AETC AIDS Education & Training Center Program Mountain West

What's New in ART?
Novel Medications & Treatment Strategies for Adults with HIV

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No conflicts of interest or relationships to disclose.

I will discuss investigational therapies.

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Session Aims

1. Review updated data on the latest ARVs, including long-acting agents
2. Discuss implementation barriers and new models for delivery of the latest ART
3. Highlight ongoing studies and future directions for HIV treatment, including the pipeline of new drugs and drug combinations

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The Latest ART
FDA Approvals & Indications, Last 3 Years

Fostemsavir

- Attachment inhibitor
- Approved July 2020
- Oral twice-daily
- Heavily treatment-experienced with few remaining ARV options

Cabotegravir/Rilpivirine

- Long-acting INSTI/NNRTI
- IM every 1 month approved 2021; IM every 2 months approved 2022
- 2022 label update: oral lead-in optional
- Virologically suppressed with no resistance to components and no HBV

Lenacapavir

- Capsid inhibitor
- Approved Dec. 2022
- SubQ every 6 months
- Heavily treatment-experienced with few remaining ARV options

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The Future of ART
What's in the Pipeline?

Potential Expanded Indications or Uses for Approved Agents

- IM cabotegravir/rilpivirine in setting of viremia
- SubQ lenacapavir as part of initial ART
- New models for delivery of long-acting ART
- Specific ART switches for cardiometabolic effects

Novel Combination Tablets

- Lenacapavir/bictegravir oral daily
- Doravirine/islatravir (NRTTI) oral daily
- Lenacapavir/islatravir oral weekly
- Islatravir/ulonivirine (NNRTI) oral weekly

New Long-Acting Agents

- Broadly neutralizing antibodies (bNAbs)
- Lenacapavir with bNAbs
- Dual-affinity retargeting (DART) proteins
- Maturation inhibitor
- Long-acting, nanoparticle forms of existing ARVs

What would you prioritize for the future of HIV treatment?

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Potential Expanded Indications and Models for Delivering Long-Acting Cabotegravir/Rilpivirine

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Poll

For your patients/clients who have expressed interest in IM cabotegravir/rilpivirine but not initiated it, what has been the most frequent reason for not starting it?

A) Cost/coverage issues or logistical barriers

B) Clinical factors (drug resistance, hepatitis B, viremia)

C) Preference (opted to continue oral ART)

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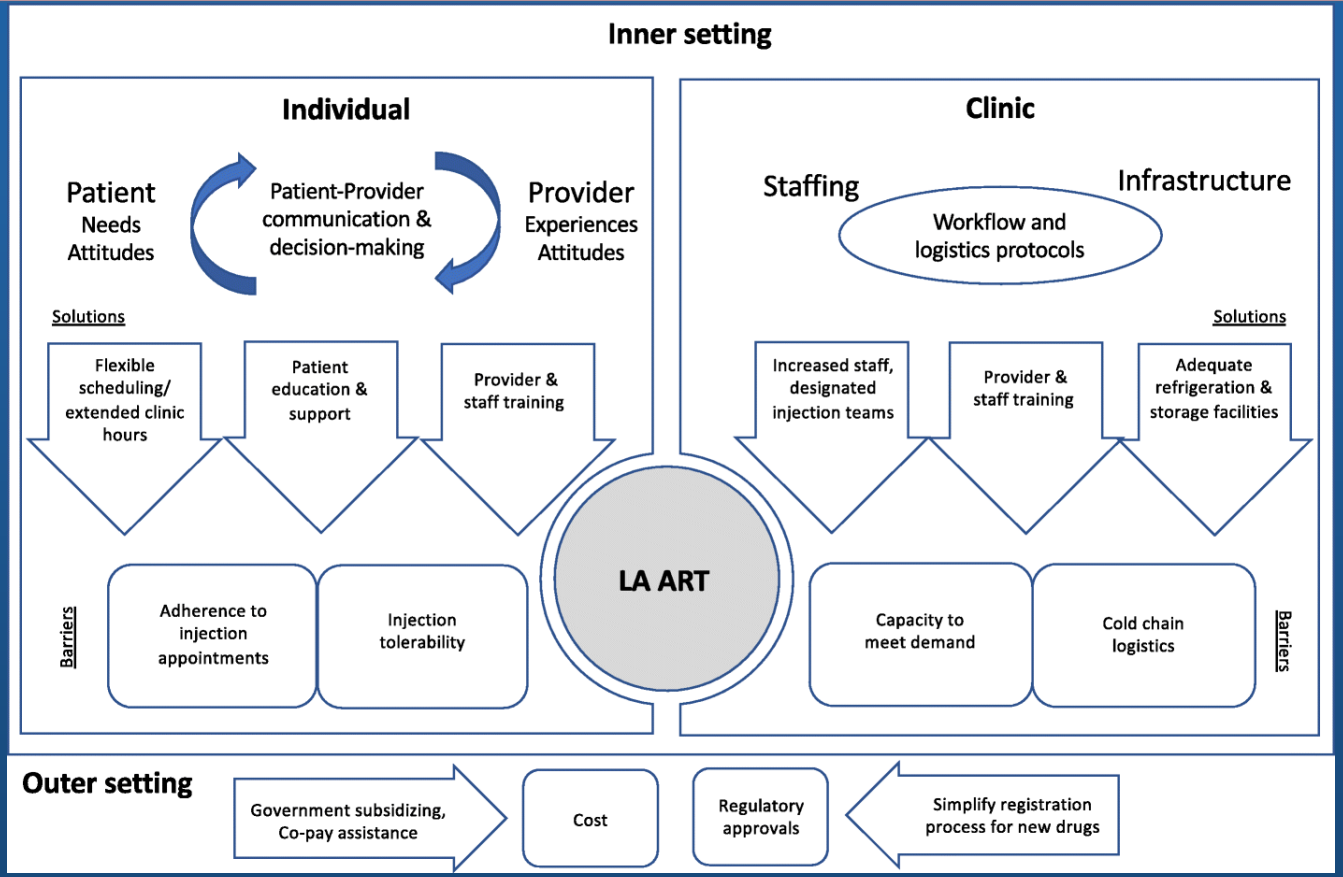
What is Required to Implement Long-Acting ART?

See excellent talk by Ji Lee, PharmD:
https://www.youtube.com/watch?v=xPB50GXSr3w&t=25s



Source: Mantsios A, et al. BMC Health Services Research 2021.

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LAI CAB/RPV with Detectable Viremia or History of Barriers to Adherence
Summary of Data to Date

Study	Method	Setting; Participants	Key Findings
UCSF Ward 86 (Gandhi M, Ann Int Med 2023)	Single center, single arm, open label	Urban academic safety-net clinic; publicly-insured patients with or without VL suppression	76/76 (100%) maintained suppression; 54/57 (95%) achieved suppression; 2 early virologic failures (1.5%)
OPERA (Hsu RK, ID Week 2023)	Observational cohort	ART-experienced adults with or without viremia (229 with VL ≥50, 93 with VL ≥200); median VL 2.1 log copies/mL	82% achieved any VL <50, 75% VL <50 at study end; 7 virologic failures (4%)
JABS (John M, IAS 2023)	Single center, single arm, open label	ART experienced adults with virologic suppression, complex medical needs, social vulnerability, historic adherence challenges	53/54 maintained VL <50 (1 participant VL 55); no virologic failures
Compassionate use (D'Amico R, HIV Med 2023)	Retrospective review	Inability to adhere to oral ART due to psychological or gastrointestinal issues	16/28 achieved and 6/7 maintained suppression; 10 developed new resistance
Other	Case series/studies	Brock JB, CID 2023 – n = 12 Kilcrease C, AIDS Res Ther 2022 – n = 3 Barnett SK, AIDS 2022 - n = 1	12/12 achieved suppression 2/3 achieved suppression 1/1 achieved suppression

