



# CROI 2026

*Conference on Retroviruses  
and Opportunistic Infections*

Annual Highlights for the HIV Community

ViiV Healthcare

Gilead Sciences

Merck & Others

Women's Health

Cardiovascular

Meth & Mental Health

Hope for the Future

March 7, 2026 · SDHIVC Monthly Science Update



**San Diego HIV  
Community Consortium**

March 7, 2026 Monthly Science Update · SDHIVC

# CROI 2026 — At a Glance



## *Key Themes Shaping HIV Medicine This Year*

### Long-Acting ART

Ultra-long-acting injectables with 4–6 month dosing on the horizon

### Next-Gen PrEP

Twice-yearly & annual prevention options expanding global access

### Cure Research

Early but meaningful signals from Africa's FRESH cohort & beyond

### Equity & Access

New data on women, diverse populations, meth & mental health

### Cardiometabolic

Heart disease risk and long-term ART safety in long-term focus

### Future Hope

Phase 3 trials underway for once-yearly PrEP & novel targets

ViiV

4 month dosing

- for injectable PrEP med and treatment regimen

Phase I every 4 month PrEP with CAB

**EMBRACE Study —**

- Lotivibart (N6LS) + Cabotegravir (Phase IIB)
- for treatment



GILEAD  
BIC/LEN daily oral to  
simplify and for resistance



ISL/LEN weekly oral vs  
Biktarvy daily 96 weeks



Twice yearly injectable  
LEN+ 2 bNAbs TAB & ZAB



Yearly LEN for prevention

MERCK

Two drug simpler for treatment

Weekly or Monthly oral for treatment

Daily Oral DOR/ISL vs Biktarvy or complicated regimen

Weekly oral LEN/ISL 96 weeks same

Monthly oral MK-8527 EXPrESSIVE 10,11 Phase 3

# ViiV Healthcare — Ultra-Long-Acting Innovation



## Phase 1 to IIb: Extending Dosing Intervals to 4+ Months

### 4-Month Dosing

The new frontier in long-acting HIV care

ViiV Pipeline at CROI 2026

VH184

VH499

EMBRACE

CAB ULA

#### VH184 — 3rd-Gen INSTI (Phase 1, Abstract #TBD)

CROI #121LB

- First-in-human Phase 1 data — novel third-generation integrase inhibitor
- Designed for long-acting injectable formulation with potential 4-month dosing intervals
- Activity against INSTI-resistant strains is a primary design goal
- Represents next evolution beyond cabotegravir

#### VH499 — Injectable Capsid Inhibitor (Phase 1, Abstract #TBD)

CROI #122

- Early Phase 1 data for injectable capsid inhibitor — novel mechanism class
- Follows lenacapavir's capsid inhibitor pathway; designed for extended-release use
- Potential for ultra-long-acting dosing intervals

#### EMBRACE Study — Lotivibart (N6LS) + Cabotegravir (Phase IIb)

CROI #418

- 12-month interim data (Abs #418): bNAb + INSTI as complete injectable ART regimen
- Lotivibart every 4 months + cabotegravir — broadly neutralizing antibody approach
- Key question: can bNAbs replace NRTIs in long-acting regimens?

#### CAB ULA 012 — 4-Month Cabotegravir PrEP (Phase 1)

CROI #89

- Phase 1 PK/safety data for ultra-long-acting (ULA) cabotegravir for PrEP (Abs #89)
- 4-month dosing interval would dramatically reduce injection burden for prevention

ViiV

4 month dosing

- for injectable PrEP med and treatment regimen

Phase I every 4 month PrEP with CAB

**EMBRACE Study —**

- Lotivibart (N6LS) + Cabotegravir (Phase IIB)
- for treatment

# Gilead Sciences — Pipeline & Prevention Breakthroughs



## ARTISTRY, PURPOSE, Cure Research — Most Anticipated Abstracts at CROI 2026

### ARTISTRY

Switch STR  
BIC/LEN

#### ARTISTRY-1 & -2 — BIC/LEN Single-Tablet Regimen (Phase 3 Late-Breaking)

CROI #LB01

- **Most anticipated late-breaking** abstracts at CROI 2026 (Abs #LB-01 / #LB-02)
- BIC/LEN: bictegravir/lenacapavir — first INSTI + capsid inhibitor STR
- ARTISTRY-2 (48-wk data): noninferior to continued B/F/TAF in virologically suppressed patients
- Novel dual mechanism: INSTI backbone + capsid inhibitor may raise resistance barrier

