CROI Update 2022:

long-acting ART, ART in pregnancy, ANCHOR Study results

Rachel Erdil, MD
Massachusetts General Hospital
HOPE Conference - March 8, 2022

Outline

- Long-acting ART
  - ATLAS-2M week 152 results – CAB/RPV Q4W vs Q8W
- ART in pregnancy
  - IMPAACT 2010 (VESTED) study – birth outcomes after exposure to maternal EFV/FTC/TDF versus DTG-based ART
  - DHHS Guideline Update – what ART to start in pregnancy
- Anal dysplasia
  - ANCHOR Study results

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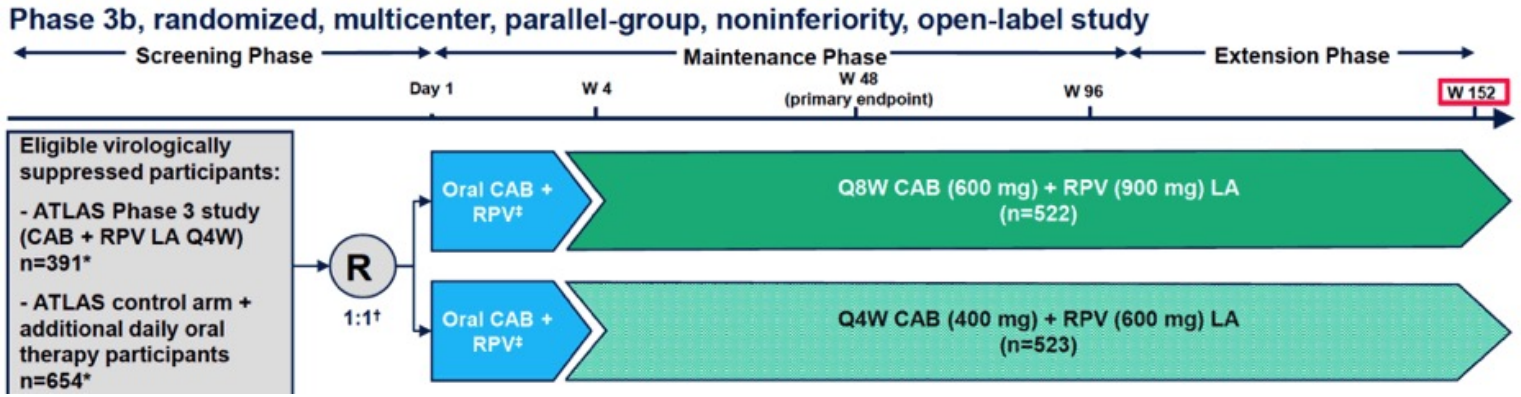
ATLAS-2M: week 152 results

- Design: Phase 3 open-label trial in PWH suppressed on CAB/RPV LA Q4W (n=391) or oral ART (n = 654)
- Randomized: CAB/RPV LA Q4 wks vs Q8 wks
- Endpoints:
  - Primary: HIV-1 RNA ≥ 50 c/mL at week 48
  - Secondary: HIV-1 RNA ≥ 50 c/mL or < 50 c/mL at week 152, incidence of confirmed virologic failure (VL ≥ 200 c/mL x2)



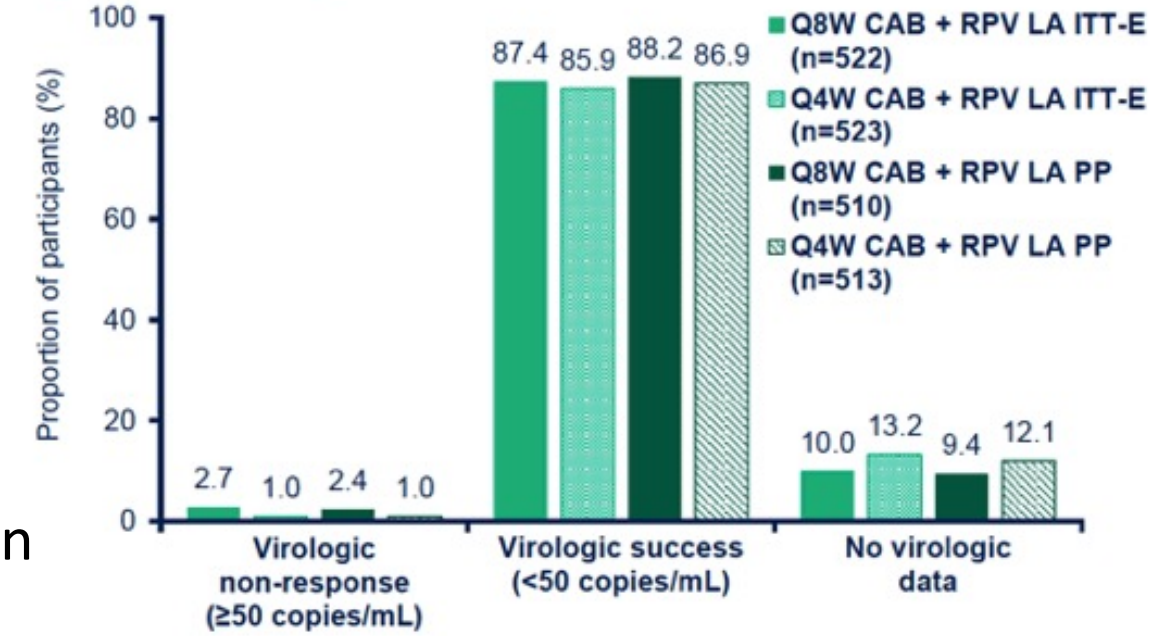
Overton, E, et al. CROI 2022. Abstract 479.

ATLAS-2M: Q8W non-inferior to Q4W

- Achieved virologic suppression in 87.4% in Q8W arm and 85.9% in Q4W arm

- Through week 152, 13 participants had confirmed virologic failure (CVF): Q8W n=11 (2%), Q4W n=2 (<1%)
  - No late injections among pts with CVF
- 11/13 developed resistance to CAB +/- RPV
- 12/13 pts w/CVF re-suppressed on alt regimen

- Risk factors for CVF include: proviral RPV RAMs, BMI >30, subtype A6/A1



Participants With CVF Since Week 96					
#, arm	Sex at birth, BMI (kg/m²), country	HIV-1 subtype at baseline	Viral load at failure (copies/mL)	RPV RAMs observed at failure	INI RAMs observed at failure
1, Q8W	Male, <30, Germany	B	24,221	E138A+M230M/L	Q148R
2, Q8W	Male, <30, Russia	A6*	59,467	E138A+Y181Y/C	Q148R

Overton, E, et al. CROI 2022. Abstract 479.

ATLAS-2M: Q8W dosing is well-tolerated

	Q8W (n=522)	Q4W (n=523)
Participants who received ≥1 injection, n (%)	516 (99)	517 (99)
Number of injections	20,563	39,478
ISR events, n*	4168	5494
Injection site pain, n (% of injections)†	3189 (16)	4180 (11)
Injection site nodule, n (% of injections)†	259 (1)	457 (1)
Grade 3, n (% of ISR events)‡	54 (1)	50 (1)
Median duration, days (IQR)	3 (2, 5)	3 (2, 5)
Participants withdrawing for injection-related reasons, n (% of participants with injections)	8 (2)	13 (3)

- Safety profiles similar to previous analyses: 99% mild-moderate - pain, nodules
- Only 2-3% discontinued study for injection-related reasons

- Treatment satisfaction scores improved from b/l to week 152 for Q8W and Q4W groups
  - Adjusted mean change from baseline favored Q8W dosing

Overton, E, et al. CROI 2022. Abstract 479.

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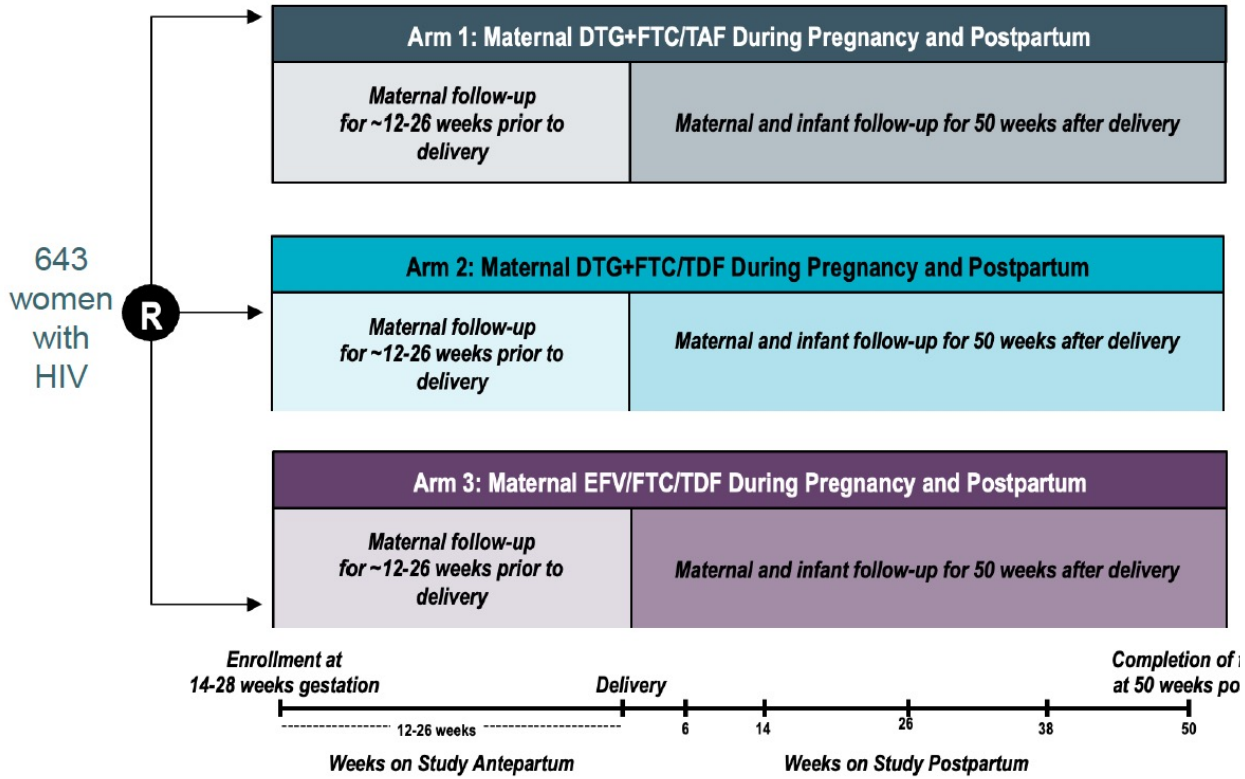
IMPAACT 2010 (VESTED) Trial

- ART-naive women initiating ART during pregnancy were randomized at 14-28 weeks to DTG + FTC/TAF vs DTG + FTC/TDF vs EFV/FTC/TDF
- Followed to 50 wks post-partum
- Adverse pregnancy outcomes less frequent with DTG + FTC/TAF vs DTG + FTC/TDF and EFV/FTC/TDF
  - Adverse outcomes linked to lower maternal weight gain – more common in women who received EFV

