adherent to treatment, and personal preference

HCP reported benefits of implementing CAB+RPV LA for people with adherence challenges (n=13)*

- **100%** Person's HIV is better controlled
- **77%** Assurance of people with HIV adherence to ART
- **92%** People with HIV have better overall engagement with care
- **69%** People are more present for vaccines and screening tests

IDWeek 2025; October 19-22, 2025; Atlanta, GA

*Responses not mutually exclusive, only the 4 more frequently reported reflected here

Henry W et al. IDWeek 2025; Atlanta, GA. Poster P-396

High effectiveness of LA ART in people with viremia at initiation

ID Week 2025			EACS 2025		
OPERA[1]	**TRIO[2]**	**Ward 86[3]**	**Dat'AIDS[4]**	**Whitman-Walker Health[5]**	**Chaudhuri 2025[6]**
N=502 Median (IQR) follow-up 12 (7–22) months	N=111 Median (IQR) follow-up 9 (3–13) months	N=96 Week 48 (±2)	N=86 Median (IQR) follow-up 11 (5–24) months	N=31 NR (latest drawn)	N=20 Week 24
79% (399/502)*	**84%** (68/81)‡	**98%** (94/96)§	**86%** (74/86)#	**94%** (29/31)¶	**85%** (17/20)¥
virologic suppression	virologic suppression	virologic suppression	virologic suppression	virologic suppression	virologic suppression
2% (7/355)† CVF	**2%** (2/111)† CVF	NR	**12.8%** (11/86)† VF	NR	NR

*VL <50 c/mL at time of analysis among those who completed initiation and had ≥1 follow-up VL; †OPERA: CVF defined as two consecutive VL ≥200 c/mL or single VL ≥200 c/mL followed by discontinuation within 2 (Q1M) or 4 (Q2M) months after suppressing to VL <50 c/mL, TRIO: NR, Dat'AIDS: VL >200 c/mL after viral suppression, 2 consecutive VL >50 c/mL after viral suppression, or failure to reach viral suppression by 6 months; ‡Last VL <50 c/mL (93% had last VL <200 c/mL); §VL ≤200 c/mL; #Proportion who achieved viral suppression <50 c/mL; ¶VL ≤50 c/mL; ¥VL <20 c/mL (100% achieved VL <200 c/mL)

1. Sension M, et al. IDWeek 2025. Poster P-371; **2.** Elion R, et al. LAAI 2025. Oral abstract 2; **3.** Gistand N, et al. CROI 2025. Poster 689; **4.** Deschanvres C, et al. EACS 2025. Poster eP.LB003; **5.** Fessler D, et al. CROI 2024. Poster 1235; **6.** Chaudhuri S, et al. IAS 2025. Poster EP0199

DISCUSSION

Apretude

Heidi Swygard, MD, MPH
Regional Medical Lead, LAI for PrEP
ViiV Healthcare

HIV: Who is Impacted in the US?[1]

New HIV diagnoses in the US and dependent areas in the most affected populations

1.1M **people living with HIV in US at the end of 2023[1]***

~39K new HIV diagnoses occurred in 2023[3]

81% occurred in cisgender men[3]

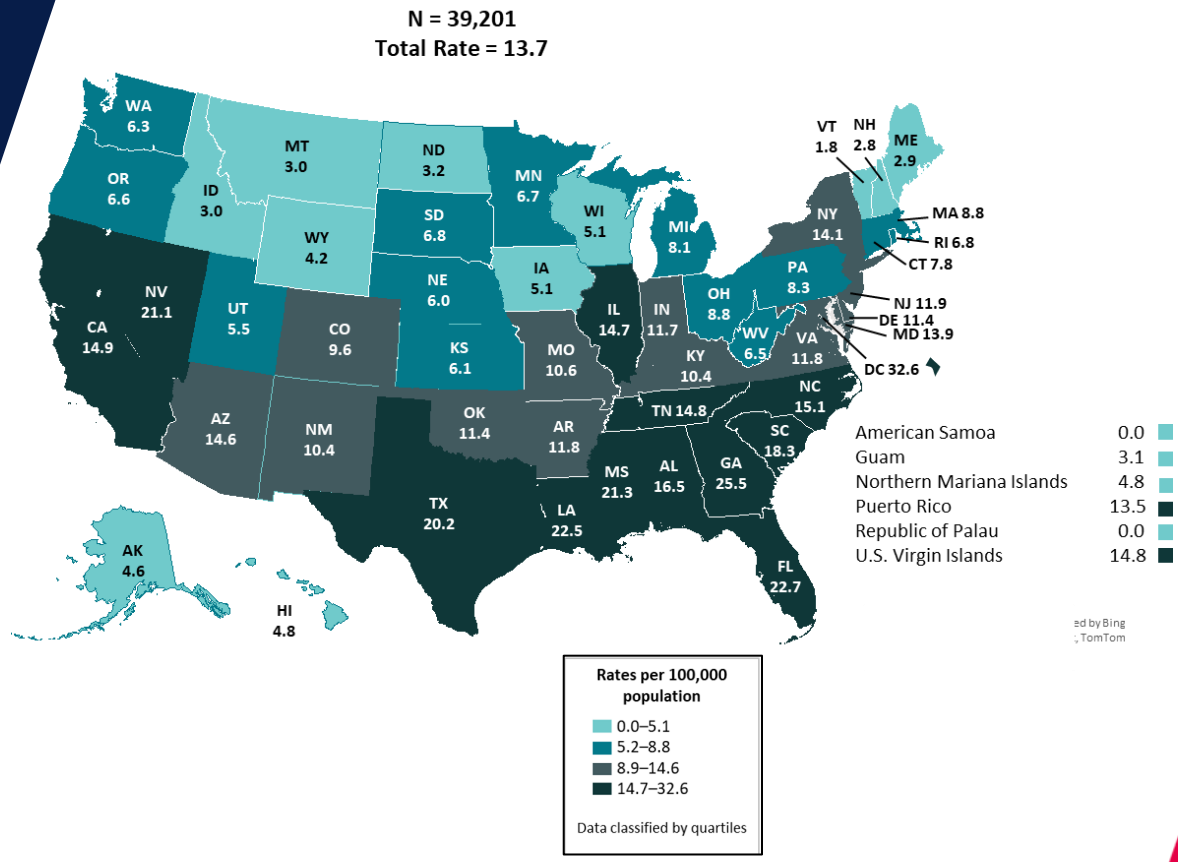
19% occurred in cisgender women[3]