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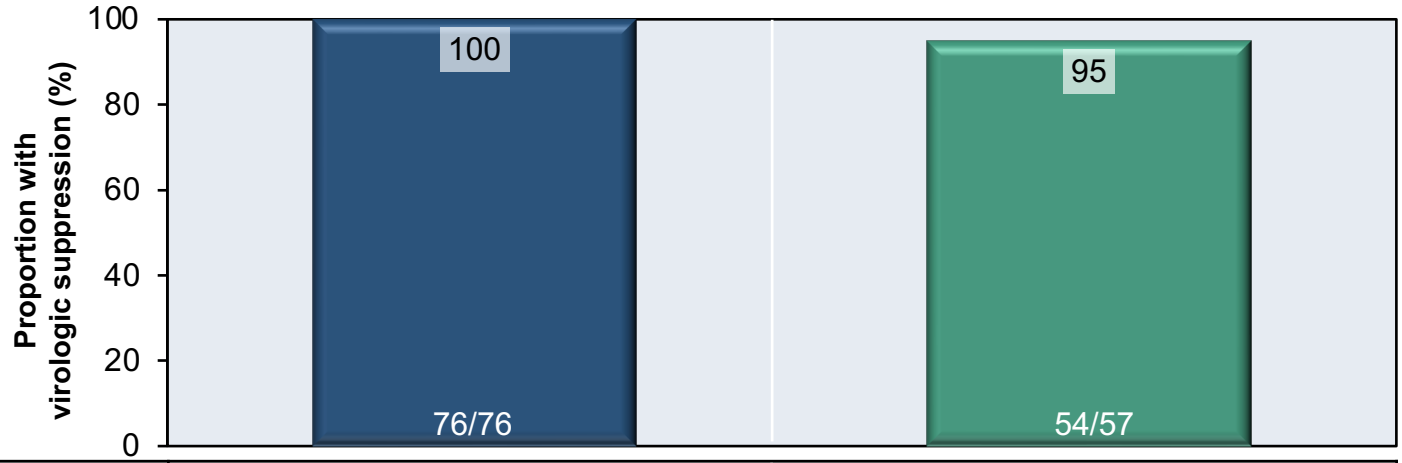
Demo Project of LAI CAB/RPV With or Without Detectable Viremia
Results (at Median Follow-Up 33 Weeks)



	Baseline HIV RNA <30 copies/mL	Baseline HIV RNA ≥30 copies/mL
Median # injections (range)	7.5 (1-17)	7 (2-18)
Changed off LA CAB-RPV	5 chose to resume oral ART due to injection site reactions, 3 due to difficulties adhering to clinic visits	2 early virologic failures, plus 1 with VL 182 copies/mL after 5 injections who added LEN to CAB/RPV; also 1 with BMI 32 suppressed then later rebounded and re-suppressed on oral DRV/cobi/TAF/FTC

Source: Gandhi M, et al. Annals of Intern Med, July 2023.

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Demo Project of LAI CAB/RPV With or Without Detectable Viremia
Results

2 Participants in Baseline Viremia Group with Virologic Failure Despite On-Time Injections	
#1	• Decrease in VL <2 $\log_{10}$ at first maintenance injection (215k to 39k copies/mL) • Genotype: new L100I → long-acting ART discontinued • Later genotype: also showed new Y181 • Risk factors: baseline V179V/I, rifabutin use 2 weeks before LAI CAB/RPV start
#2	• Decrease in VL <2 $\log_{10}$ at first maintenance injection (137k to 4,300 copies/mL) • VL at 3rd injection <30 copies/mL, but genotype showed new E138K and R263K • Risk factors: baseline minor INSTI mutation (T97A)

Source: Gandhi M, et al. Annals of Intern Med, July 2023.

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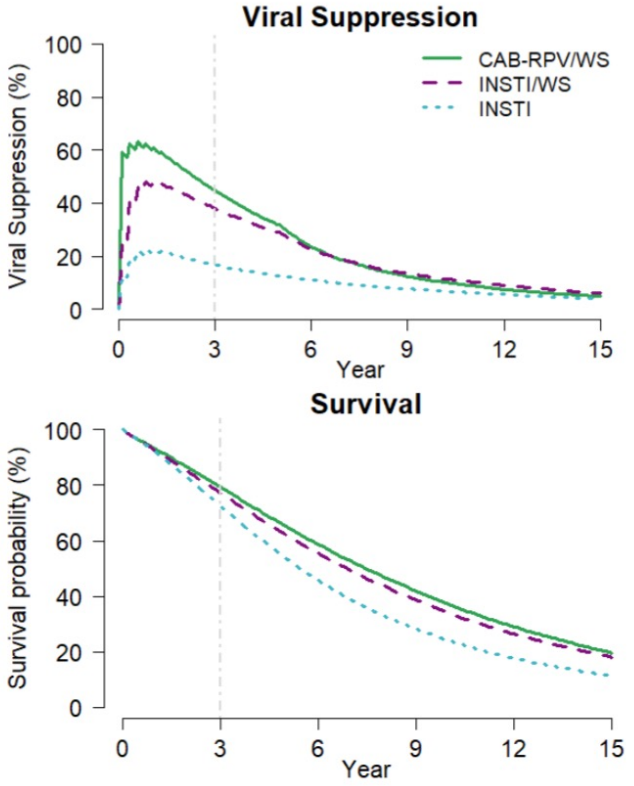
Projected Benefits of LAI CAB/RPV for Non-suppressed PWH Experiencing Barriers to Oral ART Adherence

- Comparison of INSTI vs. INSTI with wraparound services (WS) vs. LAI CAB/RPV with WS
- Simulation of participants similar to non-suppressed PWH in Ward 86 study (mean CD4 150 cells/μL, SD 75)
- **Projected viral suppression: 16% INSTI, 38% INSTI/WS, 44% CAB/RPV WS**
- Life expectancy: 7.4 LY INSTI, 9.4 LY INSTI/WS, 9.4 LY CAB/RPV WS



Source: Chen W, et al. OFID 2023 and CROI 2023.

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HHS Adult and Adolescent HIV Treatment Guidelines
New Recommendation & New Study

- "The Panel **recommends against** the use of the long-acting ART regimen of intramuscular CAB and RPV in people who have detectable viral load due to suboptimal adherence to ART and who have ongoing challenges with retention in HIV care, except in a clinical trial (AIII)"

- Ongoing clinical trial: **ACTG 5359 (LATITUDE)**
  https://actgnetwork.org/studies/a5359-the-latitude-study/

- **And new study coming! Stay tuned…**

Source: Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV (http://clinicalinfo.hiv.gov)

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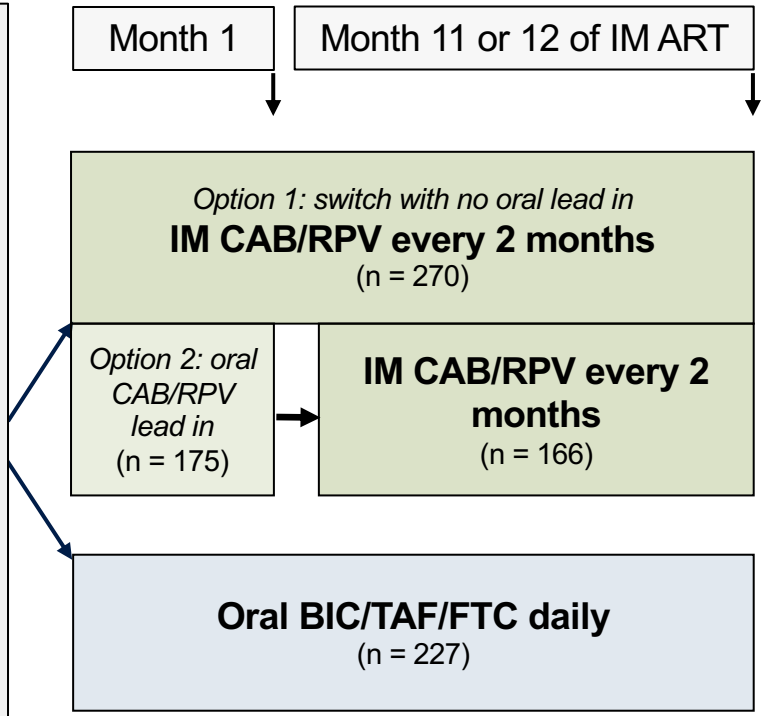
Switch to IM CAB/RPV versus Continued BIC/TAF/FTC
SOLAR: Study Design