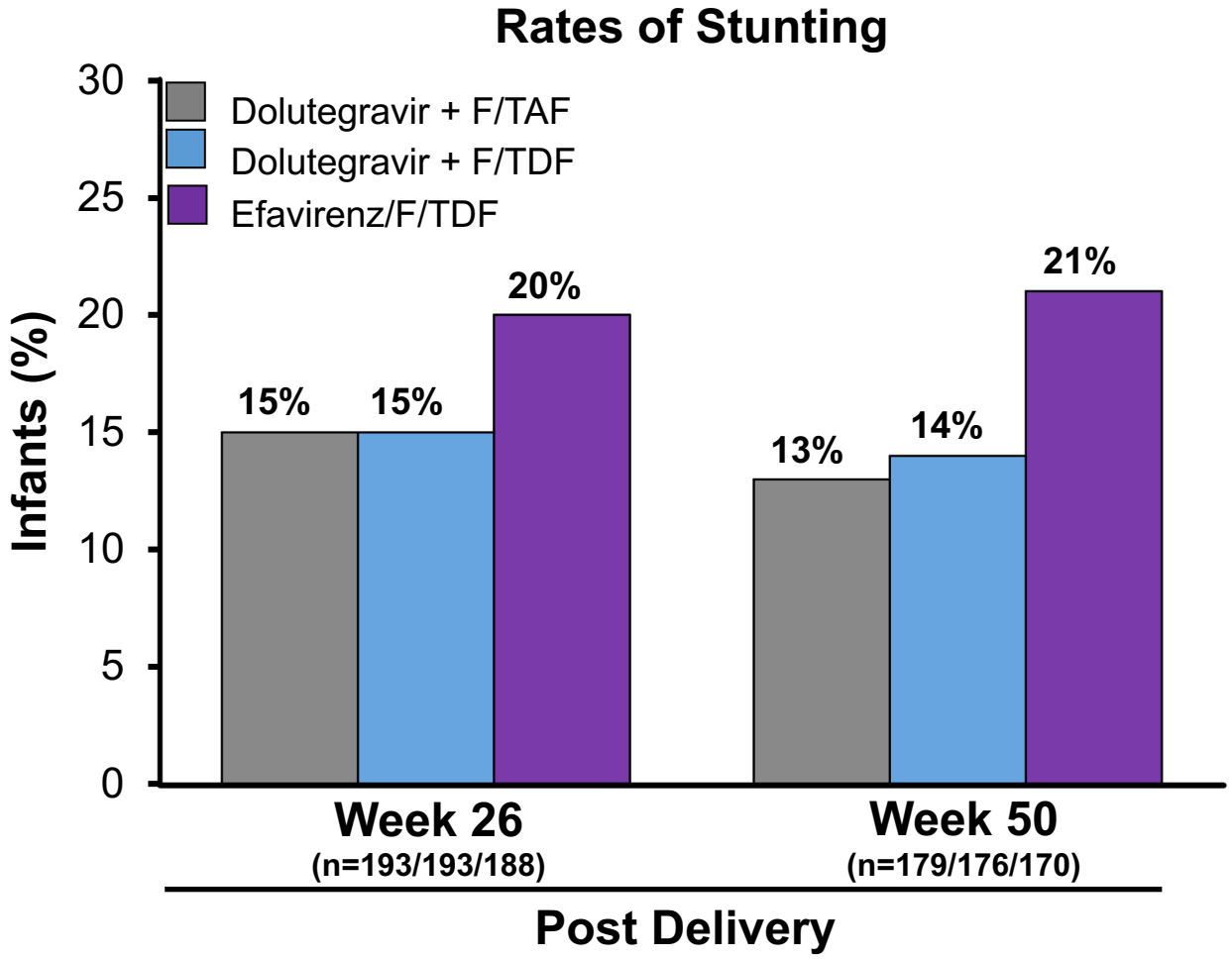


Lockman & Brummel et al, The Lancet, 2021

Chinua, CROI 2021, Abstract 177; Hoffman RM et al, CROI 2021, Abstract 13; Stranix-Chibanda, L, CROI 2022, Abstract 30

Growth of Infants with Perinatal Exposure to Maternal DTG-based ART vs EFV/FTC/TDF

- Compared growth through 1 year in infants in IMPAACT 2010 trial (n=617)
- Monitored Z-scores: length-for-age (LAZ), weight-for-age (WAZ), weight-for-length (WHZ) at 26 and 50 wks
- With maternal efavirenz/FTC/TDF exposure versus DTG-based ART
  - Infants significantly smaller (LAZ and WAZ Z-scores)
  - High rates of stunting across all arms, but highest among efavirenz/FTC/TDF group (20%) vs DTG-based ART (14%)



Stranix-Chibanda, L, CROI 2022, Abstract 30

More data showing low risk of neural tube defects with DTG use in pregnancy

- Analysis of MarketScan Claims Database and Medicare/Medicaid database in US – 35 million pregnancies between 2008-2019
  - ~3K women w/HIV with periconception or early pregnancy DTG exposure
- No neural tube defects in infants born to 509 commercially-insured women on DTG (vs 0.76/1000 births in commercially-insured women w/o HIV)
- One case of spina bifida among infants both to 2,331 women on Medicaid on DTG (vs 0.91/1000 births in women w/o HIV on Medicaid)
- Results did not demonstrate an increased risk of NTD among infants with peri-conception DTG exposure in the US

Kourtis, A, CROI 2022, Abstract 677.

What to Start in Pregnancy: DHHS Guidelines Dec 30, 2021

Two NRTIs

Abacavir/3TC or

TAF/FTC, TAF/3TC *(TAF now preferred in pregnancy and for those trying to conceive)* or

TDF/FTC, TDF/3TC

Plus

Bictegravir (limited data)
Elvitegravir/cobi (PK concerns)
DRV/cobi (PK concerns)
ATV/cobi (PK concerns)
DOR (no data)
Fostemsavir (limited data)
Oral or IM CAB/RPV (insufficient data)

Integrase inhibitor:

Raltegravir (twice daily) or

Dolutegravir (*Preferred ARV throughout pregnancy and for those who are trying to conceive*)

or

Protease inhibitor:

Darunavir/ritonavir (twice daily) or

Atazanavir/ritonavir

https://clinicalinfo.hiv.gov/en/guidelines/perinatal/whats-new-guidelines

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- **Anal dysplasia**
  - **ANCHOR Study results**

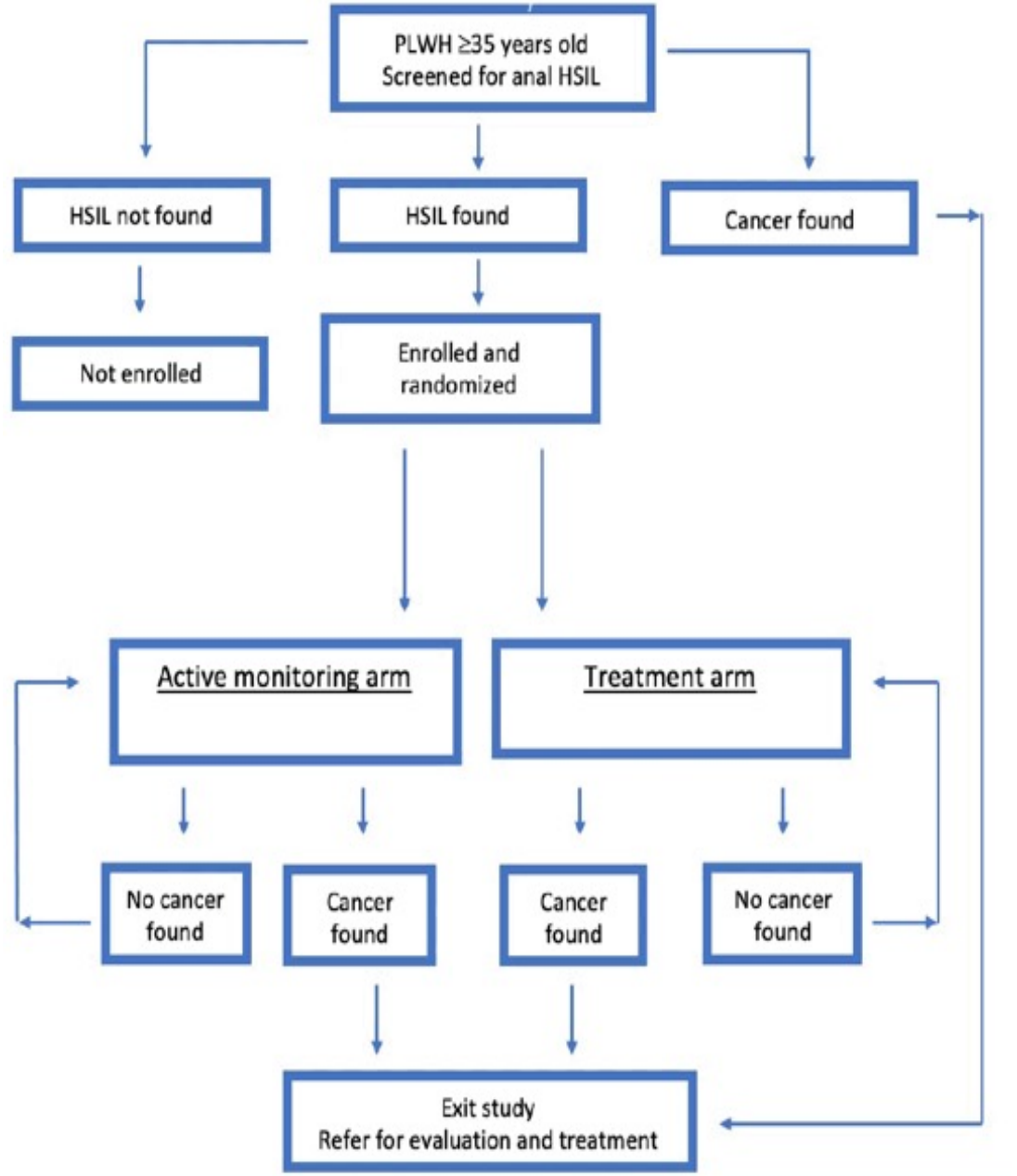
ANCHOR Study: Treatment of Anal High-Grade Squamous Intraepithelial Lesions (HSIL) to Prevent Anal Cancer

- **Background:**
  - Treatment of cervical HSIL reduces the incidence of cervical cancer
  - Regular screening for anal HSIL is not done because of unclear efficacy
- **Objective:** Randomized controlled trial to evaluate reduction in anal cancer incidence with treatment of anal HSIL vs active monitoring (AM)
- **Participants:** PWH > age 35 w/o prior tx of HSIL or hx of cancer were screened for anal HSIL using high-resolution anoscopy (HRA)
- Patients with biopsy-proven anal HSIL were randomized 1:1 to AM without treatment or HSIL treatment
- **Primary endpoint:** time-to-incidence of anal cancer

Palefsky J, et al. CROI 2022. Abstract 106.

the ANCHOR study

- **Screened 10,723 PWH** from Sept 24, 2014 - August 5, 2021
- **52.2% had HSIL**
  - 53.3% of men
  - 45.8% of women
  - 62.5% of transgender people
- **Active monitoring arm:**
  - Cytology, HRA Q6 months
  - Biopsied Q12 months
- **Treatment arm:** electrocautery (92.9%) vs topical 5-FU cream or imiquimod (8.2%)



Palefsky J, et al. CROI 2022. Abstract 106.

the ANCHOR study

Study participants:

- 80% men, median age 51
- Median time since HIV dx = 17 years
- >80% with VL < 50 copies/mL

- ~30% White, 42% African American, 16% Hispanic, 1% Asian/Pacific Islander
- 78% self-identified Homosexual