55% occurred among those 13 to 34 years of age[3]

HIV by Geography

Southern states make up 39% of the US[2] population but have the highest burden of HIV infections, accounting for **51%** of annual HIV infections in the US in 2023[3]

HIV diagnoses, 2023—United States and 6 territories and freely associated states



*CDC surveillance data are for those 13 years of age and older

HIV: Human immunodeficiency virus; **PrEP**: Pre-exposure prophylaxis; **US**: United States.

1. US Statistics. 5 December 2023. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics
2. United States Population Growth by Region, date accessed May 5, 2025
3. HIV Diagnoses, Deaths, and Prevalence: 2025 Update | HIV Data | CDC Apr 29, 2025

EHE Goals and Strategies:

Reaching

75%*

reduction in new HIV infections by 2025

and at least

90%

reduction by 2030.

HIV: Human immunodeficiency virus;; **PrEP:** Pre-exposure prophylaxis; **PWH:** People with HIV; **SSP:** syringe services program; **U=U:** undetectable equals untransmittable

1. HIV.gov. Key Strategies in the Plan. (2022, July 1). Accessed January 8, 2025 https://www.cdc.gov/ehe/php/about/goals.html

*Goal was not met

Diagnose

all individuals with HIV as soon as possible

Treat

PWH rapidly and effectively (U=U)

Prevent

new HIV transmissions by using proven interventions, such as PrEP and SSPs

Respond

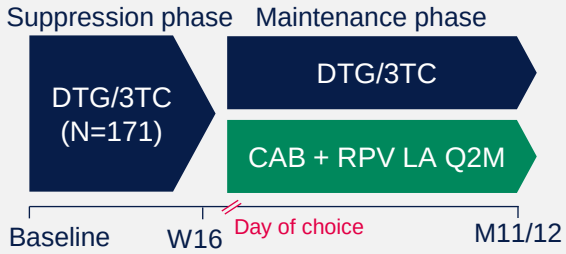
quickly to potential HIV outbreaks

Routine healthcare visits are a critical opportunity to scale up sexual health assessments and PrEP delivery

EACS 2025

VOLITION study

Phase IIIb, multicentre, non-randomised, parallel-group, open-label study



PSPs* and SSPs were surveyed at baseline to assess experience of clinical discussions around sexual wellness and HIV prevention

PSPs

74% (127/171) of total PSPs had a visit with an HCP in the previous 12 months

- **39%** (49/127) Stated sexual wellness was not assessed and/or they were not offered HIV testing or HIV prevention information
- **56%** (71/127) Affirmed HCP visit was for STI testing, PEP, substance use treatment/counseling, or sexual/reproductive healthcare/counseling

44% (76/171) of total PSPs were aware of PrEP before their HIV diagnosis

- **25%** (19/76) Were ever offered PrEP

SSPs

59% (56/95) Of SSPs assess sexual health and wellness at every visit

24% (23/95) Of SSPs only assess sexual health if brought up during the appointment

These findings demonstrate that there are missed opportunities in healthcare for HIV prevention in those who have acquired HIV

*PSPs were adults naive to antiretroviral therapy receiving initial treatment

PrEP-related adverse events not reported.

PEP, post-exposure prophylaxis; **PSP,** Patient Study Participants; **SSP,** Staff Study Participants