- **Background:** Randomized, multicenter, active-controlled, open-label, phase 3b, non-inferiority study designed to evaluate the efficacy and safety of switching to long-acting, intramuscular cabotegravir/rilpivirine versus continuing daily, oral, fixed-dose bictegravir/TAF/FTC
- **Inclusion Criteria**
  - Age ≥18 years
  - Taking bictegravir/TAF/FTC as a first or second regimen
  - No history of non-INSTI-based ART
  - No known or suspected resistance to study drugs
  - HIV RNA <50 copies/mL for at least 6 months
  - If pregnancy potential, agreed to contraception
- **Regimens (2:1 randomization)**
  - CAB/RPV (600/900 mg) IM (oral lead-in period optional)
  - Bictegravir/TAF/FTC (50/25/200 mg) daily



Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

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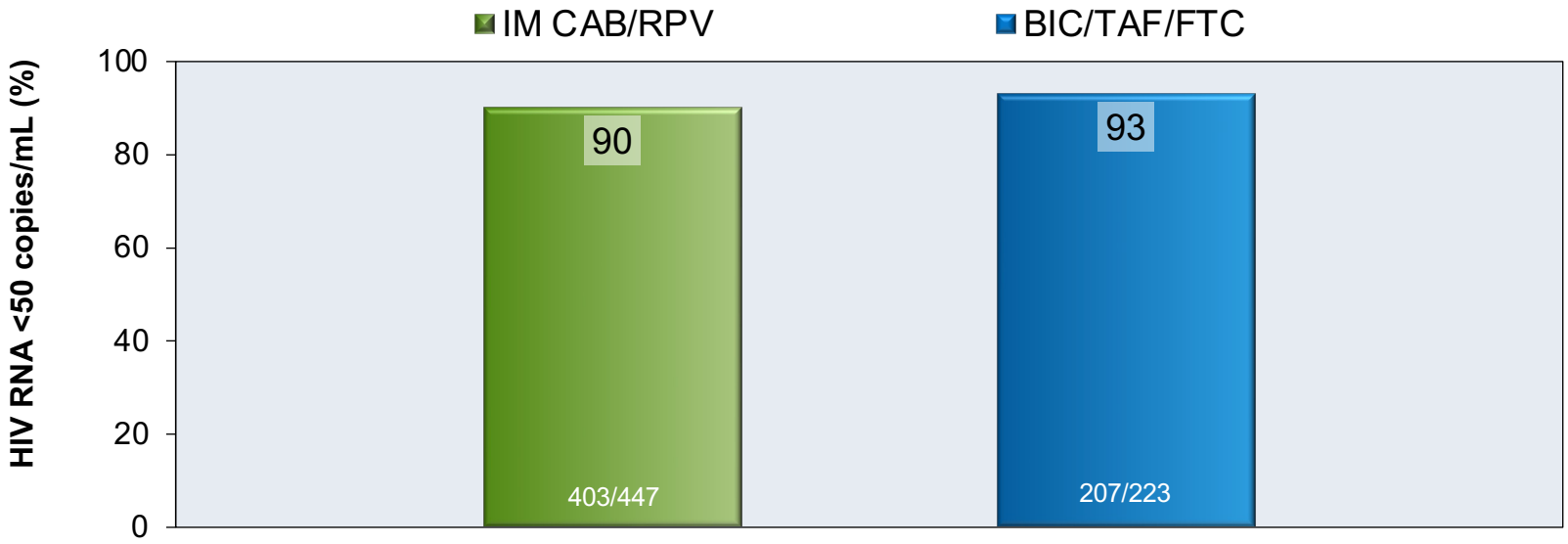
Switch to IM CAB/RPV versus Continued BIC/TAF/FTC
SOLAR: Results

Virologic Response (Modified Intention-to-Treat Analysis) at Month 11-12



*2 confirmed virologic failures in IM CAB/RPV arm, versus 0 in BIC/TAF/FTC arm
VF with CAB/RPV: on-time injections, good drug levels, 1 with CAB RAMs on PBMC genotype, 1 with RPV RAMs

Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

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Switch to IM CAB/RPV versus Continued BIC/TAF/FTC
SOLAR: Cardiometabolic Results at Month 12

- No significant difference between study arms when comparing:
  - Change in weight or BMI
  - Change in waist or hip circumference, waist-to-hip ratio, waist-to-height ratio
  - Proportion with insulin resistance, abdominal obesity, or metabolic syndrome

Parameter	Switch to IM CAB/RPV	Continue BIC/TAF/FTC
Median change in weight (kg)	-0.40 (-2.95, +2.10)	+0.05 (-2.30, +1.95)

Source: Tan DHS, et al. CROI 2023.

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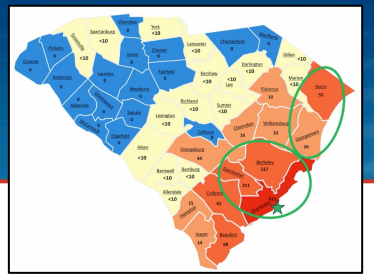
IM CAB/RPV at Home or In Clinic: Demonstration Project
Study Design



- 12-month intervention; first dose in clinic; then participant decides
- Meds obtained through insurance; cost of administration covered by study
- At home: drug delivered to patient, stored in refrigerator, LPN visit for injection
- 33 participants (30 completed, 3 ongoing)
  - 15 chose at-home, 18 chose in-clinic injections
  - No difference in mean days between injections, VL suppression
  - **Crossover was infrequent**
  - 3 switches to oral ART (1 VF, 1 provider decision, 1 possible allergic reaction)
- Conclusion: explore ways to make IM CAB/RPV accessible in non-clinic settings

Source: Meissner E, et al. ID Week 2023.

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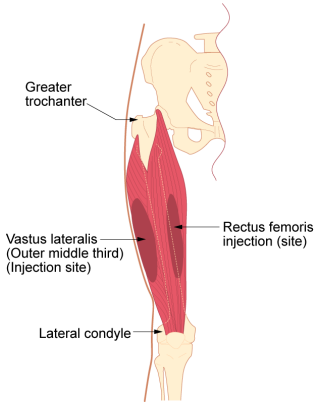
Alternate Anatomic Site of Administration
ATLAS-2M Thigh PK Study

- Participants on LA CAB/RPV ≥3 years by IM gluteal injection volunteered for **16-week IM thigh (vastus lateralis)**: N = 118 (Q4W: n = 64; Q8W: n = 54)
- **Results:**
  - Plasma trough concentrations remained above protein-adjusted IC90s
  - Plasma concentration differences not clinically relevant
  - No serious AEs; pain most common ISR
    - ISRs: mostly grade 1/2; 4% to 7% grade 3; 3.0-3.5 days
    - 1 participant withdrew for injection site pain (grade 2; Q8W arm)
  - **No VF;** high suppression rates maintained (Q8W, 94.4%; Q4W, 95.3%)
  - **~60% preferred gluteal injections** (less pain)



Source: Felizarta F, et al. CROI 2023. Image from: BC Open Textbooks.

Lenacapavir

Poll

How many of your patients/clients are currently receiving lenacapavir?