### PURPOSE

2x-Yearly  
PrEP

#### PURPOSE Program — Twice-Yearly Lenacapavir PrEP (Multiple Abstracts)

CROI #78

- PURPOSE 1 & 2 diversity data across cisgender women, MSM, transgender individuals (Abs #78)
- 96-week Phase 2 data: weekly oral islatravir + lenacapavir (Abs #201)
- Phase 3 trial design unveiled: once-yearly IM lenacapavir for PrEP (Abs #79LB)
- If approved: most durable HIV prevention option ever — transformative for adherence

### FRESH

HIV Cure  
SA Cohort

#### FRESH Cohort — HIV Cure Research in South Africa (Abs #312)

CROI #312

- Women identified at acute HIV infection (AHI) in KwaZulu-Natal
- bNAb + early ART interruption strategies — functional cure pursuit
- Critical equity dimension: cure research centered in highest-burden setting globally

Late-Breaking



GILEAD  
BIC/LEN daily oral to  
simplify and for resistance



ISL/LEN weekly oral vs  
Biktarvy daily 96 weeks



Twice yearly injectable  
LEN+ 2 bnAbs TAB & ZAB



Yearly LEN for prevention

PURPOSE 365: PopPK modeling

# Population Pharmacokinetic Modeling of Once-Yearly IM LEN to Inform Phase 3 Dose Selection and Design



A 3-compartment PopPK model developed using data from four Phase 1 studies, providing 3378 LEN concentration measurements<sup>a</sup>

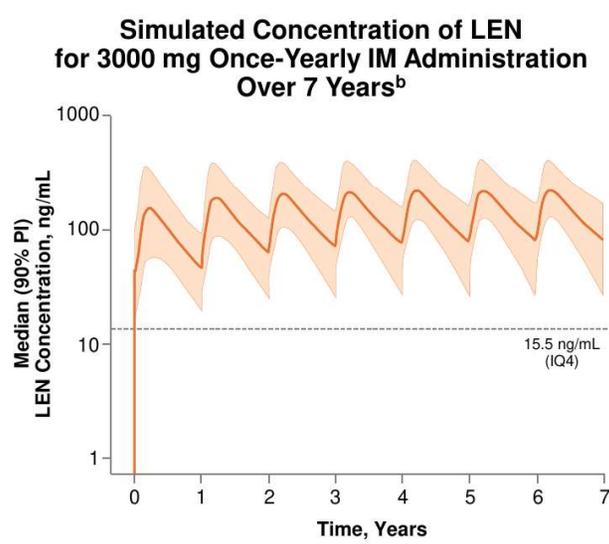
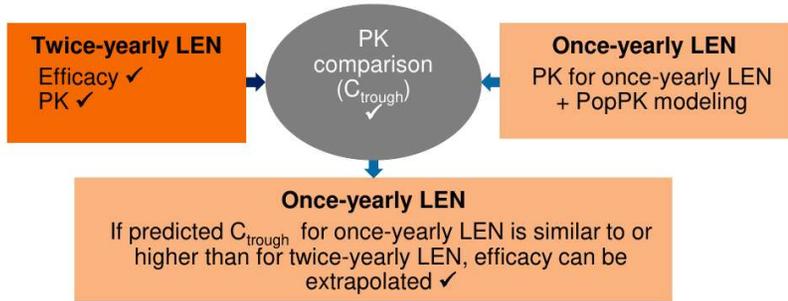


Dose selection was based on **exposure matching**, targeting a dose where the Week 52  $C_{trough}$  was projected to be equivalent to or greater than the observed Week 26  $C_{trough}$  in the PURPOSE 1 and 2 trials

### Outcome

Simulation of various oral loading frequencies and potential IM LEN doses to identify a regimen projected to maintain protective drug concentrations for  $\geq 52$  weeks in people who need or want PrEP

### Model-Informed Drug Development Efficacy Extrapolation



- PopPK simulations predicted a LEN IM dose of **3000 mg** would result in a Week 52  $C_{trough}$  exceeding the observed Week 26  $C_{trough}$  in PURPOSE 1 and 2
- **LEN 3000 mg IM** was projected to maintain **median LEN concentrations >4 times the *in vitro* IQ4 (15.5 ng/mL)** for  $\geq 52$  weeks
- Simulations indicated that **oral loading (600 mg on Days 1 and 2)** is required to achieve target concentrations rapidly by Day 2

**A LEN dose of 3000 mg IM was predicted by PopPK modeling to be suitable for once-yearly dosing; the safety and efficacy of this dose will be investigated in the Phase 3 PURPOSE 365 study**