Metzner AA, et al. EACS 2025. Poster eP456

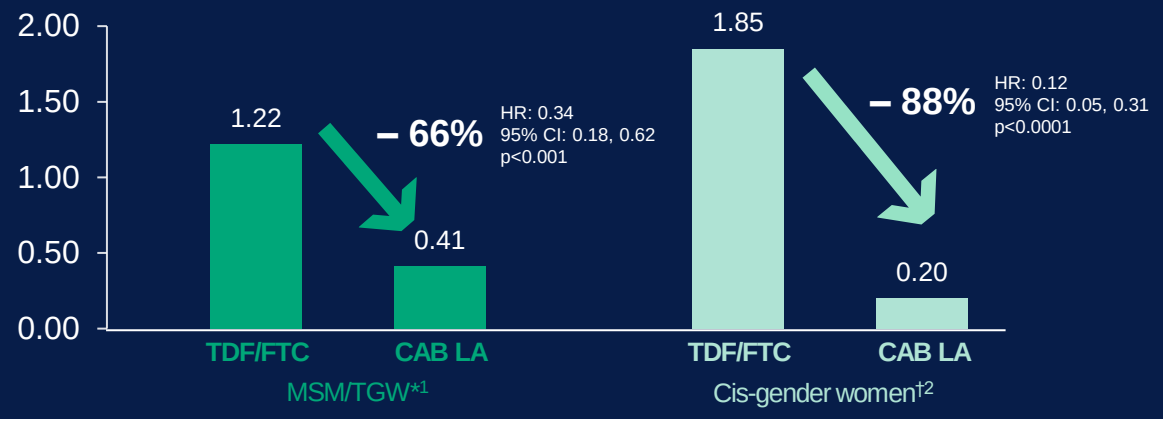
DISCUSSION

CAB LA PrEP demonstrated superior efficacy to oral TDF/FTC and has a reassuring safety and injection tolerability profile

Superior efficacy versus daily oral TDF/FTC

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

HPTN 083 and 084: HIV incidence per 100 PY (primary analysis)



CAB LA PrEP has demonstrated >99% effectiveness for HIV prevention in **over 3 years of real-world data** in diverse populations,[6–12] including data on pregnancy outcomes

CAB LA PrEP has low potential for clinically significant **DDIs**[13]

CAB LA PrEP injections are generally well tolerated, highly acceptable and discontinuations due to ISRs were rare in clinical trials[1,14,15]

Ongoing implementation studies have shown that CAB LA PrEP users **benefit from 2-monthly clinic visits**[16]

No drug-related toxicities reported; most common adverse events reported were injection site reactions ranging 0.5-83% [7-15]

1. Landovitz RJ, et al. N Engl J Med 2021;385:595–608 (and suppl. Appendix); **2.** Delany-Moretlwe S, et al. Lancet 2022;399:1779–89
3. Marzinke MA, et al. Antimicrob Agents Chemother 2023;67:e00053–23; **4.** Landovitz RJ, et al. Lancet HIV 2023;10:e767–78
5. Eshleman SH, et al. J Infect Dis 2022;225:1741–9; **6.** Delany-Moretlwe S, et al. AIDS 2022. Oral OALBX0108
7. Mills AM, et al. IDWeek 2024. Oral 508; **8.** Ramgopal M, et al. IDWeek 2024. Oral 505; **9.** Heise MJ, et al. HIVR4P 2024. Oral OA0503
10. Turner C, et al. HIVR4P 2024. Poster 01725; **11.** Hazra A, et al. CROI 2024. Poster 1241; **12.** Traeger M, et al. CROI 2025. Oral 191
13. Apretude US Prescribing Information, April 2025; **14.** Delany-Moretlwe S, et al. Lancet 2022;399:1779–89
15. Boles J, et al. EACS 2025. Poster MeP20.4.LB; **16.** Holder H, et al. IDWeek 2024. Poster P-1424

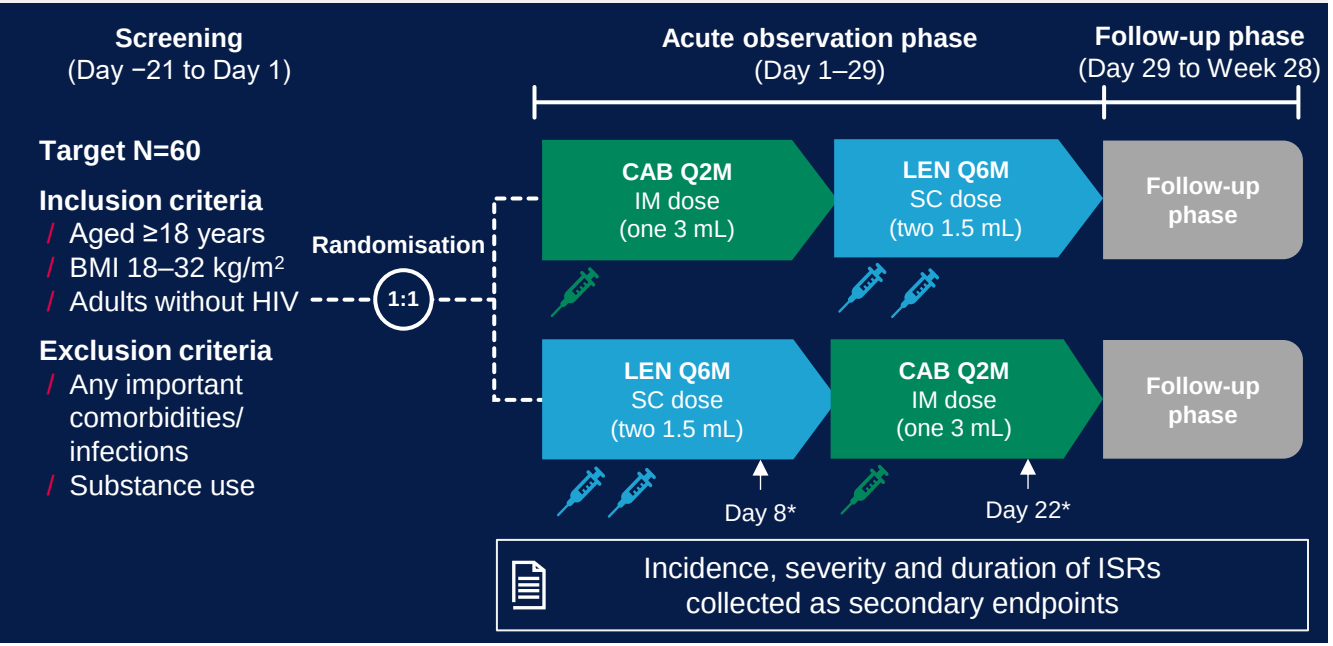
Following a single dose of each product, participants report ISRs from CAB LA PrEP injections as more acceptable than LEN LA injections