A) 0

B) 1-2

C) 3 or more

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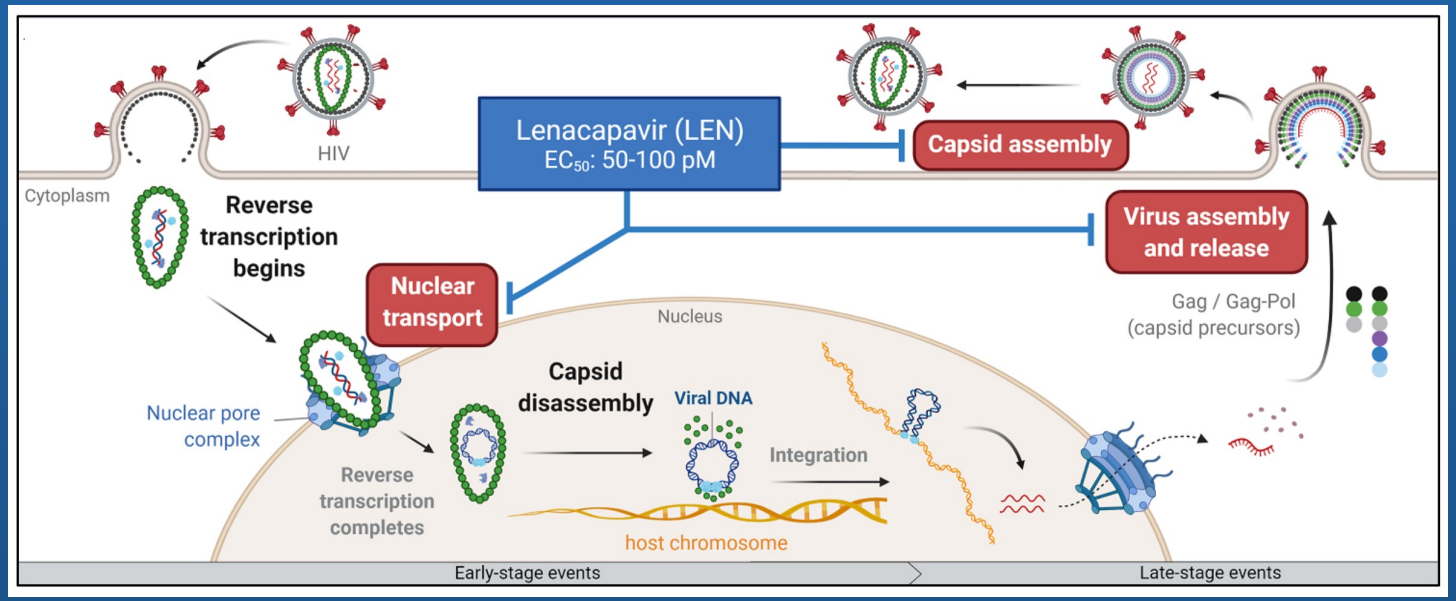
Lenacapavir (LEN)
Capsid Inhibitor: Mechanism

See David Spach's amazing talk:
https://www.youtube.com/watch?v=9IbzMbfEMIY&t=784s



Mechanism: binds to capsid, interferes with transport via nuclear pores, stabilizes shell and inhibits disassembly, plus distorts the capsid lattice resulting in abnormal structure that prevents viral maturation

Dosing: oral daily or weekly, or subcutaneous (SC) every 6 months (half-life 10-12 days oral, 8-12 weeks SC)

Sources: Molina JM et al. IAS 2021. clinicalinfo.hiv.gov

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Subcutaneous (SC) or Oral Lenacapavir (LEN)
Phase 2/3 Treatment & PrEP Studies

- **Treatment Trials**
  - CAPELLA: SC LEN plus OBR for heavily treatment-experienced PWH
  - CALIBRATE: SC or oral LEN with oral ART for treatment-naïve
- **PrEP Trials**
  - PURPOSE 1: SC LEN vs oral TAF/FTC for cisgender young women
  - PURPOSE 2: SC LEN vs oral TDF/FTC for cisgender men, transgender women, transgender men, gender non-binary individuals

December 2021: FDA hold (vial incompatibility)

May 2022: Hold lifted for all trials

December 2022 Approved by FDA

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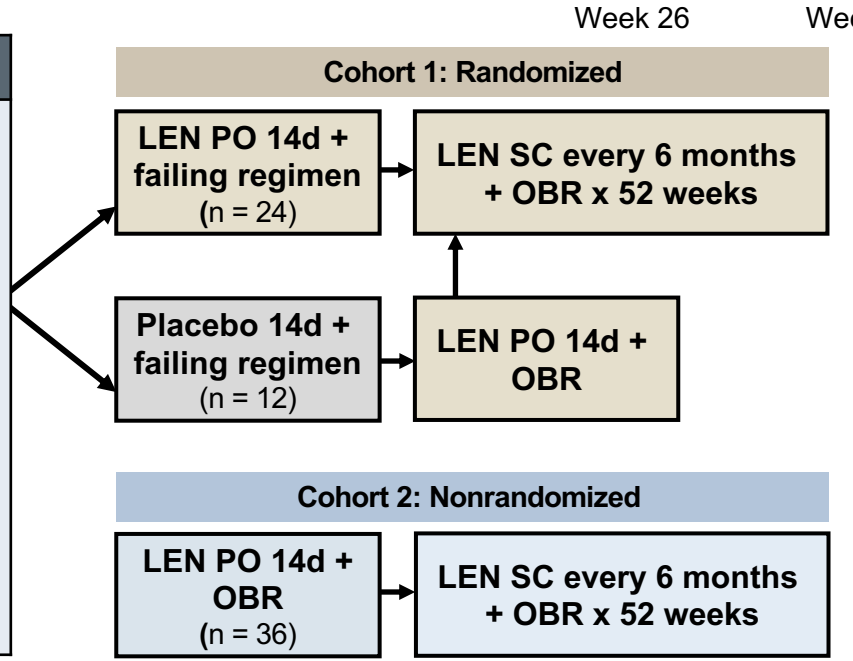
Lenacapavir (LEN)
CAPELLA Study: Background

Study Design: CAPELLA

- **Background**:
  - Phase 3, randomized controlled trial of lenacapavir plus OBR for heavily treatment-experienced PWH
- **Enrollment Criteria:**
  - Highly ART-experienced, age ≥12
  - Virologic failure on current ART
  - HIV RNA ≥400 copies/mL
  - Resistance to ≥2 agents from ≥3 of 4 main ARV classes
  - ≤2 predicted active agents



*Oral LEN for 14d = 600 mg day 1 & day 2 then 300 mg day 8; LEN SC = 927 mg (2 x 1.5 mL in abdomen)
*SC = subcutaneous; OBR = optimized background regimen

Source: Segal-Maurer S, et al. N Engl J Med. 2022;386(19):1793-1803.

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Lenacapavir (LEN)
CAPELLA Study: Results

Participant Characteristic	Total n = 72
Age, median (range), years	52 (23-78)
Sex, % female at birth	25
Race, % Black	38
Ethnicity, % Hispanic/Latinx	21
HIV RNA, median (range), log_{10} copies/mL	4.5 (1.3-5.7)
HIV RNA >75,000 copies/mL, %	28
CD4 count, median (range), cells/mm^3	150 (3-1296)
CD4 count $\leq$200 cells/mm^3, %	64
# of fully active agents in OBR, %	
0	17
1	39
$\geq$2	44

Source: Segal-Maurer S, et al. N Engl J Med. 2022;386(19):1793-1803.