<sup>a</sup>Oral data included doses from 300 to 1800 mg, and IM data included a single dose of 5000 mg. <sup>b</sup>Central solid line is the median concentration over time and the shaded region is the 90% PI  
 IQ4, inhibitory quotient 4; PI, prediction interval; PopPK, population pharmacokinetic; Q12M, every 12 months  
 Hughes E, et al. CROI 2026, Poster 996





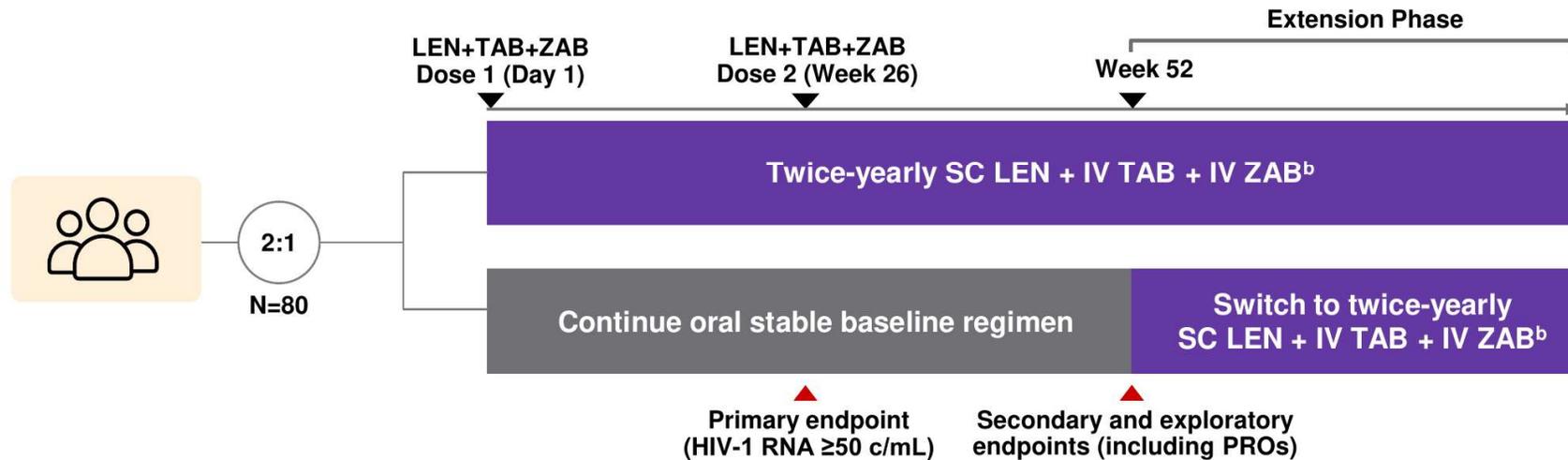
## Twice-Yearly LEN+TAB+ZAB in VS PWH: Study Design<sup>1,2</sup>



VS adults with HIV-1 on oral SBR (≤2 classes) for ≥12 months, with CD4 count ≥200 cells/μL, HBV negative and highly susceptible to both bNAbs (IC<sub>90</sub> ≤2 μg/mL)<sup>a</sup>

### Outcomes presented at CROI 2026

- **Secondary:** HIV-1 RNA <50 c/mL and ≥50 c/mL at Week 52<sup>2</sup>; post-baseline (on-treatment) resistance analysis at Week 52 for participants meeting virologic failure criteria; relative exposures to LEN, TAB and ZAB in participants with virologic rebound
- **Exploratory:** PROs at Week 52 (HIVTPQ, HIVTSQs, HIVDQoL) in people receiving LEN+TAB+ZAB<sup>1</sup>



**GS-US-536-5939 is a Phase 2, randomized, open-label study assessing the safety and efficacy of LEN+TAB+ZAB compared with an oral stable baseline regimen**

<sup>a</sup>By PhenoSense mAb Assay (Monogram Biosciences, San Francisco, CA, USA). <sup>b</sup>SC LEN 927 mg (+ oral 600 mg Days 1+2) with IV TAB 2550 mg and IV ZAB 2550 mg  
 ADA, antiretroviral drug antibody; BL, baseline; bNAb, broadly neutralizing antibody; HIVDQoL, HIV Dependent Quality of Life questionnaire; HIVTPQ, HIV Treatment Preference Questionnaire; HIVTSQs, HIV Treatment Satisfaction Questionnaire: Status version; IC<sub>90</sub>, 90% inhibitory concentration; PRO, participant-reported outcome; SBR, stable baseline regimen; TAB, teropavimab; VS, virologically suppressed; ZAB, znlirvimab  
 1. Gaur A, et al. CROI 2026, Poster 517. 2. VanderVeen LA, et al. CROI 2026, Poster 567