- ~30% smokers

	Randomized population N=4,446		P value
	Treatment arm	Active monitoring arm	
	N=2,227	N=2,219	
Median age at randomization (years, IQR)	51.0 (44.0-57.0)	51.0 (44.0-57.0)	0.79
Median years at randomization since HIV diagnosis (years, IQR)	17.0 (10.0-24.0)	17.0 (10.0-25.0)	0.96
Months of follow-up (median, IQR)	25.3 (11.7 – 42.0)	27.2 (12.0-42.1)	0.77
Gender identity N (%)			0.30[2]
Male	1793 (80.5)	1782 (80.3)	
Female	346 (15.5)	365 (16.5)	
Transgender	85 (3.8)	68 (3.1)	
Neither male nor female	2 (0.1)	2 (0.1)	
Decline to answer	1 (0.0)	2 (0.1)	

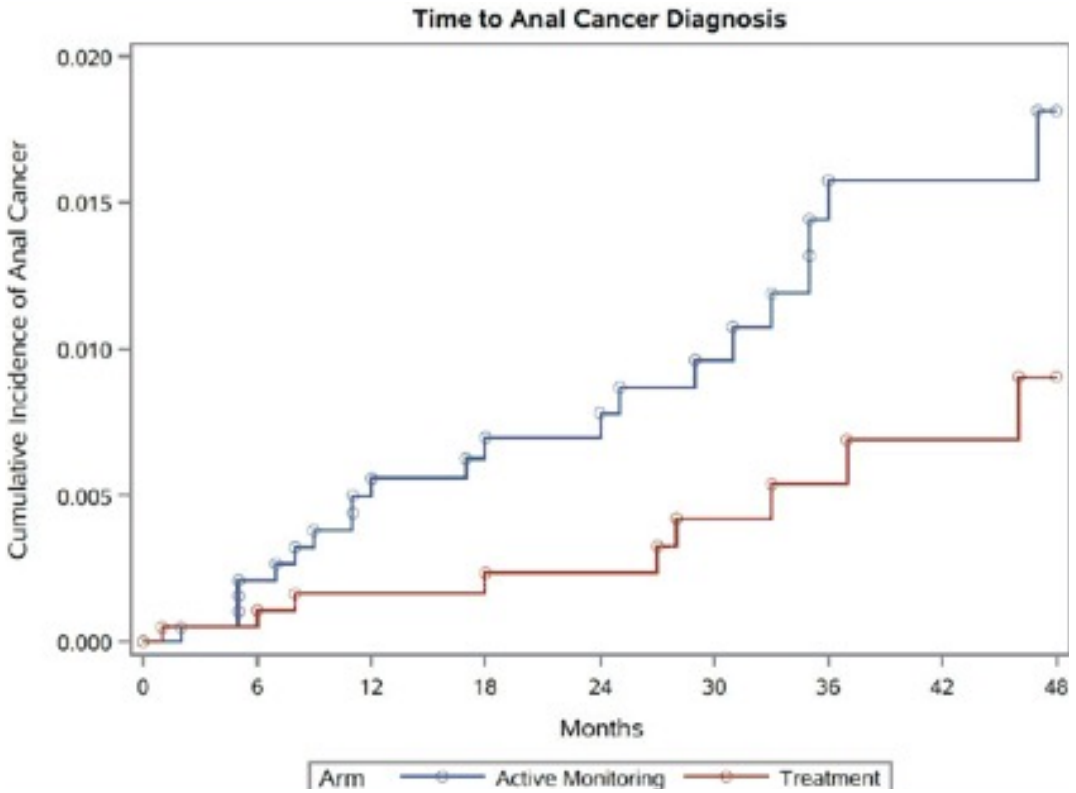
	Treatment arm	Active monitoring arm	
	N=2,227	N=2,219	
Non-Hispanic White	695 (31.2)	737 (33.2)	0.37
African-American	935 (42.0)	939 (42.3)	
Hispanic, non-African-American	381 (17.1)	339 (15.3)	
Asian/Pacific Islander	27 (1.2)	29 (1.3)	
Other/Unknown	189 (8.5)	175 (7.9)	
Homosexual	1738 (78.0)	1742 (78.5)	0.74
Heterosexual	532 (23.9)	510 (23.0)	0.48
Injection drug use	152 (6.8)	177 (8.0)	0.14
Transfusion	53 (2.4)	47 (2.1)	0.56
Hemophilia	2 (0.1)	4 (0.2)	0.41
Other high-risk group	34 (1.5)	27 (1.2)	0.37

Palefsky J, et al. CROI 2022. Abstract 106.

Treatment of HSIL reduces rate of anal cancer by 57%

the ANCHOR study

- **30 anal cancers diagnosed** in median f/u of 25.8 months
  - 9 in Treatment arm (173/100,000 PY)
  - 21 in Active Monitoring arm (402 per 100,000 PY follow-up)
- 8 study-related serious AEs:
  - 7 in Treatment arm: 3 pain, 3 abscess, 1 skin ulceration
  - 1 in AM arm: soft tissue infection



Palefsky J, et al. CROI 2022. Abstract 106.

Implications and Remaining Questions

- Results suggest that screening PWH for HSIL is warranted
- Study authors suggested focusing on highest risk patients: older PWH, those with lower nadir CD4 counts

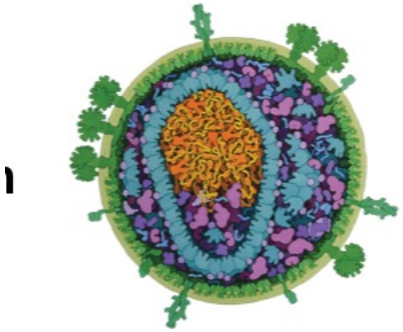
- Remaining questions:
  - Who should be screened for HSIL (all PWH, MSM, older PWH)?
  - How should they be screened (DRE, HRA, cytology)?
  - How often should screening take place?
  - Is screening cost effective?

Palefsky J, et al. CROI 2022. Abstract 106.

Summary

- CAB/RPV every 8 weeks is non-inferior to every 4 weeks in sustaining virologic suppression
- CAB/RPV remains a good option for patients who have difficulty adhering to daily oral ART; avoid if known/suspected RPV or CAB resistance
- Higher rates of growth stunting are observed in infants exposed to maternal efavirenz-based ART compared with dolutegravir-based regimens
- Tenofovir alafenamide (TAF) is now the preferred NRTI in pregnancy
- Screening and treatment of anal HSIL reduces the incidence of anal cancer
- More work is needed to determine the best screening strategy for anal cancer (who to screen, how to screen, how often)

CROI 2022 Update



CROI
Conference on Retroviruses and Opportunistic Infections

Raj Gandhi, MD
Massachusetts General Hospital
Harvard Medical School

Thanks to Efe Airewele and to Drs. Rachel Erdil, Mary Montgomery, Ken Mayer, Jeanne Triant and Kevin Ard for assistance with slides

Outline

- Current ART
- New ART
- HIV Cure
- COVID-19 Advances

Current ART

Case

- 50 yo M with HIV. Treated with variety of regimens in the 1990s.
- Resistance to NRTIs (M41L, M184V, T215Y) and NNRTIs (K103N)
- Virologically suppressed for years on TAF/FTC/Elvitegravir/cobi + Darunavir
- Because of drug interactions, you would like to change his regimen
- What regimen would you choose?

A. TAF/FTC/Bictegravir (NRTIs, INSTI)

B. TDF/FTC + Darunavir/c (NRTIs, PI)

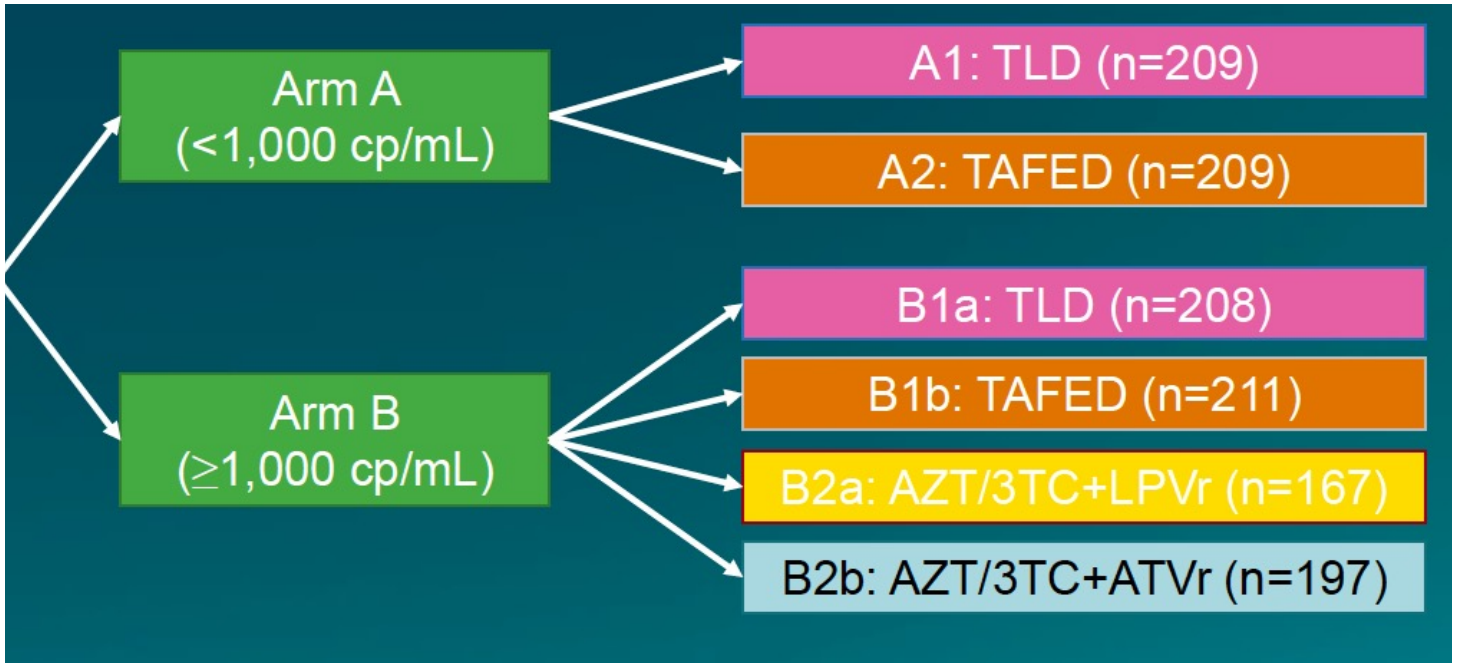
C. Darunavir/cobi + Dolutegravir (PI, INSTI)

D. TAF/FTC/Rilpivirine + Dolutegravir (NRTIs, NNRTI, INSTI)

NRTI and NNRTI resistance
Virologically suppressed on
NRTIs, INSTI + PI

VISEND: Switching Therapy in Suppressed and Non-Suppressed PWH

- Randomized trial in Zambia
- Patients switching from NNRTI-based treatment (n=1201)
- Arm A: VL <1000
  - About 20% VL 50-999
  - Randomized to TLD or TAFED
- Arm B: VL ≥1000
  - Randomized to TLD, TAFED, AZT/3TC/LPV/r or AZT/3TC/ATV/r



TLD: TDF/3TC/DTG
TAFED: TAF/3TC/DTG

Mulenga L, CROI 2022, Abstract 135

VISEND: HIV-1 RNA Suppression at Wk 48

HIV-1 RNA at Wk 48, %	VL <1000	
	DTG + TDF/3TC (n = 209)	DTG + TAF /3TC (n = 209)
ITT (FDA Snapshot) ▪ <50 c/mL	81	76
Per protocol (FDA Snapshot) ▪ <50 c/mL	90	86