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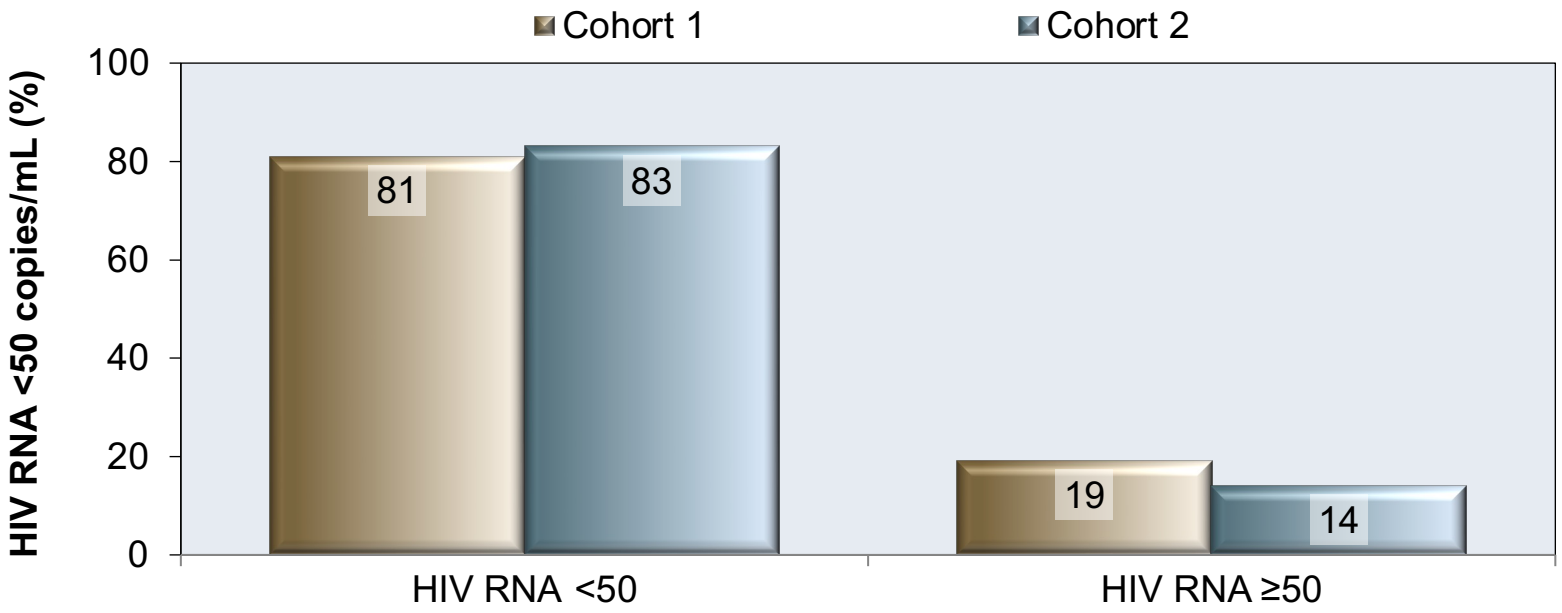
Lenacapavir (LEN)
CAPELLA Study: Results

Virologic efficacy results at 26 weeks



*In both cohorts, capsid RAMs developed in 8 participants (mostly M66I)

Source: Segal-Maurer S, et al. N Engl J Med. 2022;386(19):1793-1803.

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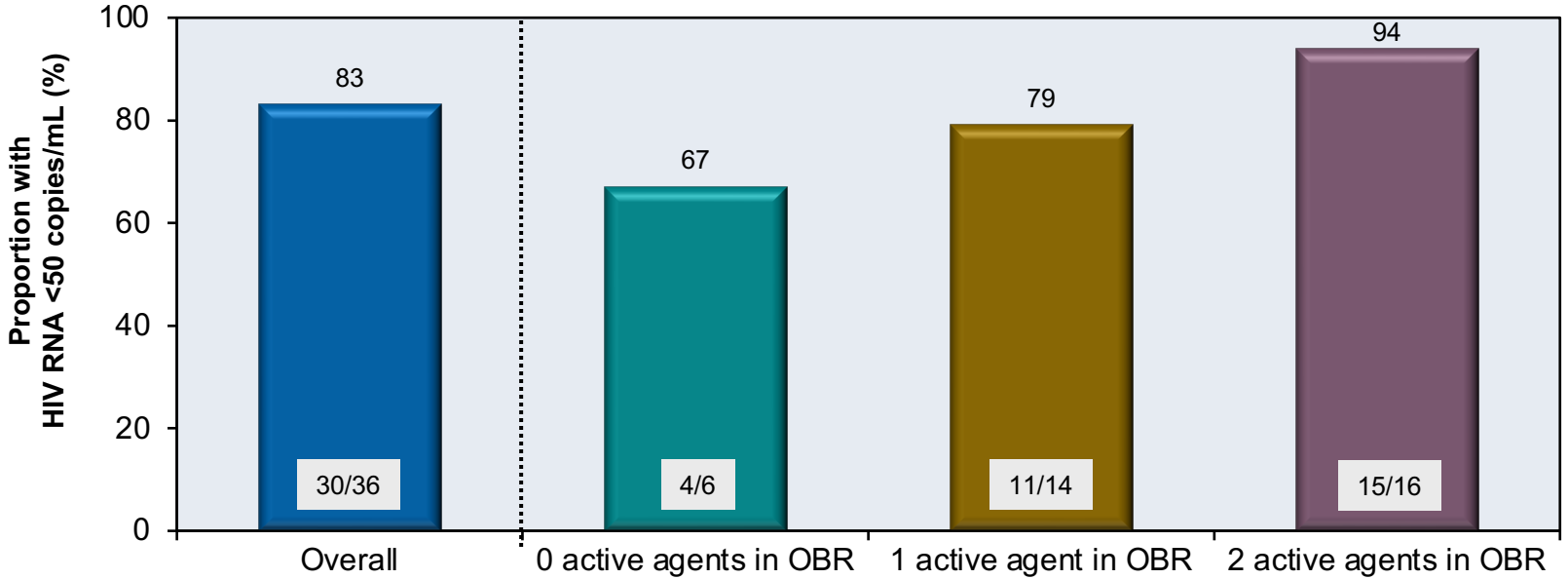
Lenacapavir (LEN)
CAPELLA Study: Results

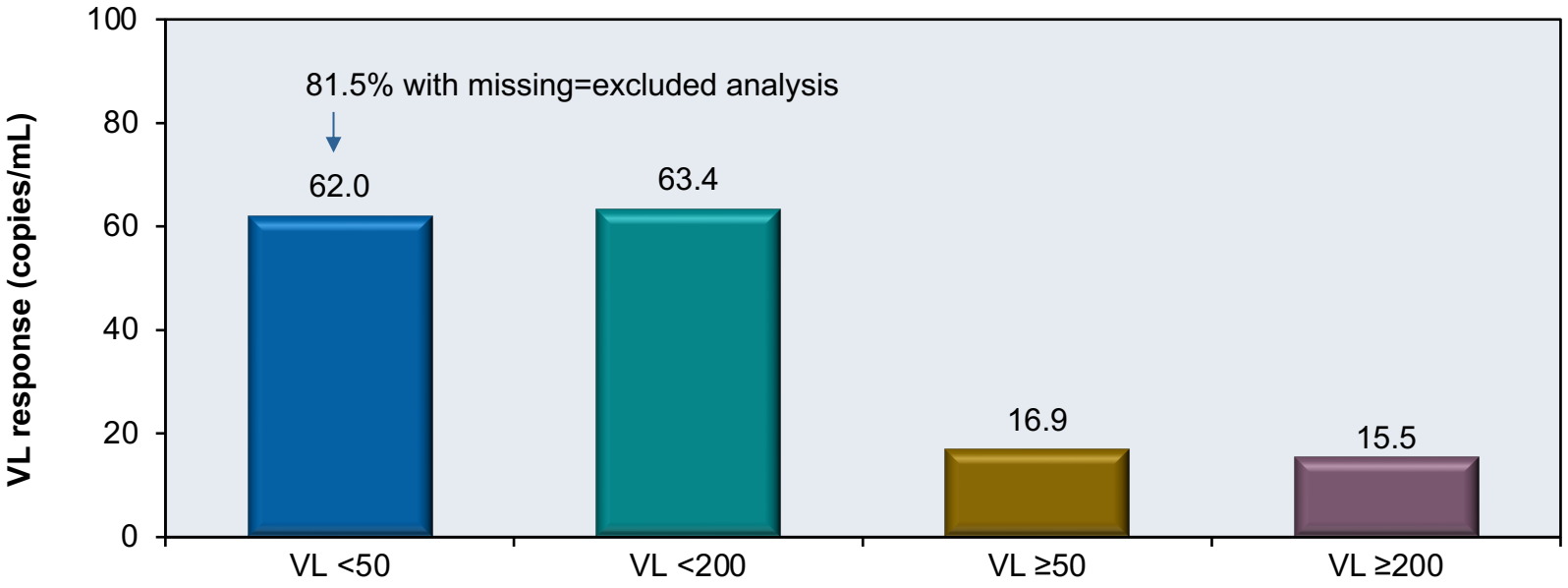
Virologic efficacy results at 52 weeks (randomized cohort)