## BIC/LEN Clinical Development Program<sup>1-4</sup>

The ARTISTRY study program is investigating whether a FDC of BIC and LEN can expand treatment options in VS PWH<sup>3,4</sup>

### ARTISTRY-1

(NCT05502341/GS-US-621-6289)<sup>1,3</sup>

Open-label study comparing BIC/LEN STR versus complex, multi-tablet regimens in VS PWH (Phase 2/3)



### ARTISTRY-2

(NCT06333808/GS-US-621-6290)<sup>2,4</sup>

Double-blind study comparing BIC/LEN and a guideline-recommended standard-of-care regimen (B/F/TAF) in VS PWH (Phase 3)

**Global study** including participants from **15 countries or territories**



**Global study** including participants from **13 countries or territories**<sup>5</sup>

**ARTISTRY-1** Phase 3 demonstrated that BIC/LEN STR was non-inferior and generally well tolerated through 48 weeks in PWH who switched from complex regimens<sup>3,6</sup>

**ARTISTRY-2** Phase 3 demonstrated that BIC/LEN STR was non-inferior and generally well tolerated through 48 weeks in PWH who switched from standard-of-care B/F/TAF<sup>4,7</sup>

**Data from these studies will support regulatory filings of the BIC/LEN STR as a potential treatment option for broad range of virologically suppressed PWH<sup>6,7</sup>**

FDC, fixed dose combination; STR, single tablet regimen; VS, virologically suppressed. 1. NCT05502341. <https://clinicaltrials.gov/study/NCT05502341> (accessed Feb 11, 2026); 2. NCT06333808. <https://clinicaltrials.gov/study/NCT06333808> (accessed Feb 11, 2026); 3. Orkin C, et al. CROI 2026, Oral 181; 4. Meissner EG, et al. CROI 2026, Poster 513; 5. Gilead Sciences Inc. Gilead announces topline data from ART-1 Ph3 study. Press release, November 13, 2025, <https://investors.gilead.com/news/news-details/2025/Gileads-Investigational-Single-Tablet-Regimen-of-Bictegravir-and-Lenacapavir-for-HIV-1-Treatment-Meets-Primary-Endpoint-in-Phase-3-ARTISTRY-1-Trial/default.aspx>; 7. Gilead Sciences, Inc. Gilead announces topline data from ART-2 Ph3 study. Press release, December 12, 2025. <https://www.gilead.com/news/news-details/2025/gileads-investigational-single-tablet-regimen-of-bictegravir-and-lenacapavir-for-hiv-treatment-meets-primary-endpoint-in-phase-3-artistry-2-trial>



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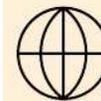
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**Data from these studies will support regulatory filings of the BIC/LEN STR as a potential treatment option for broad range of virologically suppressed PWH<sup>6,7</sup>**



**Study sites:** Argentina, Australia, Canada, Dominican Republic, France, Germany, Italy, Japan, Puerto Rico, South Africa, South Korea, Spain, Taiwan, UK, US

### Eligibility criteria

- VS adults (≥18 years old)
- HIV-1 RNA <50 c/mL
- On a stable complex ART<sup>a</sup>
- No prior exposure to LEN or resistance to BIC
- No HBV infection
- eGFR ≥15 mL/min, not on renal replacement therapy



**ARTISTRY-1 is a Phase 2/3 randomized study evaluating the safety and efficacy of switching to BIC/LEN vs. continued complex ART in VS PWH**