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 injection using questions from the 21-item PIN questionnaire*



Acceptability of ISRs

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

CAB LA†	LEN LA†
69%	48%
"totally or very acceptable" (42/61)‡	"totally or very acceptable" (29/60)‡

Results statistically significant in a post-hoc analysis (P=0.019)

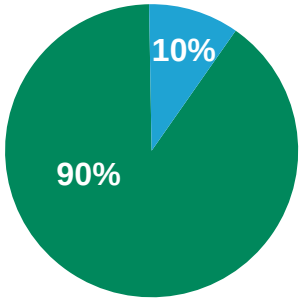
Participant preference

Day 22 (N=60)§¶

The Majority of Participants Preferred CAB Injections Over LEN Injections

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

Local reactions from CAB LA PrEP injections were less frequent and visible than LEN LA

CLARITY study

EACS 2025

LEN LA injections led to more visible ISRs versus CAB LA injections

- **No serious AEs** or discontinuations due to drug-related AEs were reported
- A total of **36 and 221 visible ISR events** were reported by participants receiving **CAB LA and LEN LA, respectively** (ISR events were defined as any visible nodule, induration, swelling, erythema or hyperpigmentation)
- **49%** of participants receiving **CAB LA** and **100%** of participants receiving **LEN LA** experienced a **physical non-pain ISR event**
  - **33%** of participants receiving **CAB LA** and **74%** of participants receiving **LEN LA** experienced **nodules**

Representative images of CAB LA and LEN LA injection sites

CAB LA (Day 25)

Gluteal injection

LEN LA (Day 25)

Abdominal injection

LEN LA injections led to more frequent and visible ISRs after a single dose

Following single doses of LEN LA and CAB LA, there were differences in ISR acceptability and tolerability with participants and HCPs favoring CAB LA

AE, adverse events

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

DISCUSSION

CAB LA PrEP users benefit from regular clinic visits

IDW 2025

OPERA[1]

HIV-negative adults who received ≥1 CAB LA injection or ≥1 oral PrEP prescription in the OPERA cohort* were included

1,025 CAB LA episodes

22,776 oral PrEP episodes

STI testing was 1.5 times more frequent for those receiving **CAB LA PrEP** (IR: 5.18; 95% CI: 5.02, 5.35) versus oral PrEP (IR: 3.42; 95% CI: 3.39, 3.44)

Increased clinical contact from regular CAB LA PrEP injection visits may encourage **more frequent STI testing**

IDW 2025

EBONI[2]

130 Black women from 19 clinics completed surveys on implementing CAB LA PrEP

Interim (4-month) experiences among Black CGW and TGW

According to self-completed electronic surveys, Black women reported that the following were **acceptable or very acceptable** while receiving CAB LA:

- **Frequency of HIV testing (95%)**
- **Frequency of STI testing (94%)**

Ancillary benefits observed in OPERA and EBONI were improved engagement in PrEP services and broader sexual health care utilisation

*Enrolled in the OPERA cohort 21 Dec 2021 to 30 Jun 2023 and were followed through 30 Jun 2024

No adverse events reported.

CGW, cisgender women; **IR,** incidence rate; **STI,** sexually transmitted infection

1. Barnett S, et al. IDWeek 2025. Poster P-332
2. Nelson KL, et al. IDWeek 2025. Poster P-313

DISCUSSION

Dovato

Gustavo Verdier, BSc, BPharm, MBA
Regional Medical Lead, Oral Treatments Team
ViiV Healthcare