Source: Ogbuagu O, et al. CROI 2022. Abstract 491.

Lenacapavir (LEN)
CAPELLA Study: Week 104 Results

Virologic efficacy results at 104 weeks (both cohorts, FDA snapshot analysis)



Source: Ogbuagu O, et al. ID Week 2023.

Lenacapavir (LEN)
CAPELLA Study: Week 104 Results

Virologic efficacy results at 104 weeks

Virologic Result	
Emergent LEN resistance (RAMs): M66I, Q67H/K/N, K70H/N/R/S, N74D/H/K, A105S/T, T107A/C/N/A	14
No fully active agents in OBR	4
Inadequate adherence to OBR	10
Resuppressed on LEN after LEN resistance emerged	
Yes	7
With OBR change	2
Without OBR change	5
No	7
Continued study drug	4
Discontinued study drug for reasons not related to efficacy	3

Source: Ogbuagu O, et al. ID Week 2023.

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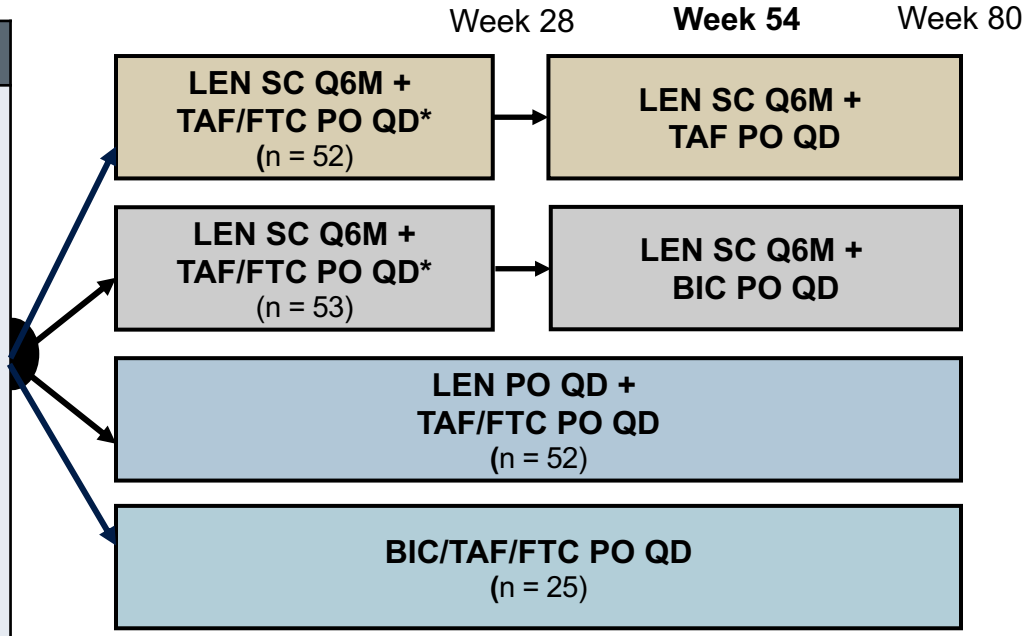
Lenacapavir (LEN)
CALIBRATE Study: Background

Study Design: CALIBRATE

- **Background**:
  - Phase 2, randomized, open-label trial of lenacapavir (LEN) plus NRTI(s) vs BIC/TAF/FTC for treatment-naïve PWH
- **Enrollment Criteria:**
  - ART-naïve adults
  - HIV RNA ≥200 copies/mL
  - CD4 ≥200 cells/mm^3
  - No active HCV or HBV
- **Primary Outcome:**
  - Proportion with HIV RNA <50 copies/mL at week 54



*Oral lead-in: oral LEN for 14d (600 mg day 1 & day 2 then 300 mg day 8)
*Transition to LEN SC if HIV RNA <50 copies/mL proximal to week 28
*LEN subcutaneous (SC) = 927 mg (2 x 1.5 mL in abdomen)

Source: Gupta S, et al. CROI, Feb 2022. Abstract 138.

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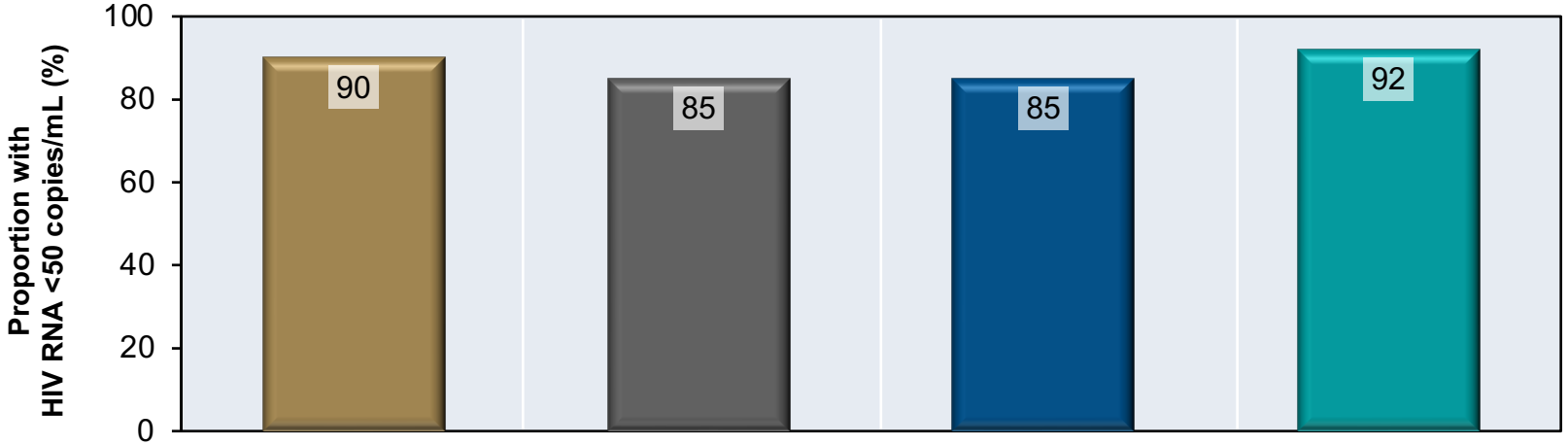
Lenacapavir (LEN)
CALIBRATE: Phase 2 Treatment-Naïve Trial (Week 54 Results)



	SC LEN + TAF	SC LEN + BIC	PO LEN + FTC/TAF	BIC/FTC/TAF
Participants, n	52	53	52	25
Confirmed VF, n	1	1	3	1
New RAM(s), n	0	1, Capsid: Q67H, K70R RT: M184V/I	1, Capsid: Q67H	0

Source: Gupta S, et al. CROI, Feb 2022. Abstract 138.