Mulenga L, CROI 2022, Abstract 135

VISEND: HIV-1 RNA Suppression at Wk 48

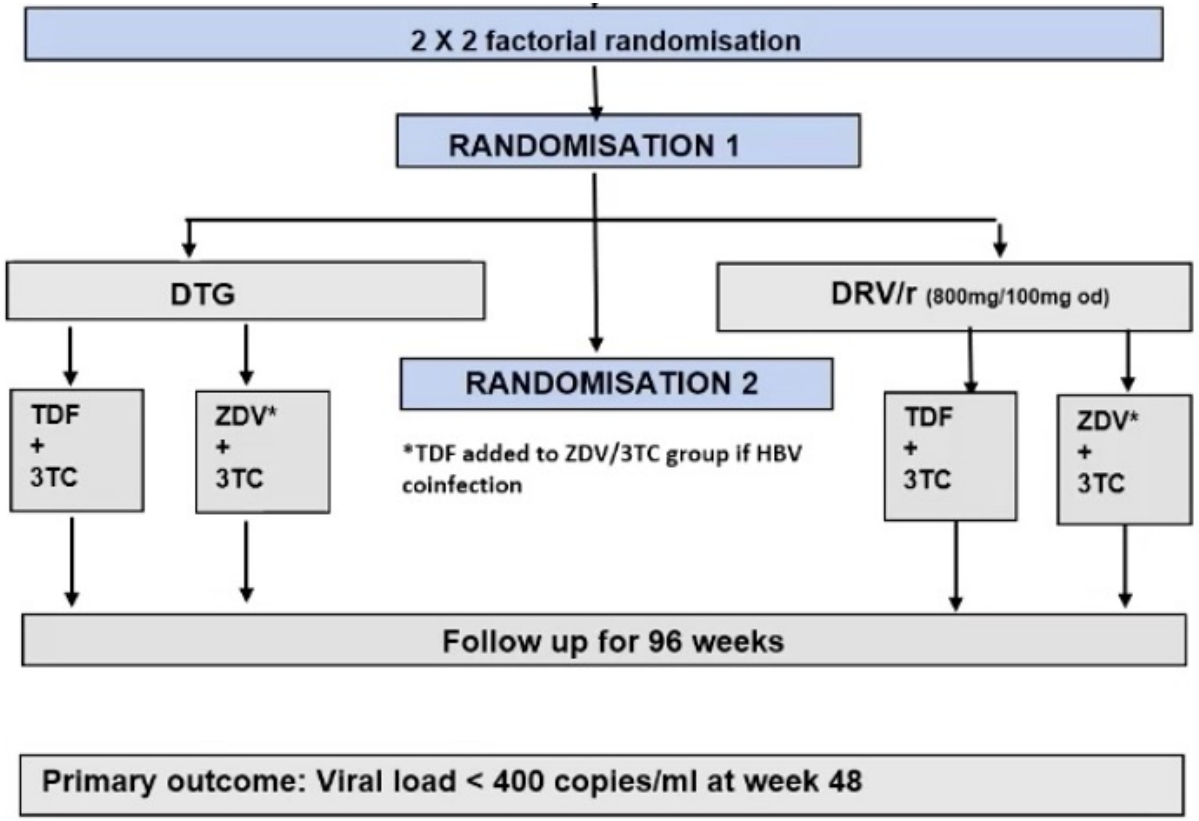
HIV-1 RNA at Wk 48, %	VL <1000		VL ≥1000			
	DTG + TDF/3TC (n = 209)	DTG + TAF /3TC (n = 209)	DTG + TDF/3TC (n = 208)	DTG + TAF /3TC (n = 211)	ATV/r + 3TC/ZDV (n = 197)	LPV/r + 3TC/ZDV (n = 167)
ITT (FDA Snapshot) ▪ <50 c/mL	81	76	72	82	71	56
Per protocol (FDA Snapshot) ▪ <50 c/mL	90	86	82	89	78	68

- In PWH on NNRTI-based regimen with virologic suppression (VL<1000) or non-suppression (VL≥1000), switching to DTG + tenofovir/3TC results in high rates of viral suppression
- In PWH with VL≥1000, DTG + tenofovir/3TC superior to AZT/3TC +PI/r

Mulenga L, CROI 2022, Abstract 135

NADIA: 2nd-Line ART after NNRTI Failure

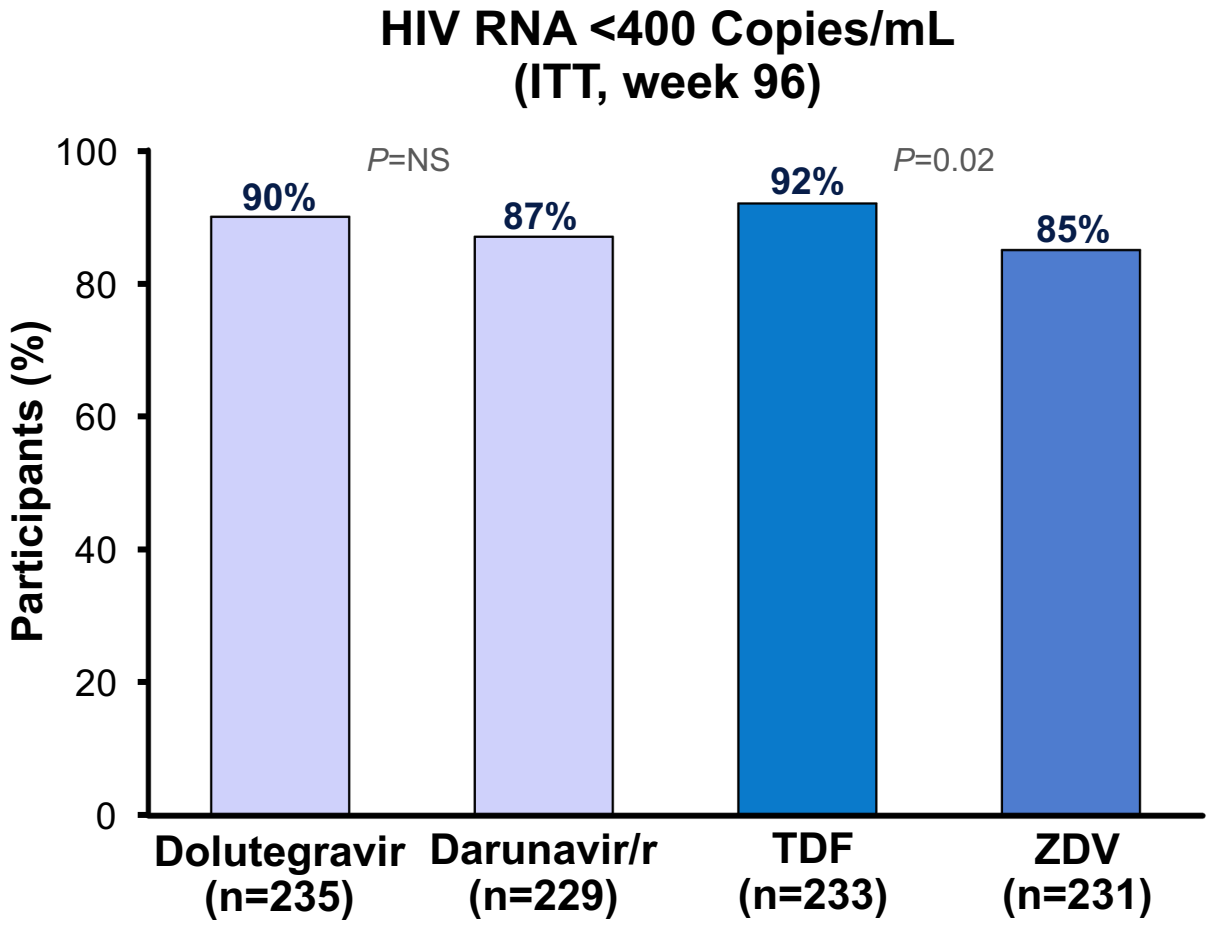
- Participants in Sub-Saharan Africa with virologic failure on TDF/3TC/NNRTI (n=464)
- 2x2 factorial randomization (open label)
- Study participants:
  - CD4 ≤200: 51%
  - VL ≥100,000: 28%
  - Resistance:
    - K65R/N: 50%
    - M184V: 86%
    - Int/high resistance: TDF: 59%. AZT resistance: 18%; 3TC: 92%



Paton N et al, NEJM, 2021.

NADIA: 2nd-Line ART after NNRTI Failure

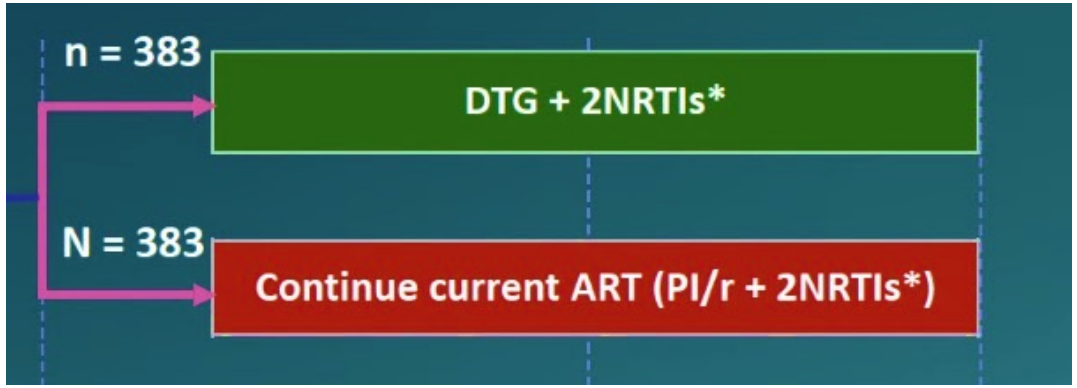
- DTG + 2 NRTIs non-inferior to DRV/r + 2 NRTIs
  - High rate of suppression even when no NRTIs predicted to be active!
- Continuing TDF/3TC superior to switching to AZT/3TC
- Confirmed viral rebound ≥1000 c/mL with ≥1 resistance mutation to DTG or DRV:
  - N=7 (all DTG)
  - TDF/3TC (n=2 – intermediate level DTG resistance)
  - AZT/3TC (n=5 – high level DTG resistance)



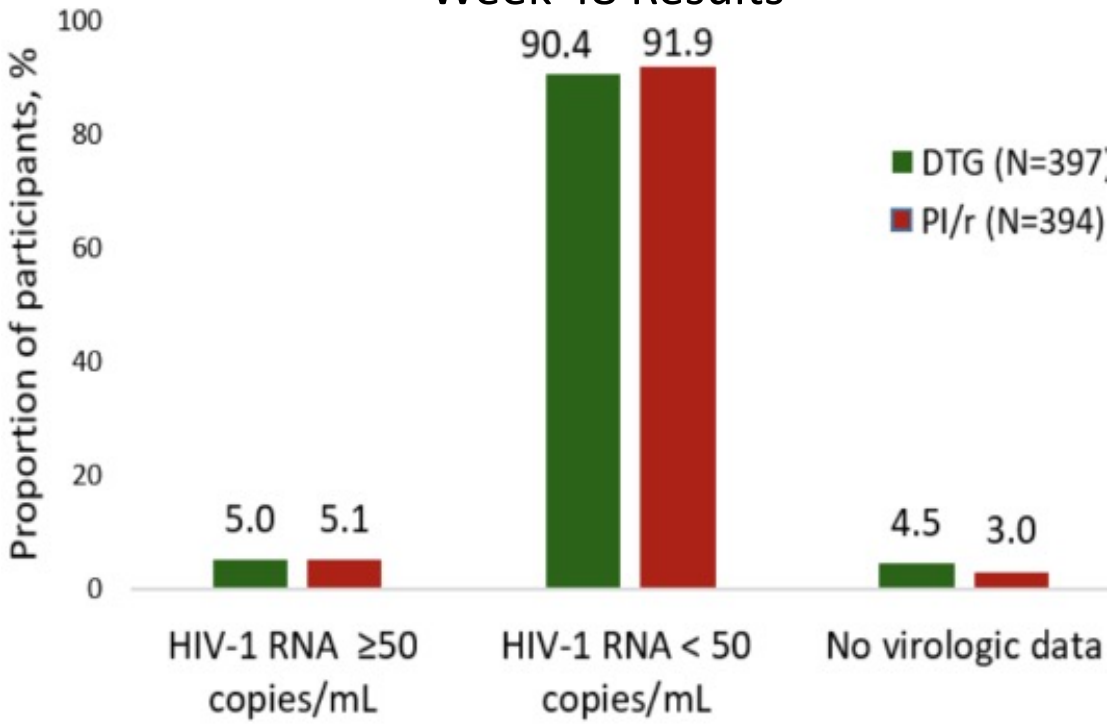
Paton N, et al. CROI 2022. Abstract LB-137.