The group studied included switching from many



simpler the BIC/LEN combination, which

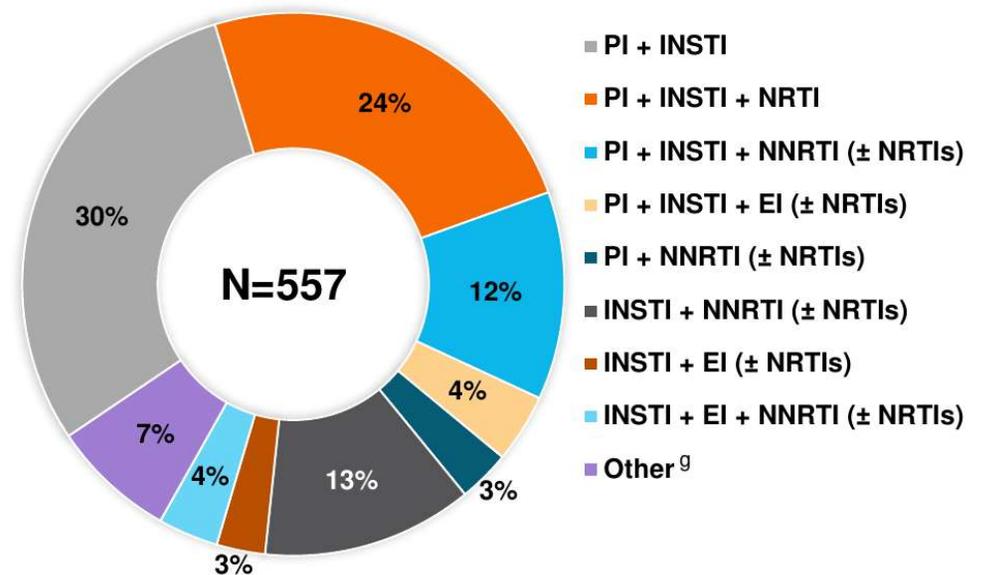


different drug combinations to the



worked well in all of them.

## Diversity of Complex ART at Baseline



77% of participants were on a PI-containing regimen

# Merck & Other Companies — Notable Pipeline Data



## *Broadly Neutralizing Antibodies, New Targets & Novel Agents*

### **Merck — Islatravir & Pipeline (Abs #156, #157)**

CROI #156

- Islatravir (ISL) — NRTTI: 96-week Phase 2 data with weekly oral ISL + lenacapavir (Gilead collab)
- Long-acting oral PrEP combinations with ISL under active evaluation
- Doravirine long-acting injectable formulation PK studies — early data
- MK-8507: next-gen NNRTI for long-acting combinations

### **Broadly Neutralizing Antibodies — bNAbs (Abs #290–295)**

CROI #290

- VRC01, N6LS (lotivibart), 3BNC117+10-1074 combinations — updated data
- ACTG bNAb studies: treatment intensification & cure strategies
- Challenge: cost, resistance footprint, and equitable access in high-burden settings
- EMBRACE (ViiV): 12-month bNAb + CAB interim data — ART replacement?

### **Novel Mechanisms & Cure Science (Abs #400–410)**

CROI #401

- CD4-mimetic compounds: block HIV entry via novel envelope targeting
- HIV latency reversal: updated 'kick and kill' approaches — TLR agonists
- Gene therapy: CRISPR & zinc-finger nuclease — HIV reservoir reduction data
- Therapeutic vaccines: updated trials with MVA, mRNA HIV vaccine platforms

### **Implementation & Access Science (Abs #500–510)**

CROI #502

- Long-acting ART rollout: real-world CAB/RPV adherence in US clinics & Africa
- Dolutegravir generic access in LMICs — 5-year viral suppression outcomes
- Telehealth + community-based testing expansion data — post-COVID era
- PrEP equity: oral vs injectable uptake across race, gender & geography

# Merck — Pipeline & Prevention Breakthroughs



## Non-InSTI/non-TAF daily regimen and long-acting oral options for treatment and prevention

### Daily treatment

DOR/ISL

#### DOR/ISL in Initial Therapy (Phase 3 Late-Breaking) and DOR/ISL 96-week data in Switch

CROI #LB177  
#LB514/#LB515

- Non-inferior to B/F/TAF for initial HIV treatment (Abs #LB177)
- In switch studies, non-inferior to B/F/TAF and any background regimen and well-tolerated out to 96 weeks (#LB514/#LB515)
- Safe in renal impairment down to 30 mL/min (Abs #519)

### Once weekly treatments

ISL/LEN  
ISL/ULO

#### Oral once-weekly ISL plus LEN and once weekly ISL and a new NNRTI, Ulonivirine

CROI #516, #583

- In collaboration with Gilead, ISL and LEN once weekly Phase 2 non-inferior to B/F/TAF, high adherence, and well-tolerated (Abs #516)
- Phase 3 trials of ISL/LEN have completed enrollment
- Ulonivirine (ULO), a long half-life NNRTI like doravirine, has a complementary resistance profile to ISL (Abs #583)
- ISL/ULO in Phase 2/3 trials for naïve and switch

### Oral once monthly PrEP

MK-8527

#### Modeling to inform dose of MK-8527 for Phase 3 Trials

CROI #126

- MK-8527 is a translocation inhibitor like ISL
- 11mg once monthly achieves protective levels within an hour of dosing, has a 7-day forgiveness window for missed dose
- EXPRESSIVE 10 and EXPRESSIVE 11 Phase 3 trials of oral once monthly MK-8527 11mg underway