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Lenacapavir (LEN) Updates

Study, Conference	Principal Findings
Lat A, et al. ID Week 2023.	Typical injection site is abdomen, but alternative sites worked well (thigh, upper arm, gluteal region)
Jogiraju V et al. IAS 2023.	Participants in CAPELLA (n=57) and CALIBRATE (n=82) received weekly oral LEN 300 mg during FDA clinical hold of subcutaneous LEN (December 2021-May 2022) and did well
Kumar PK, et al. ID Week 2023.	In CALIBRATE, weight and BMI changes no different after 80 weeks when comparing: - SC LEN+PO TAF - SC LEN+PO BIC - PO LEN+TAF/FTC - BIC/TAF/FTC

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Reminders from the Lenacapavir FDA Package Insert

- Two different initiation options
- Two 1.5 mL injections required for complete dose
- Missed dose: repeat initiation if more than 28 weeks passed
- Residual drug levels may remain in system for ≥12 months
- Drug-drug interactions: substrate of CYP3A4, P-gp, UGT1A1; moderate inhibitor of CYP3A4

Initiation Option 1	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Initiation Option 2	
Day 1	600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Day 8	300 mg orally (1 x 300 mg tablet)
Day 15	927 mg by subcutaneous injection (2 x 1.5 mL injections)
Maintenance	
927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/-2 weeks.	

Source: Lenacapavir FDA Package Insert

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Islatravir

Islatravir (ISL)
NRTTI: Mechanism, Advantages, & Lymphocyte Toxicity

Translocation Inhibition

- Translocation inhibition prevents opening of the RT nucleotide binding site
- Nucleotides cannot be incorporated into vDNA
- **Viral replication is inhibited**

Delayed Chain Termination

- ISL changes vDNA structure such that nucleotide incorporation is prevented
- As ISL is not in the RT active site, it is not susceptible to resistance-conferring mutations
- **Viral replication is inhibited**

December 2021:
FDA hold due to decreases in total lymphocytes & CD4 T cells (high cellular levels of ISL-TP cause apoptosis)

September 2022:
Hold lifted for treatment trials with lower ISL dose

- Active against isolates with pre-existing NRTI resistance
- Potent viral load reduction plus high barrier to resistance
- Potential daily, weekly, or monthly oral dosing

Sources: McComsey G. CROI 2020. Markowitz M, Sarafianos SG. Curr Opin HIV AIDS. 2018;13(4):294-299. Amblard F et al. Eur J Med Chem. 2022;240:114554.

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Islatravir (ISL) Lymphopenia

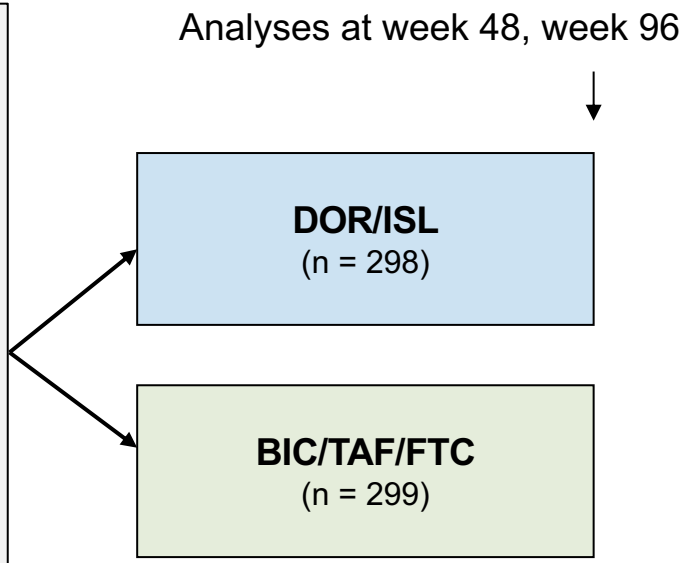
011 Study: phase 2 RCT that compared DOR/ISL to DOR/TDF (with 3TC for first 24 weeks) for treatment-naïve PWH; change to laboratory parameters at 72 weeks			
ARV	**Total Lymph**	**CD4 T Cell**	**B Cell**
TDF	+16%	+60%	+108%
ISL 0.25 mg	+20.5%	+80%	+90%
ISL 0.75 mg	-0.4%	+47%	+55.5%
ISL 2.25 mg	-16%	+24%	+7.5%

- Changes dose-dependent, reversible, not associated with increased infections
- Equal virologic efficacy at 96 weeks; 0.25 mg predicted active against M184V/I
- Similar trends in phase 3 studies (treatment-naïve, switch, and with OBR for HTE)

Sources: Correll TA, et al. HIV Drug Therapy, Glasgow, UK, 23-26 October 2022.
Vargo R, et al. HIV Drug Therapy, Glasgow, UK, 23-26 October 2022.
Molina J-M, et al. J Aquir Immune Defic Syndr. 2022 Sep 1;91(1):68-72.

MK-020: DOR/ISL (100 mg/0.75 mg) vs. BIC/TAF/FTC as Initial ART
Study Design

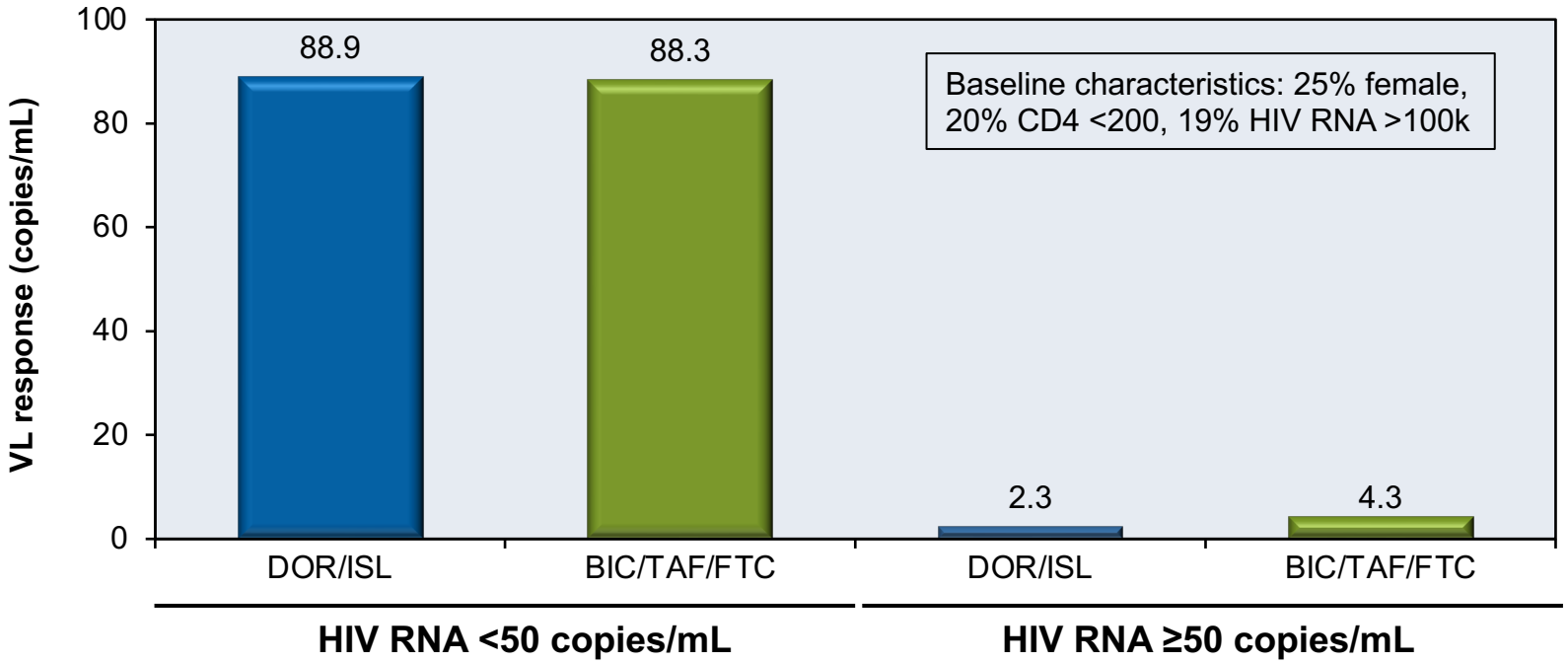
- **Background**: Randomized, double-blind, phase 3 trial comparing doravirine/islatravir (DOR/ISL) to bictegravir/tenofovir alafenamide/emtricitabine (BIC/TAF/FTC) for treatment-naïve PWH
- **Inclusion Criteria** (n = 597)
  - Antiretroviral-naïve
  - Age ≥18 years
  - HIV RNA ≥500 copies/mL
  - No resistance to study drugs
  - No HBV
- **Treatment Arms**
  - DOR/ISL (100 mg/0.75 mg) once daily
  - BIC/TAF/FTC once daily