2SD: Randomized Trial of Switching Treatment Experienced Virally Suppressed Adults from PI/r to DTG

- Randomized study in Kenya (n=795)
- Participants on second line ART with PI/r + 2 NRTIs
- VL <50 for at least 12 weeks
- No assessment of prior drug resistance



Week 48 Results



Ombajo L et al, CROI 2022, Abstract 136

No treatment emergent INSTI or PI resistance

Current ART

Lessons from Trials of Switching ART: NADIA, VISEND, 2SD

- DTG + TDF/3TC suppresses HIV RNA in majority of PWH even when NRTIs not anticipated to be active
- In treatment experienced patients with viral suppression, switching from PI/r to DTG maintains viral suppression even when resistance testing results not known
- In patients virologically suppressed on complicated regimens, switching to tenofovir/FTC + drug with high barrier to resistance (DTG, BIC, PI) likely to maintain suppression, even when there is pre-existing NRTI resistance

ART: Short Takes

- In PWH on ART who have cognitive impairment, adding DTG or DTG + MVC (ART intensification) does not improve neuropsychological performance or depressive symptoms (ACTG A5342, InMIND)
- In transgender individuals, hormone (estrogen or testosterone) therapy does not affect tenofovir-diphosphate concentrations; serum estradiol levels not affected by TDF/FTC
- In patients with multi-drug resistant HIV who had not failed an INSTI and who had no evidence of DRV resistance, switching to once daily DTG + DRV/c maintained virologic suppression

Letendre, S, CROI 2022, Abstract 133; Blumenthal, J, CROI 2022, Abstract 84; Santos, J, CROI 2022, Abstract 510

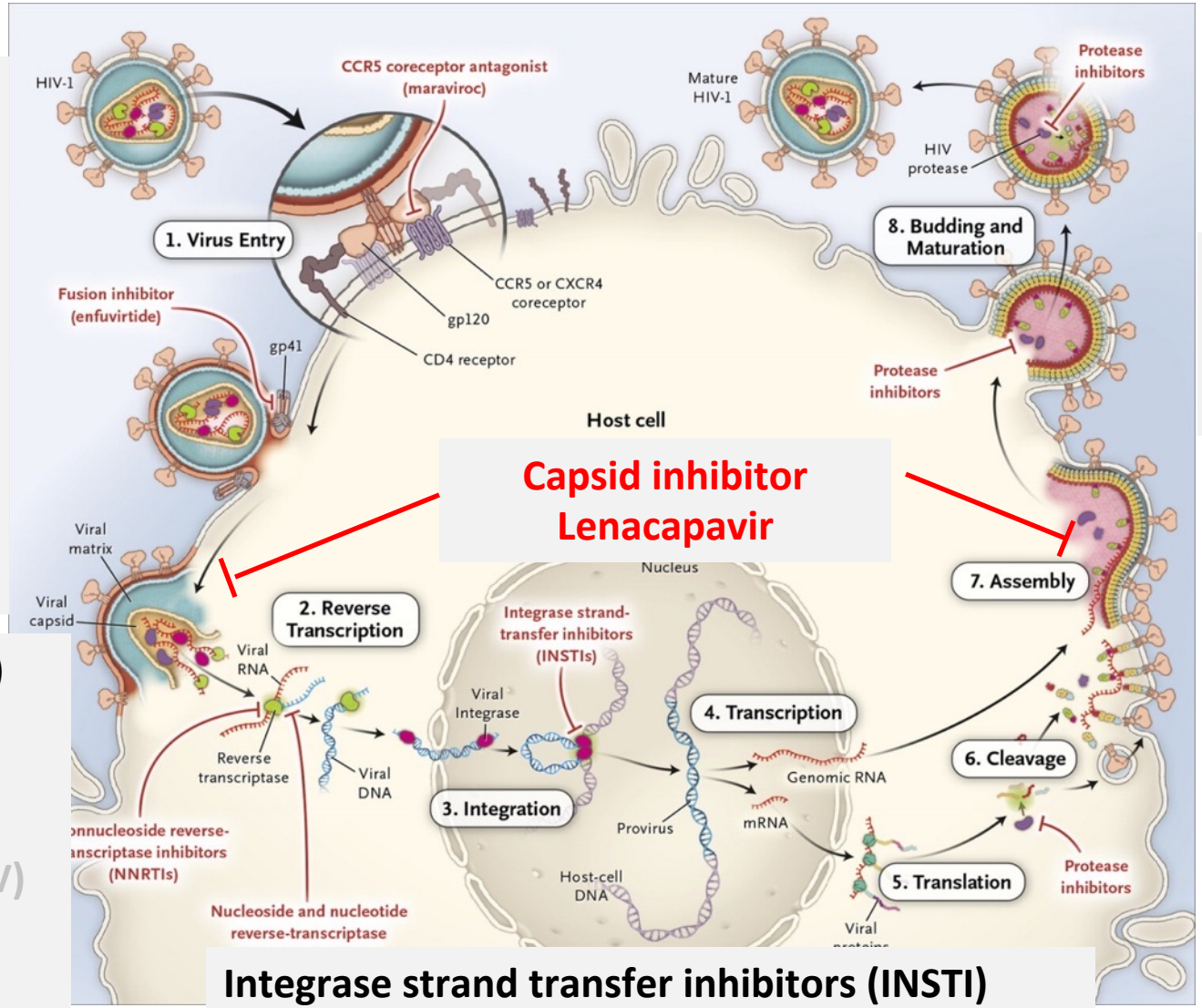
New ART

Entry inhibitors:

- Attachment inhibitor:
  - Fostemsavir
  - UB-421
- CCR5 Antagonist:
  - Leronlimab
- Fusion Inh.: Albuvirtide
- Multisite: Combinectin
- Broadly neutralizing Abs

Reverse Transcriptase Inh. (RTI)

- Nucleoside RTI (NRTIs)
- Nonnucleoside RTI (NNRTIs)
  - Long-acting rilpivirine (RPV)
  - MK-8507
- **Nucleoside RT translocation inhibitor: Islatravir**



Maturation inhibitor

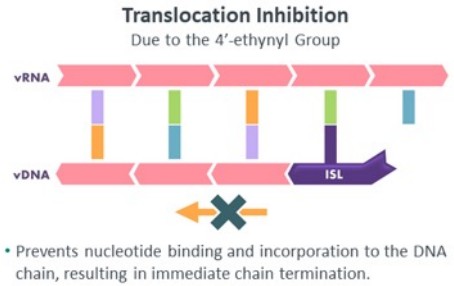
- GSK3640254 (non-boosted)

Integrase strand transfer inhibitors (INSTI)

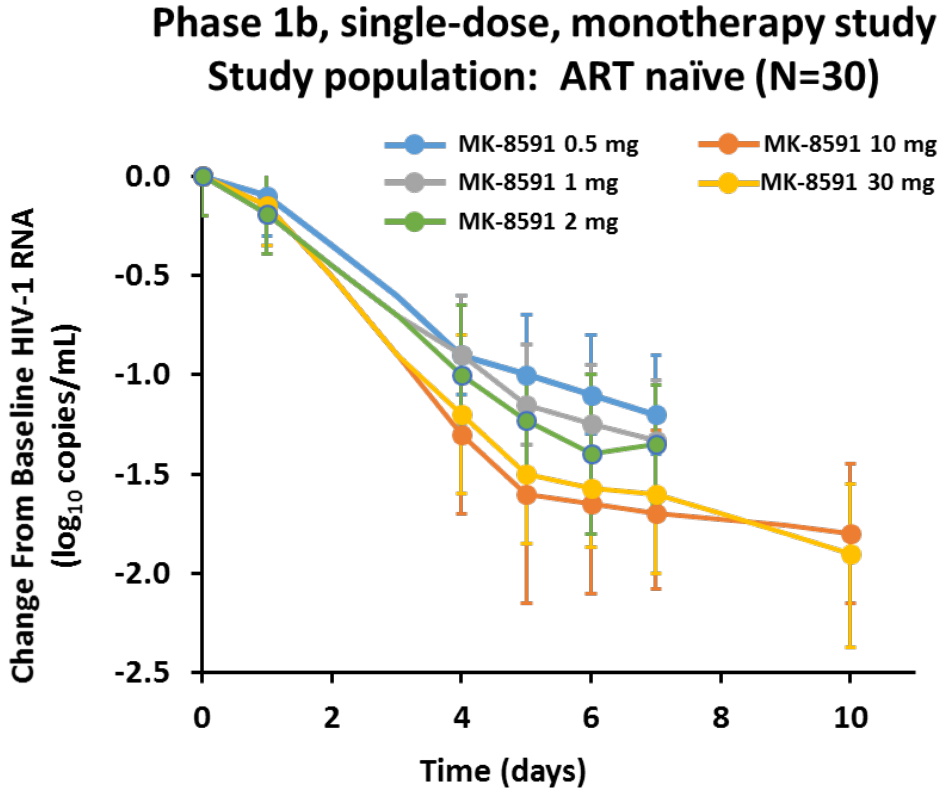
- Long-acting cabotegravir (CAB)

Gandhi M, Gandhi RT. NEJM 2014;371:248-259.