Late-Breaking

MERCK

Two drug simpler for treatment

Weekly or Monthly oral for treatment

Daily Oral DOR/ISL vs Biktarvy or complicated regimen

Weekly oral LEN/ISL 96 weeks same

Monthly oral MK-8527 EXPrESSIVE 10,11 Phase 3

# Women Living with HIV — CROI 2026 Focus



## Reproductive Health, Aging, Pharmacology & Sentinel Reports

Women now represent >50% of people living with HIV globally — yet remain underrepresented in clinical trials (CROI 2026 Plenary)

### Pharmacology & ART (Abs #167)

CROI #167

- Sex-based PK differences in long-acting agents — weight & BMI interactions
- CAB/RPV injectable safety in pregnancy — growing real-world data
- Lenacapavir PK in women: ARTISTRY sub-analyses pending
- Hormonal contraception + ART drug interactions updated

### Reproductive & Maternal (Abs #220)

CROI #220

- IMPAACT: ART safety in pregnancy, infant outcomes — updated
- Breastfeeding & HIV transmission in era of universal ART
- Dolutegravir neural tube defect risk: 5+ year surveillance data
- Fertility preservation for women on long-term HIV treatment

### FRESH Cohort — South Africa (Abs #312)

CROI #312

- Women identified at acute HIV infection in KwaZulu-Natal
- Early treatment + bNAb interventions — functional cure pathway
- Viral reservoir size in women — key data for cure research
- Equity-centered cure science in highest-burden setting

### Aging & Long-Term Health (Abs #345)

CROI #345

- Bone density: TDF vs TAF in postmenopausal women — 5-yr data
- Menopause interactions with HIV immune activation and inflammation
- Cardiovascular risk multiplier: HIV + menopause + long-term ART
- Frailty, multimorbidity & mental health in aging women with HIV

### PrEP for Women (Abs #78, #79LB)

CROI #78

- PURPOSE-1 & -2: lenacapavir PrEP in cisgender women — 100% efficacy data
- CAB PrEP adherence vs daily oral TDF/FTC in African women cohorts
- Dapivirine vaginal ring — updated sub-Saharan Africa access data
- Long-acting PrEP: unique appeal for women facing daily pill barriers

# Heart Health & HIV — Cardiovascular Risk Data



## Long-Term ART Effects, Inflammation & Sentinel Reports at CROI 2026

PLWH have 1.5–2× the cardiovascular risk of the general population — even on effective ART (CROI Plenary; D:A:D cohort Abs #388)

### Immune Activation & Inflammation (Abs #388)

CROI #388

- Persistent immune activation with undetectable VL drives CVD risk
- IL-6, D-dimer, sCD14 as CVD biomarkers in HIV — updated D:A:D data
- REPRIEVE trial follow-up: statins reduce MACE events in PLWH
- Gut microbiome translocation & systemic inflammation — new mechanistic data

### ART & Metabolic Effects (Abs #392)

CROI #392

- TAF vs TDF: weight gain, dyslipidemia, insulin resistance at 5 years
- INSTI class effect on weight gain — updated mechanistic & clinical data
- BIC/LEN switch: CVD risk markers vs continued B/F/TAF (ARTISTRY sub-analysis)
- Dolutegravir + cardiometabolic outcomes — large cohort update

### Aging Cohort Data (Abs #395)

CROI #395

- Veterans cohort: MI rates in PLWH vs HIV-unaaffected controls — 10-yr data
- Women & aging: menopause + HIV as compounding CVD risk factor
- Frailty, sarcopenia & cardiac risk in older PLWH — new endpoints
- Polypharmacy: ART + cardiac medication interactions — safety signals

### Preventive Strategies (Abs #396, #397)

CROI #396

- Statin therapy: expanded indication evidence — NNT data for PLWH under 50
- GLP-1 agonists (semaglutide) in PLWH: emerging cardiometabolic safety data
- Aspirin use — rethinking risk-benefit analysis in HIV-positive adults
- Exercise & lifestyle: community-based cardiac rehab data in PLWH

# Methamphetamine, Mental Health & HIV



## Critical Intersections: Substance Use, Adherence & Wellbeing — CROI 2026

*Meth use is surging in San Diego & nationally — directly impacting HIV incidence, ART adherence & outcomes (CROI Abs #430, #431; SDHIVC local data)*