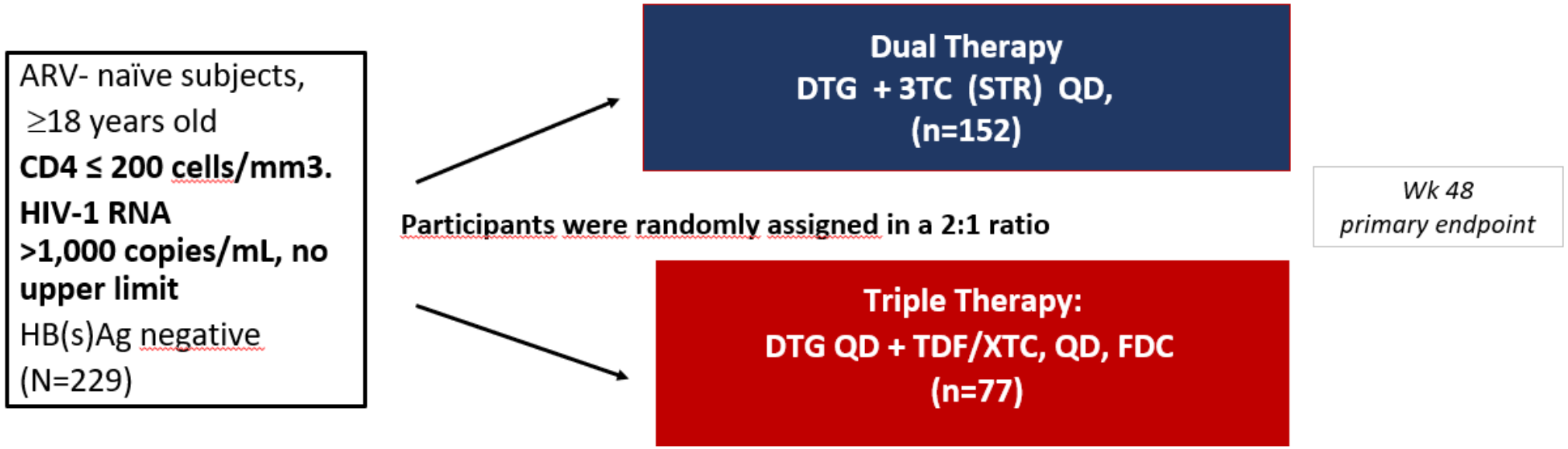
Subgroup Analysis of Dolutegravir/Lamivudine in ART-Naive Adults Living With HIV With CD4 Counts Below 200 Cells/mL: Results From the DOLCE Study

C Brites,[1,2] M Figueroa,[3] D Cecchini,[4] A Ramalho,[5] JL Francos,[6] M Lacerda,[7] MJ Rolon,[8] J Valdez Madruga,[9] E Sprintz,[10] T Newman Lobato Souza,[11] P Parenti,[12] D Converso,[3] G Miernes,[3] O Sued,[3] P Cahn[3]

[1]Fundação Bahiana de Infectologia, Salvador, Bahia, Brazil; [2]Universidade Federal da Bahia/EBSERH, Salvador, Bahia, Brazil; [3]Fundacion Huesped, Ciudad de Buenos Aires, Argentina; [4]Hospital General de Agudos Dr. Cosme Argerich, Ciudad de Buenos Aires, Argentina; [5]Hospital Geral de Nova Iguaçu, Nova Iguaçu, Rio de Janeiro, Brazil; [6]Hospital de Infecciosas Francisco Javier Muñiz, Ciudad de Buenos Aires, Argentina; [7]Fundação de Medicina Tropical do Amazonas, Manaus, Brazil; [8]Hospital Juan A. Fernandez, Ciudad de Buenos Aires, Argentina; [9]Centro de Referência e Treinamento DSTAIDS, Sao Paulo, Brazil; [10]Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil; [11]Instituto de Infectologia Emílio Ribas, San Pablo, Brazil; [12]Instituo CAICI, Rosario, Santa Fe, Argentina

Study Design

✓ **Phase IV, exploratory, open-label , multicenter study including naïve PLWHIV in 11 sites in Argentina and Brazil**



Randomization was stratified by country and by plasma HIV-1 RNA at screening (> or ≤ 100.000 copies/mL)

Treatment period: 48 weeks, followed by a 4 week period to document late adverse events

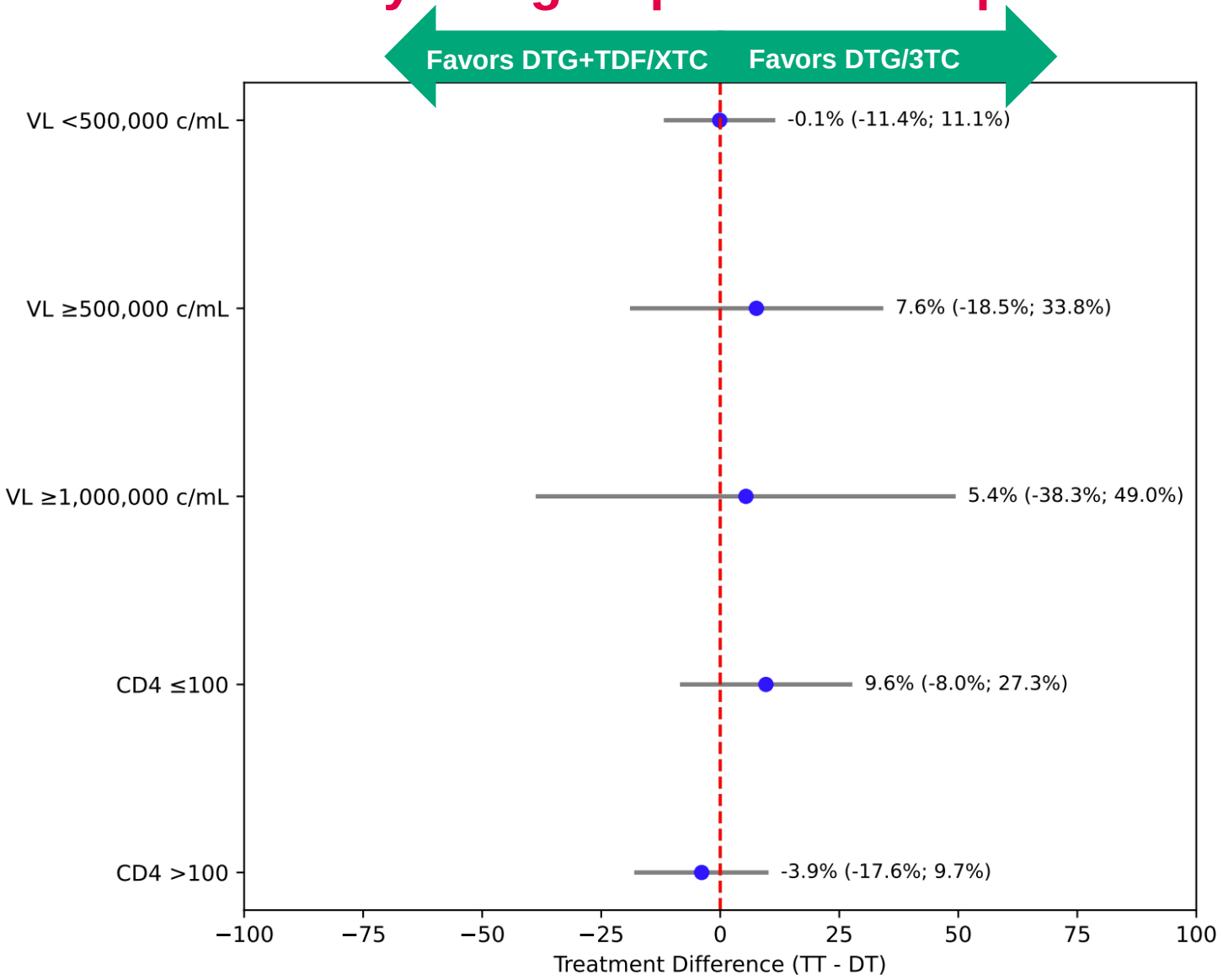
Figueroa et al. HIV Glasgow 2024; Glasgow, Scotland. Oral O24.