Islatravir (ISL)



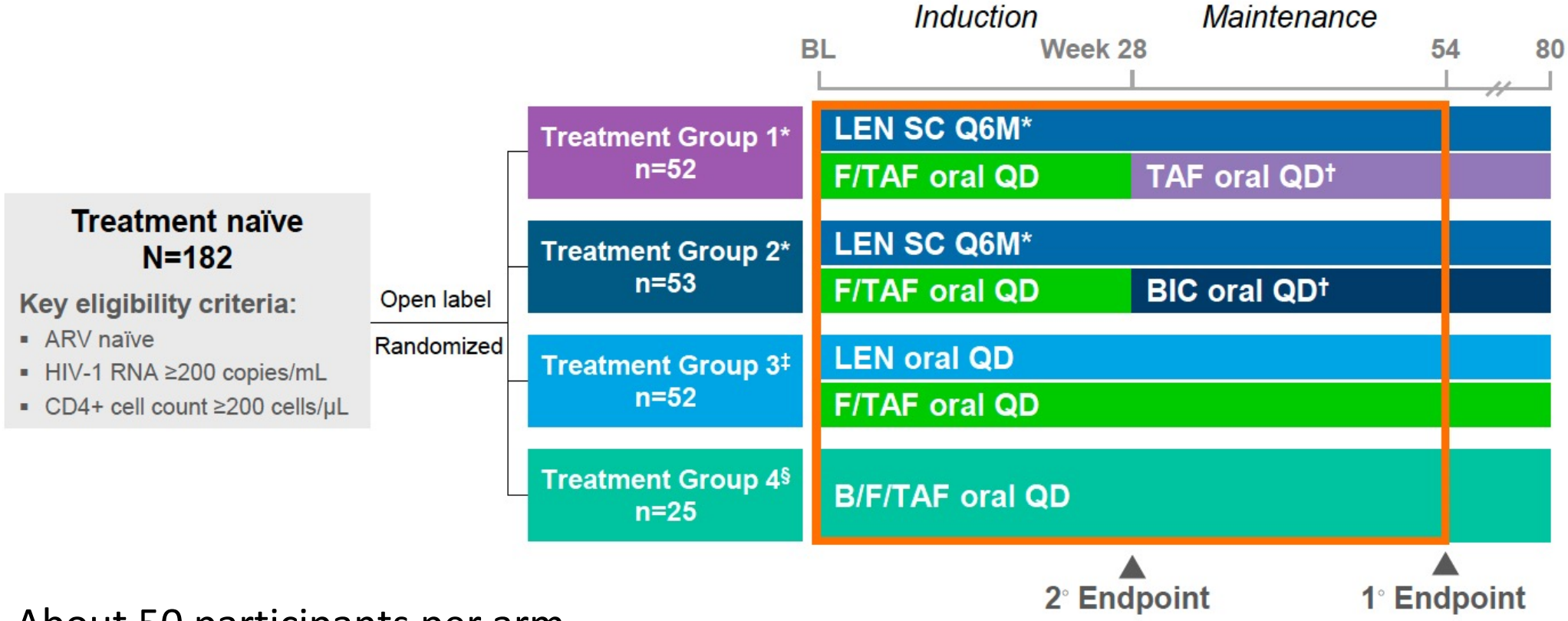
- Nucleoside RT translocation inhibitor (NRTTI)
- Being evaluated for treatment: daily dosing (ISL/doravirine) or weekly dosing (ISL + lenacapavir)
- Being evaluated for pre-exposure prophylaxis trial: monthly dosing; ISL implant
- Studies on hold: dose dependent lymphopenia, decline in CD4 cell count
  - In some participants who received higher dose, CD4 cell decline of >50%



https://www.aidsmap.com/news/dec-2021/trials-long-acting-islatravir-hiv-treatment-and-prevention-placed-hold

CALIBRATE: LEN in Treatment Naïve PWH

- Oral formulation: half-life 11-13 d; subcutaneous injection: every 6 months

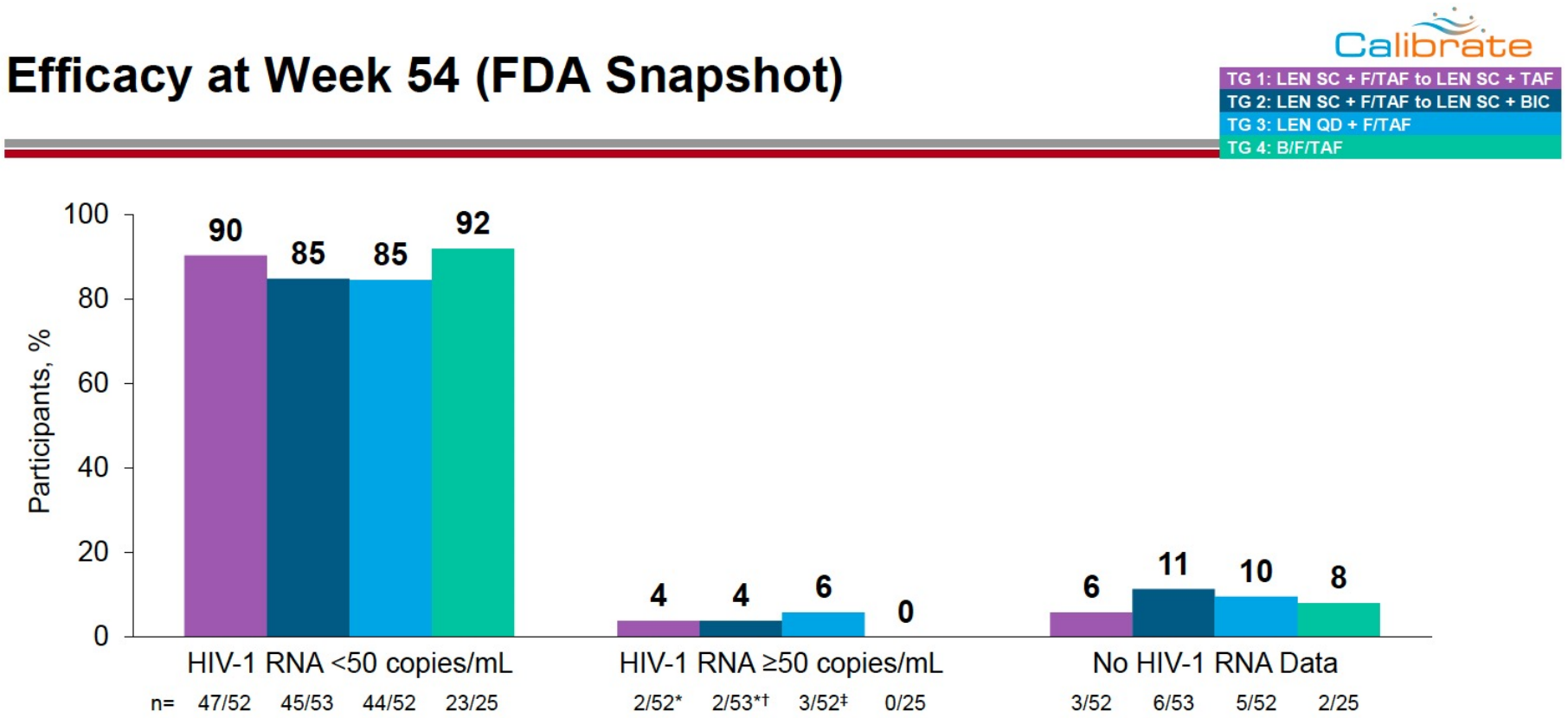


- About 50 participants per arm
- Maintenance phase: SC LEN q 6 m + TAF or BIC daily; PO LEN+TAF/FTC daily; or BIC/TAF/FTC

Gupta, S, CROI 2022, Abstract 138

CALIBRATE: LEN in Treatment Naïve PWH

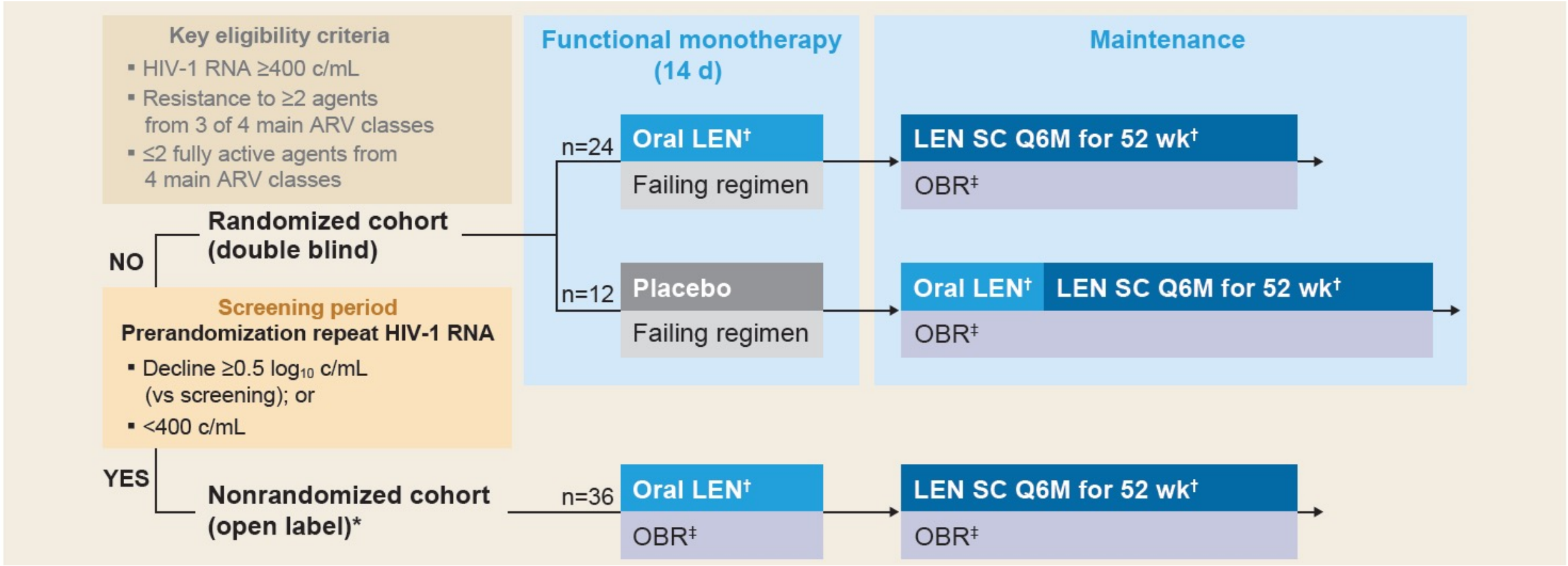
Efficacy at Week 54 (FDA Snapshot)



In LEN SC cohort (Groups 1, 2; LEN initially with F/TAF then with TAF or BIC): 88% achieved and maintained virologic suppression at Wk 54

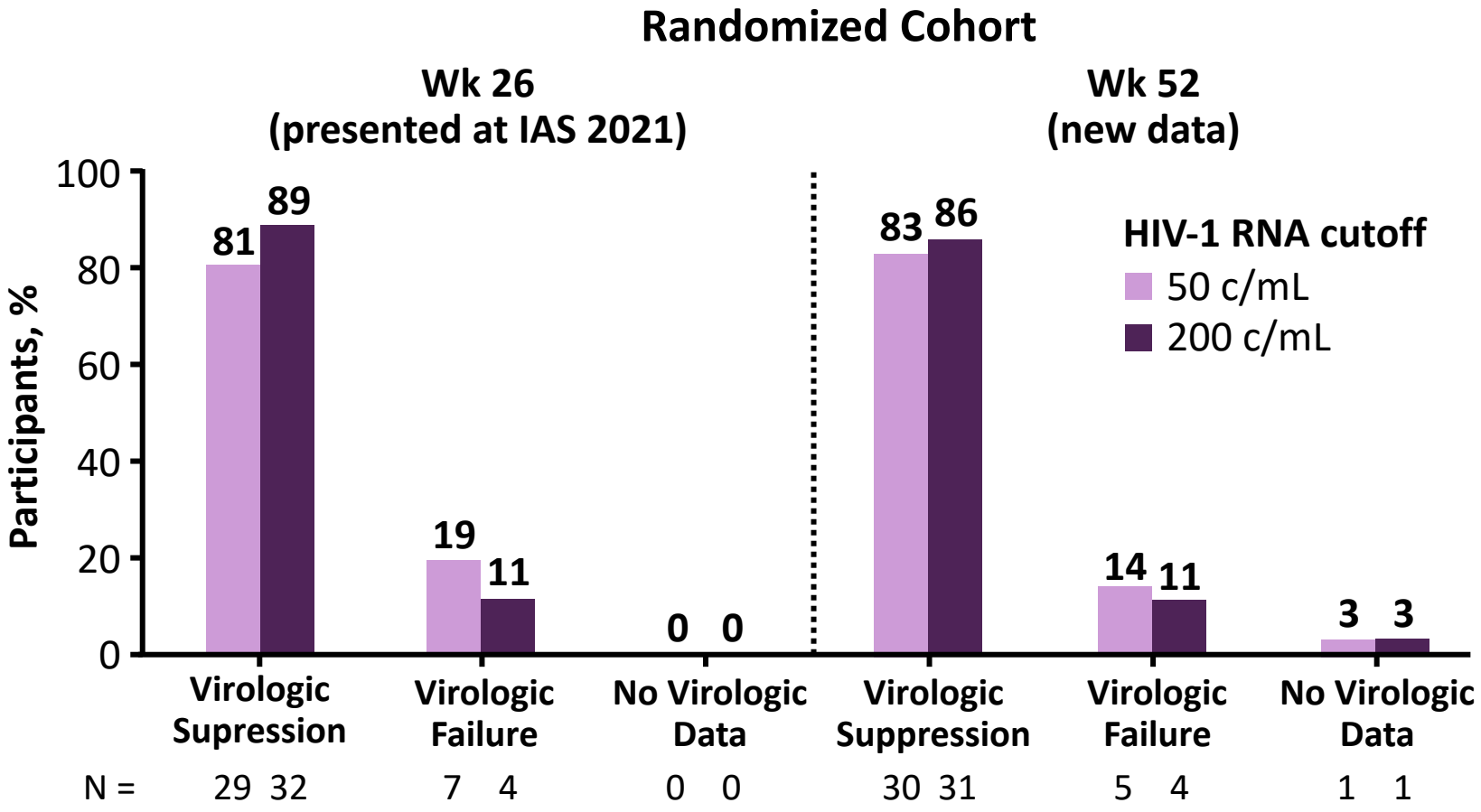
- 2 of 157 (1.5%) developed LEN resistance
- 1 developed Q67N +70R in CA preceded by M184M/I
- 1 developed Q67H; non-adherence to F/TAF
- Both resuppressed on 2 NRTI + INSTI
- 3 d/c due to ISR