### Meth & HIV Acquisition (Abs #430)

CROI #430

- Meth use associated with increased HIV incidence — updated national NHBS data
- Chemsex practices: meth, GHB, MDMA and HIV risk in MSM & TGW populations
- PrEP adherence severely compromised in active meth users — adherence data
- Long-acting CAB injectable PrEP: key advantage for PWUD who struggle with daily pills

### ART Adherence & Viral Outcomes (Abs #431)

CROI #431

- Meth use strongly linked to virologic failure and emergent drug resistance
- PLWH + meth: significantly higher hospitalization rates and opportunistic infections
- Long-acting injectables (CAB/RPV) as adherence solution for PWUD — outcome data
- Integrated harm reduction + HIV treatment: 12-month outcomes from pilot programs

### Mental Health in PLWH (Abs #445, #446)

CROI #445

- Depression & anxiety: 2–4× more prevalent in PLWH vs general population
- Depression independently predicts ART non-adherence and higher viral loads
- Integrated mental health + HIV care: significant outcome improvements at 12 months
- Stigma as structural driver of poor mental health — new measurement frameworks

### Treatment Interventions (Abs #447, #450)

CROI #447

- Contingency management for meth use disorder — expanding RCT evidence base
- Buprenorphine/naloxone for co-occurring opioid + stimulant use — safety data
- Community co-location: mental health services + HIV care — access & retention
- Yoga, mindfulness & wellness therapies — integrative care outcome data in PLWH

# Hope for the Future — Where Are We Headed?

Cure Research · Prevention Innovation · Equity & Access · A Generation Free of HIV

HIVC

## Annual PrEP

Phase 3 trial launched for once-yearly IM lenacapavir (Abs #79LB). If successful, the most durable HIV prevention tool in history.

CROI #79LB

## HIV Cure

FRESH cohort, bNAb strategies, CRISPR/gene therapy closer than ever (Abs #312, #401). First HIV remissions guiding next generation of trials.

CROI #312

## 4-Month ART

VH184, VH499, lotivibart + CAB all in pipeline (Abs #121LB, #418). Quarterly injectable ART may become standard of care by 2030.

CROI #121LB

## Global Equity

Generic DTG in 100+ LMICs. PURPOSE in Africa. Cure research centered in KZN. Science & access moving together (Abs #502).

CROI #502

## Whole Person Care

Integration of mental health, substance use, yoga & wellness into HIV care — beyond viral suppression (Abs #447, #450). SDHIVC model.

CROI #447

## End of HIV

The tools to end HIV transmission exist today. With sustained political will & community leadership, a generation free of HIV is achievable.

CROI #Plenary

# GLP-1 Agonists & STI Surge — Two Major Plenary Topics



## Sentinel Findings: Weight Loss Drugs in HIV · Syphilis Crisis · DoxyPEP Update

Plenary Session: Brown (Johns Hopkins) on GLP-1s + Marrazzo (IDSA) on Syphilis & Superbugs — two of the most-discussed sessions at CROI 2026

### GLP-1 Agonists in HIV — Are They Anti-Inflammatory? (Plenary)

- GLP-1s (semaglutide/tirzepatide) reduce weight AND inflammation in PLWH — key new data
- Randomized tirzepatide vs. placebo: ~48% reduction in CRP independent of weight loss
- Anti-inflammatory effect occurs before fat loss — suggests direct immunomodulatory benefit
- May address INSTI-related weight gain + residual immune activation simultaneously
- Source: Brown JT. CROI 2026 Plenary: Managed Healthcare

### NeuroHIV & Cognitive Aging (Poster Sessions E1–E4)

- HIV reservoir established in CNS — unclear which cells, how it differs from blood reservoir
- Cognitive decline persists in subset of PLWH despite viral suppression
- Depression & cognitive vulnerability: complex interaction of HIV, aging, ART & inflammation
- New biomarkers: CSF neurofilament light chain as early neurodegeneration marker

### STI Crisis: Syphilis, Superbugs & DoxyPEP (Plenary)

- Gonorrhea +37%, syphilis +155%, congenital syphilis +696% since 2015 — crisis level
- Women now 29% of new syphilis cases — syphilis no longer only affects MSM
- DoxyPEP: ~50% reduction in syphilis/chlamydia in MSM & trans women in SF data
- Antibiotic resistance emerging — WHO guidelines for DoxyPEP expected later in 2026
- Source: Marrazzo JM. CROI 2026 Plenary: CDC data: Managed Healthcare