Baseline Characteristics

	Total n = 230	Triple therapy (TT) n = 77	Dual therapy (DT) n = 153
CD4 count			
CD4 cell count, cells/mL: (median-IQR)	116 (53.3- 188)	128 (58.5 - 200)	109 (48.8 - 177)
CD4% [Median (IQR)]	8 (4, 13)	10 (4.1, 13)	8 (4, 12)
CD4 cells count < = 100 cells/mL	98 (43.4%)	29 (39.2%)	69 (45.4%)
HIV RNA			
HIV-1 viral load (copies/mL) [Median (IQR)]	151,000 (49,027.5, 446,947)	137,084 (43,901 - 419,628)	180,000 (57,309 - 468,691)
HIV RNA, log 10,(median-IQR)	5 (4.7-6)	5 (4.6- 6)	5 (4.8- 6)
HIV RNA, >100,000 c/mL,(n, %)	141 (61.3%)	47 (61.0%)	94 (61.4%)
HIV RNA, =>500,000 c/mL,(n, %)	53 (23.0%)	18 (23.4%)	35 (22.9%)
HIV RNA = > 1,000,000 copies/mL(n, %)	23 (10.0%)	7 (9.1%)	16 (10.5%)
Viral Subtype			
• Subtype B	143 (63.0%)	51 (68.0%)	92 (60.5%)
• Subtype BF	62 (27.3%)	18 (24.0%)	44 (28.9%)
• Other subtypes	17 (7.5%)	4 (5.3.%)	13 (8.5%)

Figueroa et al. HIV Glasgow 2024; Glasgow, Scotland. Oral O24.

Proportion of Participants With Plasma HIV-1 RNA <50 Copies/mL at Week 48. Snapshot Outcomes by Subgroups - ITT-E Population Efficacy



Brites et al. EACS 2025; Paris, France. Poster eP134.