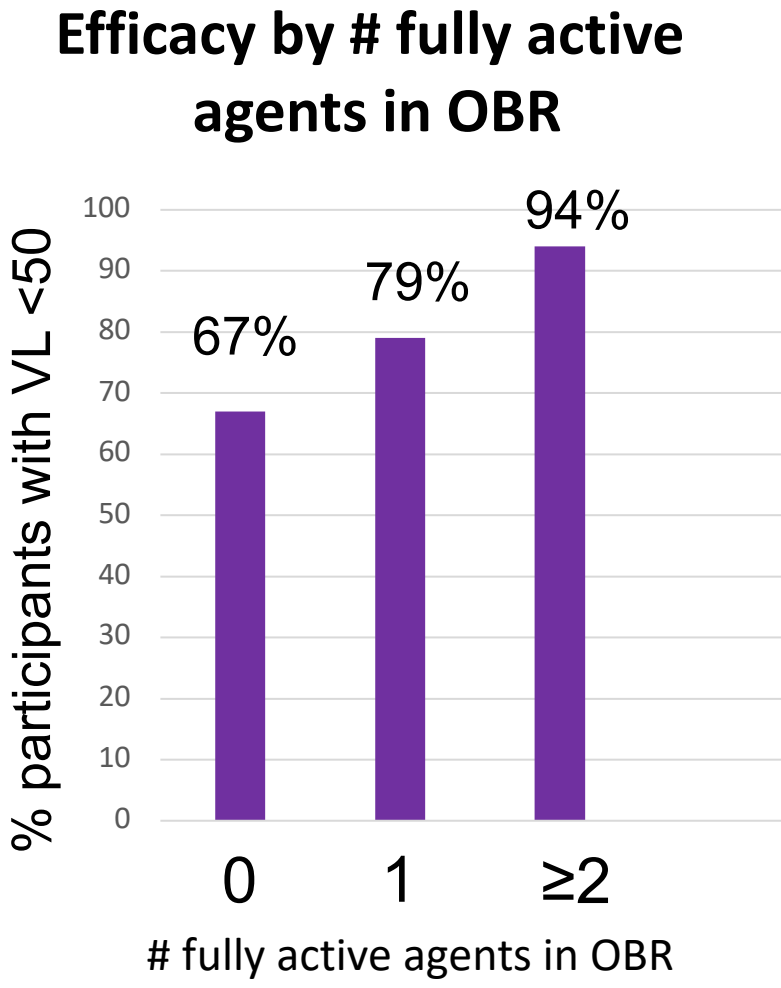
CAPELLA: Lenacapavir (LEN) in People with MDR HIV



Ogbuagu, O, CROI 2022, Abstract 491

CAPELLA: Viral suppression with LEN





LEN + OBR led to viral suppression at wk 52 in 83%

Ogbuagu, O, CROI 2022, Abstract 491

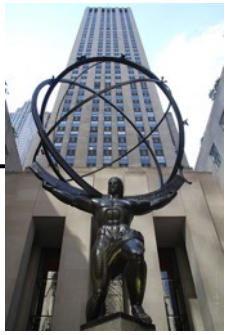
CAPELLA: Treatment Emergent Resistance

- In overall cohort (randomized + non-randomized, n=72), 21 of 72 participants met criteria for resistance testing
- N=8 with treatment emergent LEN resistance: M66I most common
- All 8 persons with LEN resistance at high risk for resistance: 0 active drugs in OBR, n = 4; inadequate adherence to OBR, n = 4
- 3 participants resuppressed (1 without and 2 with OBR change)

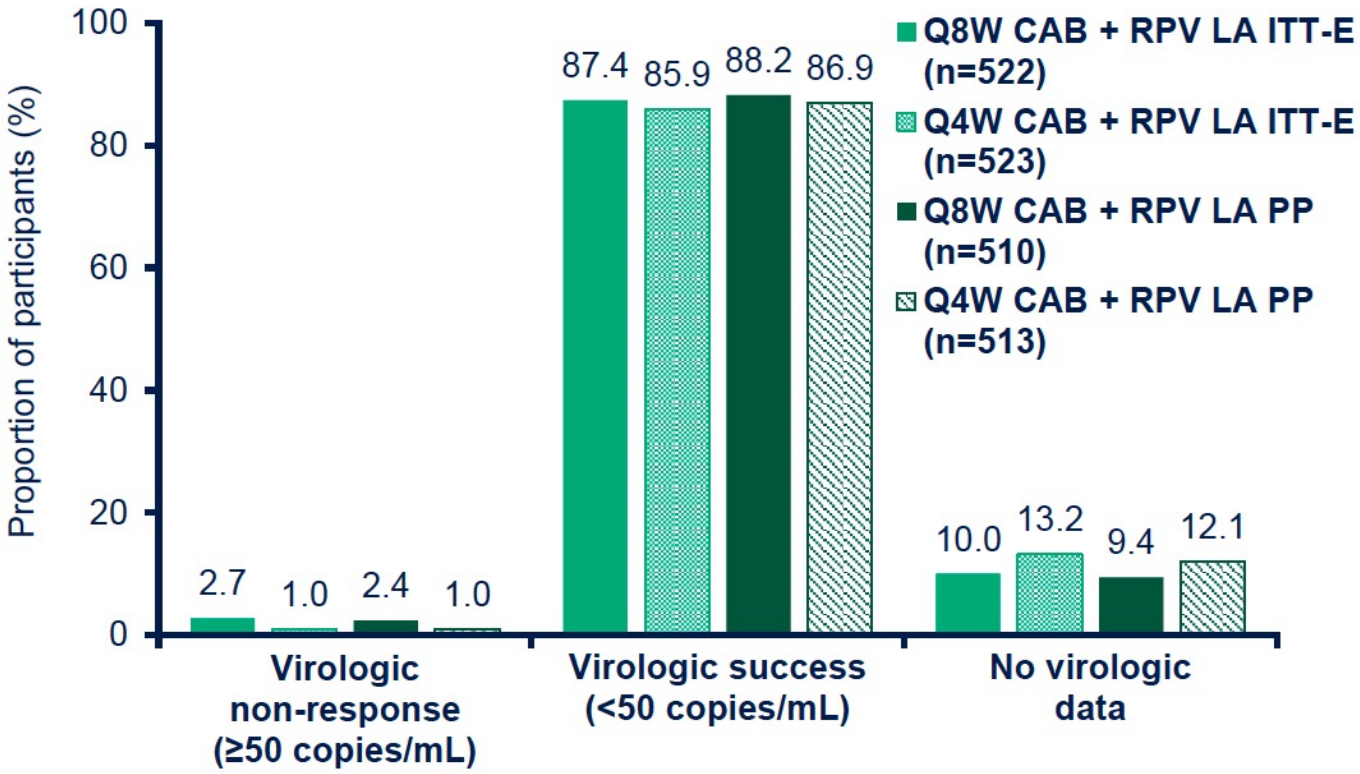
- LEN trials currently on hold because of concerns about compatibility with glass vials

Ogbuagu, O, CROI 2022, Abstract 491

ATLAS-2M: 152 Week Results



- Phase 3 open-label trial in PWH suppressed on CAB/RPV LA Q4W (n=391) or oral ART (n=654)
- Randomized: CAB/RPV LA q4W or Q8W
- CAB/RPV Q8W non-inferior to Q4W
- Through week 152, 13 participants had confirmed virologic failure: q8W n=11 (2%); q4W, n=2 (<1%)
- 11/13: resistance to CAB and/or RPV
- Risk factors for CVF include: proviral RPV RAMs, BMI >30, subtype A6/A1



Overton, E, CROI 2022, Abstract 479

HIV Cure Research

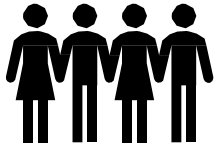
IMPAACT P1107: HIV-1 Remission With CCR5 Delta 32 Haplo-Cord Transplant in a Woman

- 59-year-old woman
- 2013: diagnosed with acute HIV
- 2017: diagnosed with acute myeloid leukemia
- 2017: CCR5Δ32/Δ32 cord blood transplant (5/8 match) + peripheral blood mononuclear cells (to aid engraftment) from relative
  - Induction chemotherapy = fludarabine/melphalan/ATG + TBI with 400 cGy
- Day 100: 100% cord chimerism and full remission of acute myeloid leukemia
- ART stopped 37 months post-transplant
- 14 months off ART with no viral rebound (no ARVs in plasma)
- Loss of HIV specific antibody responses; undetectable HIV DNA, no detectable replication competent latent reservoir

Bryson Y, et al. CROI 2022. Abstract 65.