### HIV Vaccine Progress (Wednesday Plenary)

- Kevin Saunders (Duke): 'Successes in HIV-1 Vaccine Design' — optimism from mRNA era
- Broadly neutralizing antibody (bNAb) vaccine platforms: inducing bnAbs via vaccination
- Germline targeting approaches: prime-boost strategies showing durable B-cell responses
- Progress notable but access to trial populations constrained by funding cuts

# ⚠️ The Funding Crisis: Science Under Threat — CROI 2026 Sentinel Session

"Sleepless in Denver" — Impact of PEPFAR/USAID Cuts on Global HIV Response (Themed Discussion Session, Feb 23, 2026)

**26M**

Lives saved  
by PEPFAR  
since 2003

**21M**

People on ART  
in sub-Saharan  
Africa via PEPFAR

**47%**

US clinics reporting  
service disruptions  
(rapid survey)

**\$1.9B**

Proposed FY2026  
cut to PEPFAR  
budget

## Peter Staley Opening Address (Martin Delaney Lecture)

- "Annus Horribilis" — most challenging year for HIV since early epidemic
- DOGE dissolved USAID; PEPFAR stop-work orders halted ART in sub-Saharan Africa overnight
- NIH workforce cut 18% in 2025; thousands of research grants cancelled
- Good news: Congress rejected proposed NIH reorganization; NIAID received an increase
- PEPFAR 'battered but standing' — continued pressure essential to prevent backsliding
- Source: Staley P. Martin Delaney Lecture, CROI 2026; POZ Magazine, Feb 24, 2026; Aidsmap, Feb 23, 2026

## "Sleepless in Denver" — Real-World Impact Data (Themed Discussion 04)

- Jennifer Kates (KFF): 'fundamental rupture' in global HIV service delivery
- Rapid survey of 32 countries: 71% of PEPFAR partners cancelled ≥1 category of services
- Brazier et al: disruption linked to reduced ART, PrEP, CD4/VL testing access (Abs #1051)
- Filiatreau et al: population-level consequences for HIV services in South Africa (Abs #1054)
- Modelling: PEPFAR pause could cause 10,000+ additional infections over 5 years (Lancet HIV 2025)
- Source: Kates J. CROI 2026 Themed Discussion 04; Aidsmap, Feb 24, 2026; Lancet HIV 2025

# Sentinel Reports & Key Take-Aways



## Other Important Findings — CROI 2026, Denver, February 22–25

### Epidemiology & Surveillance (CROI 2026 Program)

- US HIV incidence: plateauing in MSM, rising in Black women & women overall (CDC/NHBS data)
- 50%+ of US PLWH now over 50 — care systems must adapt to aging epidemic
- Pediatric/adolescent HIV: dedicated sessions on prevention, treatment, cure in children
- Global: eastern Europe & Central Asia fastest growing epidemic; PEPFAR cuts compound crisis
- Source: CROI 2026 Program; AVAC CROI Summary, Feb 25, 2026; AJMC, Feb 18, 2026

### Community Implementation Science (CROI SEARCH + AVAC data)

- SEARCH study (Chamie): digital tools + community health workers → 70% HIV incidence reduction
- Malawi CAB-LA PrEP: 61% continuation at month 1 vs. 21% for oral PrEP — major adherence win
- Taxi driver self-testing distribution: 2,474 kits/12 months, 97% used — community models work
- Thailand Tangerine Clinic: community data drove gender-affirming services into national insurance
- Source: AVAC CROI 2026 Day 3 Summary, Feb 25, 2026; CROI Program Session on Implementation

### STIs, Mpox & Co-Infections (Plenary + Poster Session G1)

- Syphilis +155%, gonorrhea +37%, congenital syphilis +696% since 2015 — syndemic level
- DoxyPEP: ~50% syphilis/chlamydia reduction in MSM/TGW but resistance signals emerging
- Mpox poster session G1: pathogenesis, clinical predictors, vaccine & antiviral resistance
- PLWH have more severe mpox outcomes — management guidance updated
- Source: Marrazzo JM CROI 2026 Plenary; Managed Healthcare Executive, Feb 26, 2026; CROI Program

### San Diego Relevance & SDHIVC Connection

- DoxyPEP SF data: 51%/49% syphilis-chlamydia reductions — directly applicable to SD practice
- GLP-1 anti-inflammatory data: relevant for PLWH in SD with weight/CVD concerns
- Funding crisis: SD clinics likely among 47% reporting service disruptions nationally
- Get Tested checklist: aligns with CROI prevention & STI screening consensus
- Source: AVAC, Aidsmap, POZ, Managed Healthcare Executive — CROI 2026 coverage, Feb 2026