DISCUSSION

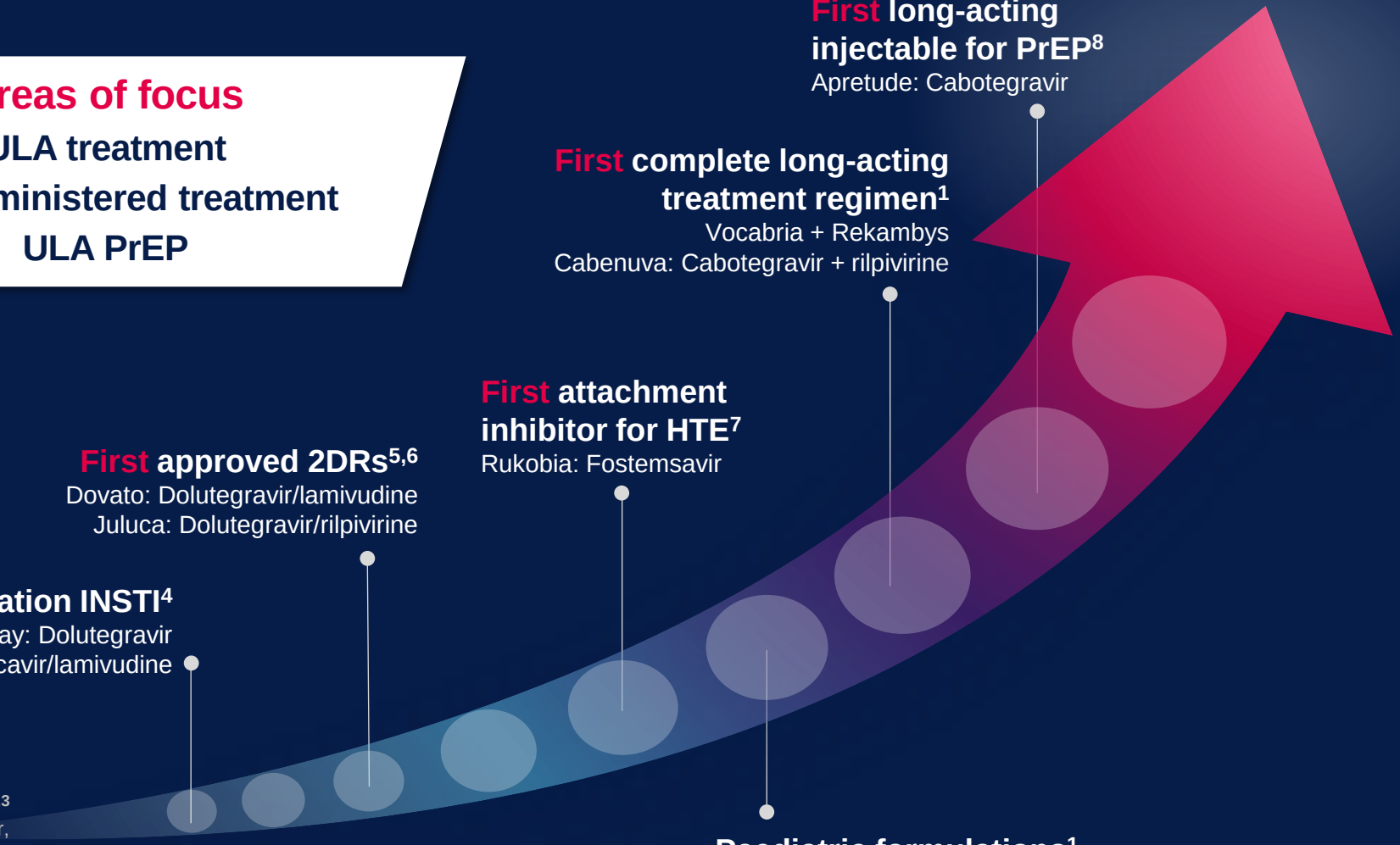
Pipeline

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

ViiV Portfolio
Pioneers in innovation[1]

Areas of focus
ULA treatment
Self-administered treatment
ULA PrEP

Search for remission and cure



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

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

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

First attachment inhibitor for HTE[7]
Rukobia: Fostemsavir

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

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

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

Pipeline*[1,9]

INSTIs
CAB-ULA
VH4367310 (VH-310)
VH4524184 (VH-184)
– Third-generation

bNAbs
VH3810109 (VH-109)
– N6LS
VH4527079 (VH-7079)
– Bi-specific

Capsid inhibitor
VH4011499 (VH-499)

*Potential new medicines not currently approved for prescription
ARV, antiretroviral; **bNAb,** broadly neutralising antibody; **ULA,** ultra-long acting; **VH,** ViiV Healthcare

See slide notes for references

ViiV Pipeline

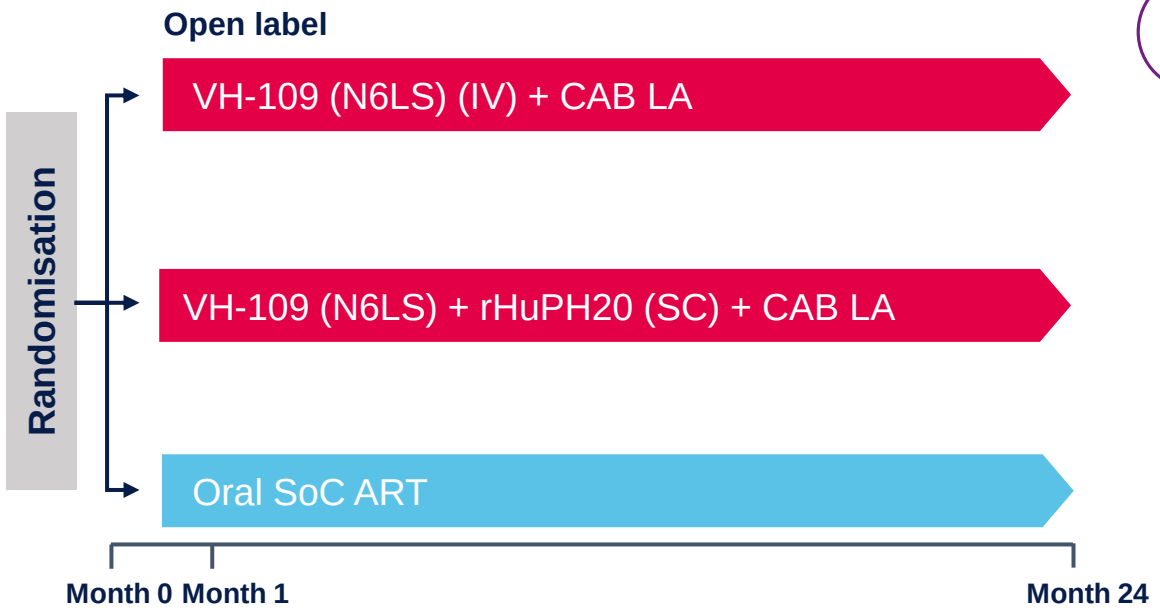
Innovative long-acting partners: bNAbs

EMBRACE study design – Part 1: VH-109 (N6LS) Q4M + CAB Q1M

Phase IIb, multicentre, randomised, open-label study comparing the efficacy, safety, PK and tolerability of VH-109 (N6LS), administered either IV or as an SC infusion with rHuPH20, in combination with CAB LA to SoC in virologically suppressed adults