Source: Rockstroh J, et al. IAS 2023.

MK-020: DOR/ISL (100 mg/0.75 mg) vs. BIC/TAF/FTC as Initial ART Results

Virologic Efficacy Results at Week 48



Source: Rockstroh J, et al. IAS 2023.

MK-020: DOR/ISL (100 mg/0.75 mg) vs. BIC/TAF/FTC as Initial ART
Results

Protocol-Defined Virologic Failures				
Arm	**Week**	**Response**	**Treatment-Emergent RAS**	**Phenotype**
DOR/ISL	24	Incomplete	NNRTI: V106A, P225H; NRTI: M184I	DOR resistance
BIC/TAF/FTC	8	Rebound	None	Susceptible
BIC/TAF/FTC	36	Rebound	No result	Unavailable
BIC/TAF/FTC	24	Incomplete	None	Susceptible
BIC/TAF/FTC	36	Incomplete	No result	Susceptible

- Similar rates of AEs and serious AEs (except DOR/ISL higher rates of lymphocyte count decrease)
- Mean change in weight: DOR/ISL +3.45 kg (95% CI 2.83-4.06), BIC/TAF/FTC +3.32 kg (95% CI 2.86-3.96)
- *Switch to DOR/ISL: weight/body composition changes similar to other ART, unless switch off TDF or EFV

Sources: Rockstroh J, et al. IAS 2023. *McComsey G, et al. IAS 2023.

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Islatravir (ISL) Oral 0.25 mg Daily or 2 mg Weekly

Phase 2/3 Treatment Studies Launched or Active in 2023

- **Initial ART**
  - MK-053: daily DOR/ISL vs. BIC/TAF/FTC for treatment-naïve PWH
- **ART Switch Trials**
  - MK-051: DOR/ISL daily vs. continue 3-drug ART
  - MK-052: DOR/ISL daily vs. continue BIC/TAF/FTC
  - MK-054: DOR/ISL 0.25 mg daily for participants of 0.75 mg studies
  - GS-6041: Switch to weekly LEN/ISL vs. continue BIC/TAF/FTC

DOR/ISL & LEN/BIC: last new daily oral options in the pipeline?

Source: clinicaltrials.gov

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Broadly Neutralizing Antibodies

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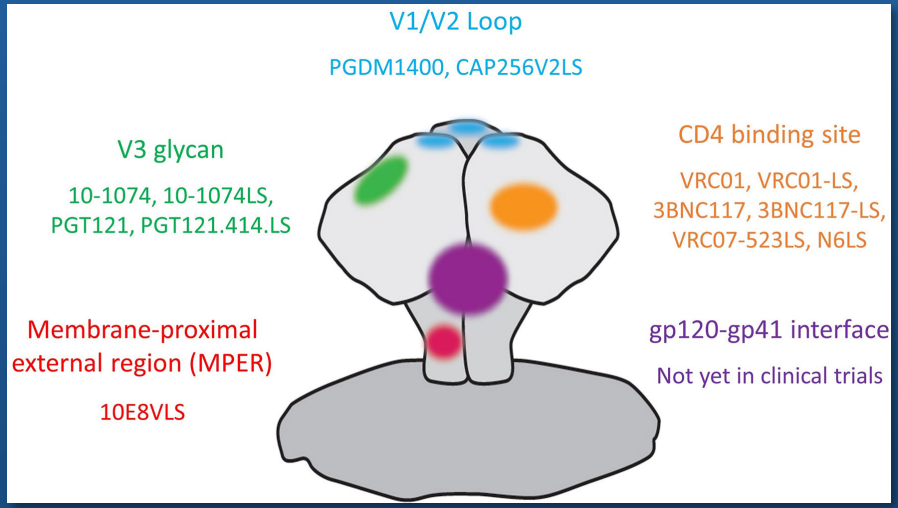
Broadly Neutralizing Antibodies (bNAbs)

- Target conserved epitopes, neutralize multiple HIV-1 viral strains
- Potential for viral suppression alone or in combination with ART, latency reversing agents, immune activating agents, dual-affinity retargeting (DART) molecules, or therapeutic vaccine
- HIV envelope protein targets:



Source: Hsu D, et al. Front Immunol 2021.

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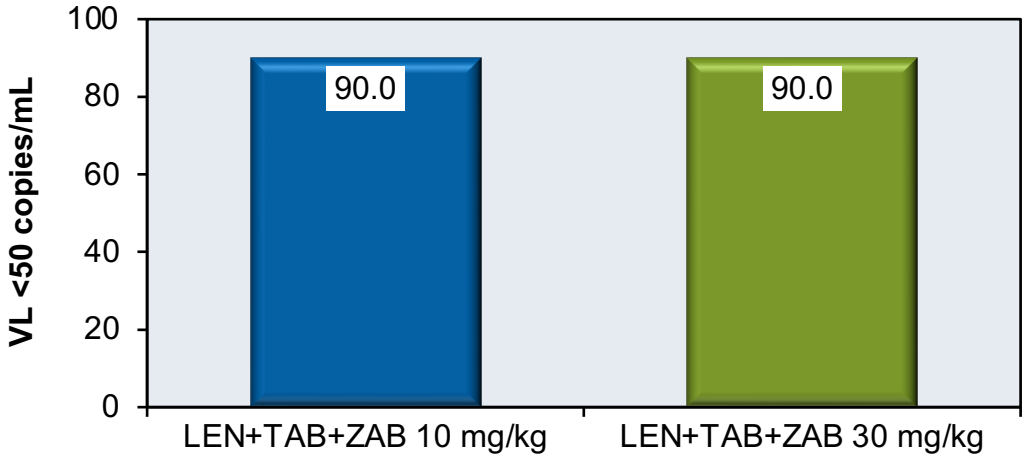
Lenacapavir with Long-Acting Broadly Neutralizing Antibodies (bNAbs) Teropavimab (TAB) & Zinlirvimab (ZAB)

- Question: can a single infusion maintain VL suppression for 6 months?
- Enrolled 20 participants (45% of PWH screened were susceptible)
- Two arms, blinded to bNAb dose
- 26 weeks: 18/20 suppressed
  - 1 withdrew after week 12 (last VL suppressed)
  - 1 low-level virologic rebound at week 16, resuppressed on baseline RPV/TAF/FTC
- Phase 2 study to launch



Sources: Eron J, et al. CROI 2023. Abstract 193. Selzer L, et al. CROI 2023. Abstract 580.

Poll

Where should the greatest investment be placed for future HIV treatment?

A) Make current treatment options more accessible

B) Identify the simplest oral options that have the fewest long-term side effects

C) Develop new long-acting agents

D) Something else

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Questions or comments?
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