COVID-19 Advances

Molnupiravir: Phase 3 Trial in Mild COVID-19 in India



- Adults (≥18 - ≤60 years) with mild COVID-19
- Symptom duration ≤5 days at entry

- Randomized, open label
- 800 mg MOV + SOC vs SOC alone BID for 5 days (~609 per arm)

- Primary Endpoint: hospitalization up to Day 14

- Total Phase 3 Recruitment: n=1218

COVID-19

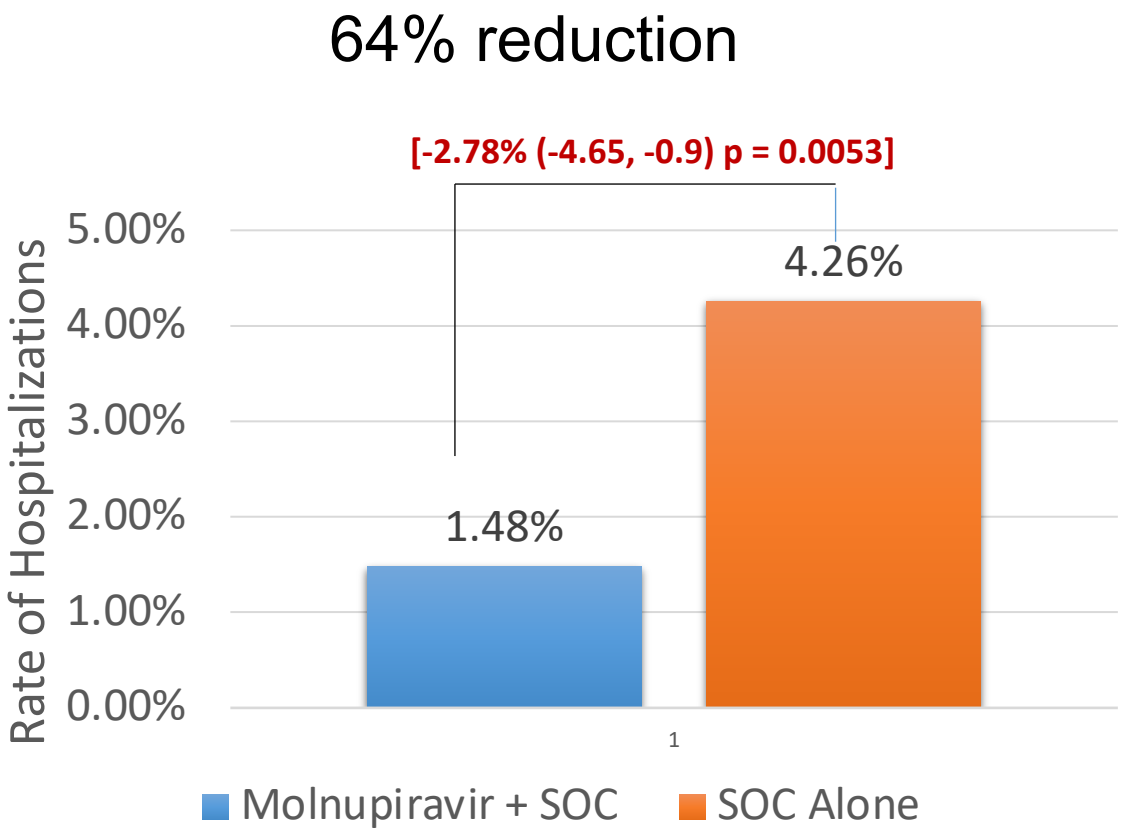
Kumarasamy, N, CROI 2022, Abstract 101

Patient Characteristics

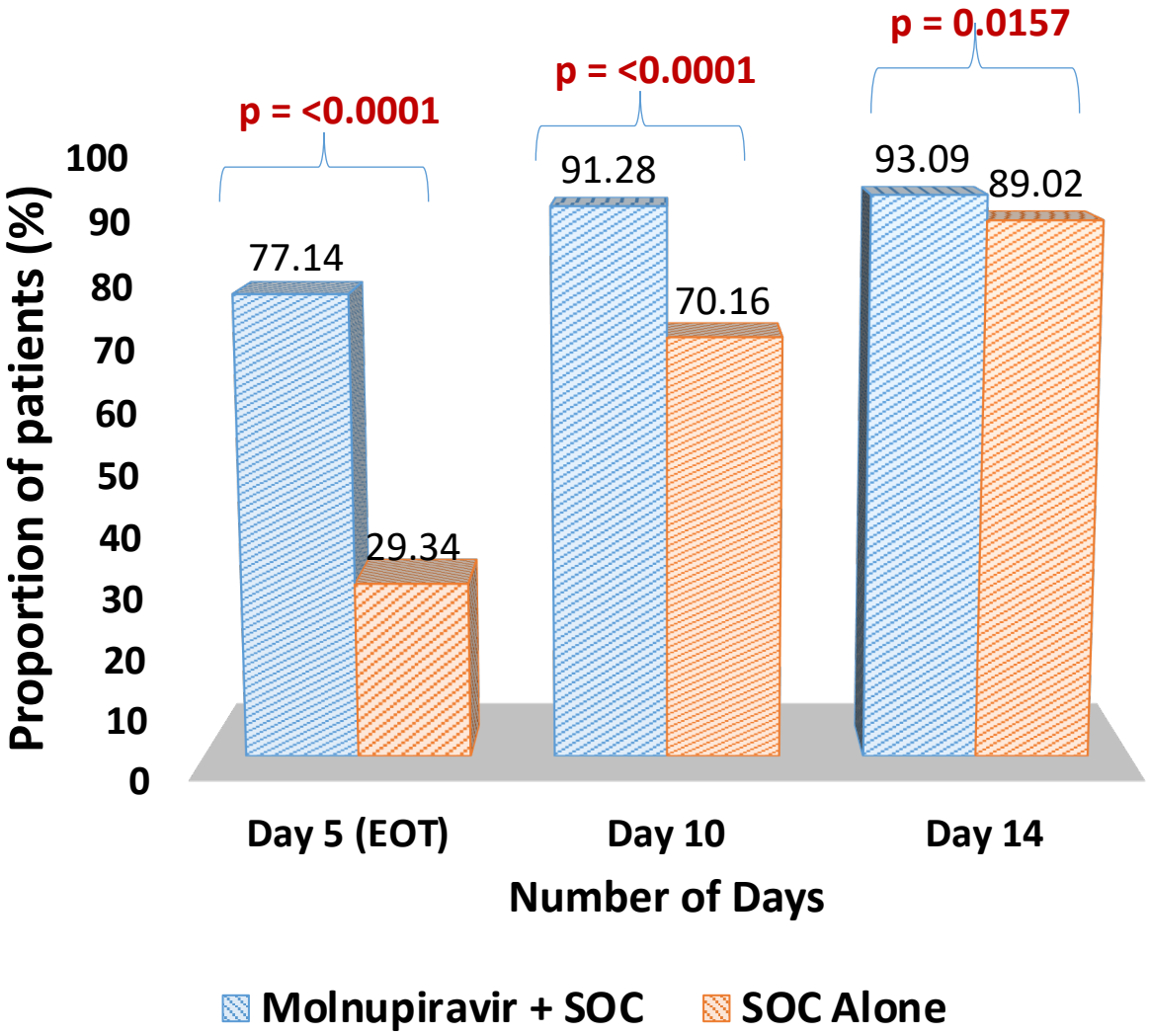
Characteristics	Molnupiravir (N=608)	Standard of Care (N=610)
Age (years, Mean ± SD)	35.2 ± 10.8	34.8 ± 10.8
BMI (kg/m2, (Mean ± SD)	23.5 ±2.6	23.4 ±2.6
Comorbidities		
Obesity (BMI > 30)	19 (3.12)	17 (2.78)
Diabetes Mellitus	2 (0.32)	2 (0.32)
Hypertension	3 (0.49)	7 (1.14)
Standard of Care Provided		
Ivermectin	296 (48.68)	472 (77.38)

Kumarasamy, N, CROI 2022, Abstract 101

Hospitalization by day 14



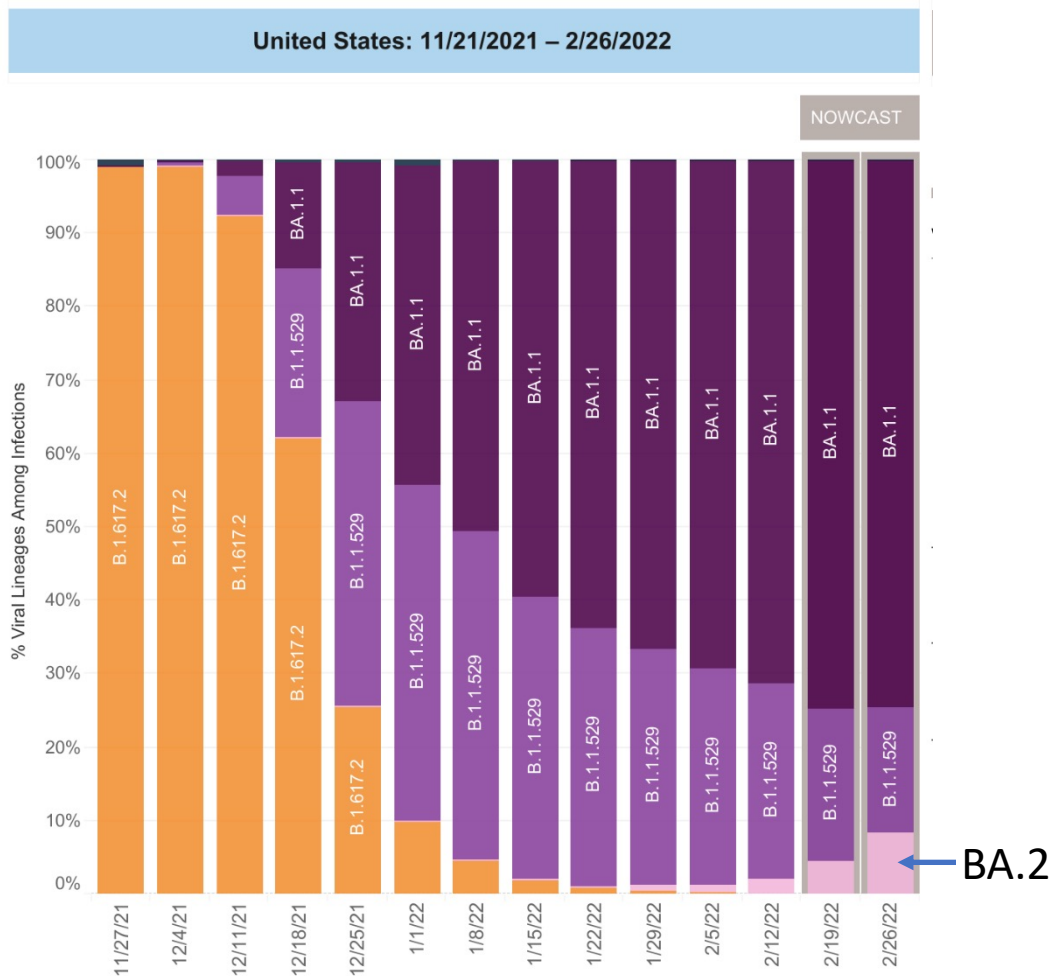
SARS CoV-2 PCR Negative



Kumarasamy, N, CROI 2022, #101

What About Omicron Lineage BA.2?

- BA.2 has replaced BA.1 in many parts of the world; about 8% of US isolates, 20% in Northeast
- Sotrovimab: decreased activity in lab studies
- Bebtelovimab: active against BA.1, BA.2
    - Authorized when alternative treatments not available or clinically appropriate
- Nirmatrelvir/ritonavir, remdesivir, molnupiravir still expected to be active



Iketani S et al, Nature 2022

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Outpatient Treatment Options for COVID-19

Option	Patient Population
Nirmatrelvir/ ritonavir	• Patient not on interacting medications • As soon as possible and within 5 days of symptom onset
Sotrovimab	• Patient on interacting medication/able to come to health care facility • As soon as possible and within 7 days of symptom onset
Remdesivir	• Patient in health care facility or through home infusion service • As soon as possible and within 7 days of symptom onset
Bebtelovimab	• Not able to be treated with one of the options above • As soon as possible and within 7 days of symptom onset
Molnupiravir	• Adult not able to be treated with one of the options above • Not pregnant (if given during pregnancy, shared decision making) • As soon as possible and within 5 days of symptom onset

Summary

- In patients with NRTI resistance, treatment with DTG or DRV/r + Tenofovir/FTC results in high virologic suppression rate
- CAB/RPV every 2 months non-inferior to every 1 month in sustaining virologic suppression; avoid if known or suspected RPV or CAB resistance
- Novel ART: islatravir (NRTTI) on hold because of lymphopenia; lenacapavir (capsid inhibitor) advancing but recent issues related to glass vials
- HIV Cure: another case; woman who received cord blood transplant
- COVID-19 treatment: multiple options; keep your eye on BA.2