Inclusion criteria*

- Age 18–70 years
- HIV-1 RNA <50 c/mL at screening
- Not currently on CAB or FTR
- Stable oral ART for 6 months
- No history of VF (HIV-1 RNA ≥200 c/mL)



Endpoints

- **Primary endpoint:** HIV-1 RNA ≥50 c/mL at Month 6†
- **Secondary endpoints:** HIV-1 RNA <50 c/mL, incidence of CVF, safety and tolerability, treatment-emergent genotypic/phenotypic resistance

*Participants were tested for viral phenotypic sensitivity to VH-109 based on IC_{90} of ≤2 µg/mL and a maximum percent inhibition >98% using the monogram PhenoSense monoclonal antibody assay on sample obtained at a screening visit
†Number of participants with plasma HIV-1 RNA ≥50 c/mL per snapshot algorithm at Month 6
CVF, confirmed virologic failure; **FTR,** fostemsavir; **IC_{90},** 90% maximal inhibitory concentration
rHuPH20, recombinant human hyaluronidase PH20; **VF,** virologic failure

EMBRACE (NCT05996471). Available at: https://clinicaltrials.gov/study/NCT05996471. Accessed May 2025

DISCUSSION

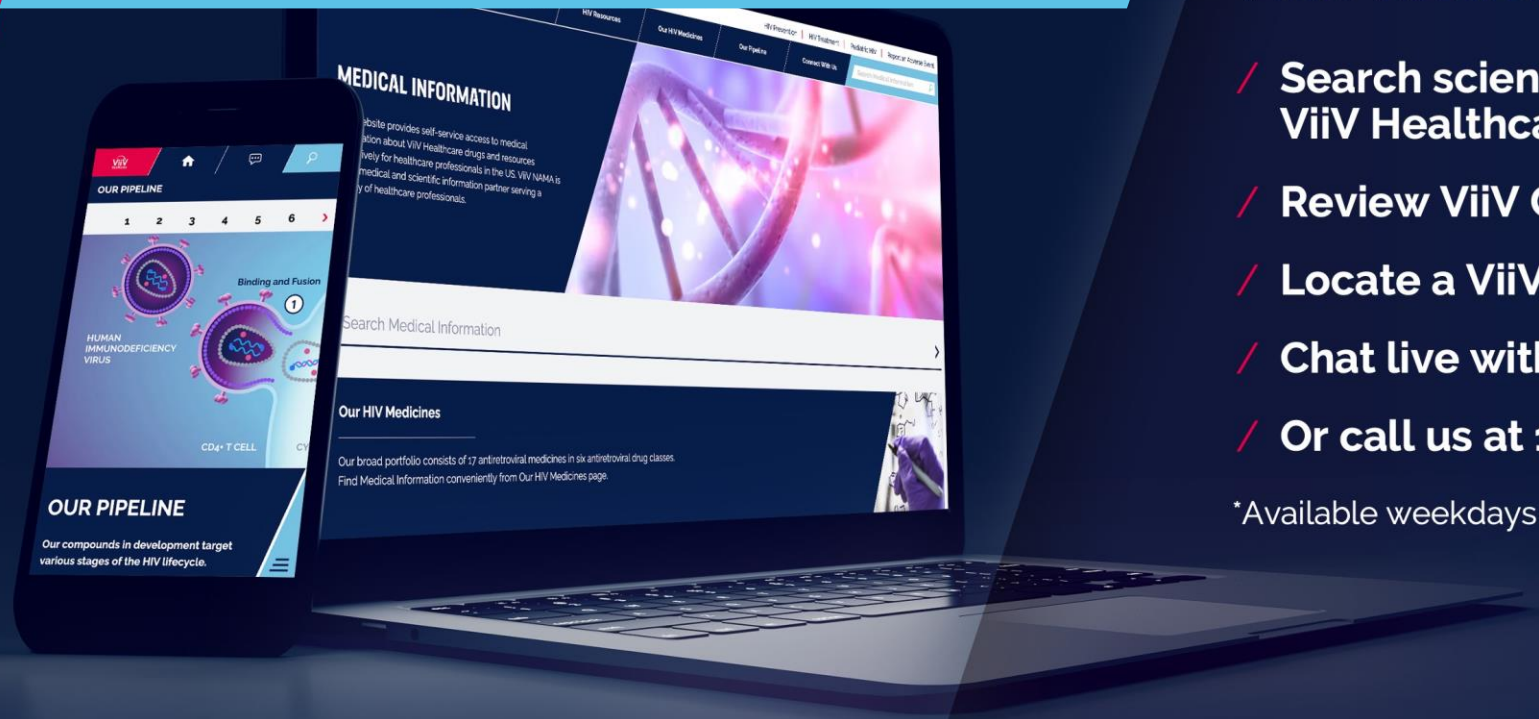
Q&A

- **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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