The Evolution of
HIV Care

Kiat Ruxrungtham

Professor of Medicine, School of Global Health,
ChulaVRC, Chulalongkorn University;

and HIV-NAT, Thai Red Cross AIDs Research Center

Chula VRC
Chula Vaccine Research Center
Faculty of Medicine, Chulalongkorn University

School of
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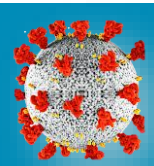
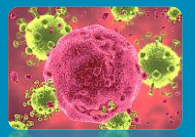
Global Situation (24 Aug 2022)

Covid-19

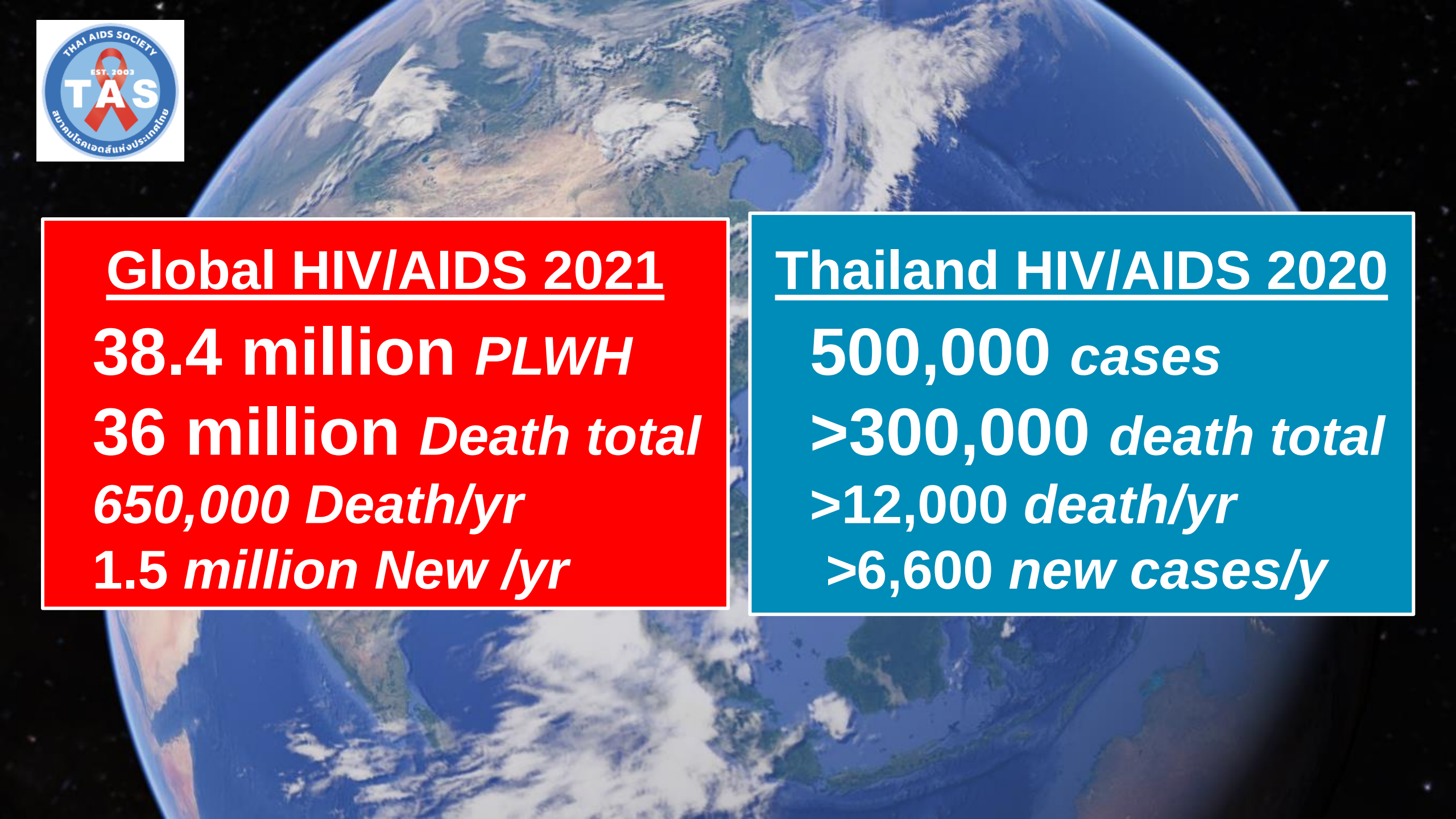


- Pandemic since Jan 2020 x **2.9 Yrs**
- **602 million** *confirmed cases*
- **6.5 million** *confirmed death*
- **Transmission:** droplets, airbourne, contact
- **Vaccines** : >6 vaccines approved
- **Effective treament** : few
- **Prevention**: Mask, Distancing, Cleaning
- **Global impact** : Very high

HIV /AIDS



- Epidemic since 1981 x **41 yrs**
- **38.4 million** living with HIV
- **36 million** died from 1981-2020
- **1.5 million** New Infection/year
- **0.65 million** died/year
- **Transmission** : Sexual, blood
- **Vaccine** : Unlikely up-to-now
- **Effective treament** : **Yes, highly effective**
- **Prevention**: Condom, PrEP, TasP
- **Global impact** : high



Global HIV/AIDS 2021

38.4 million *PLWH*

36 million *Death total*

650,000 Death/yr

1.5 *million New /yr*

Thailand HIV/AIDS 2020

500,000 *cases*

>300,000 *death total*

>12,000 *death/yr*

>6,600 *new cases/y*

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Four Decades of HIV Therapy

Present and the Future

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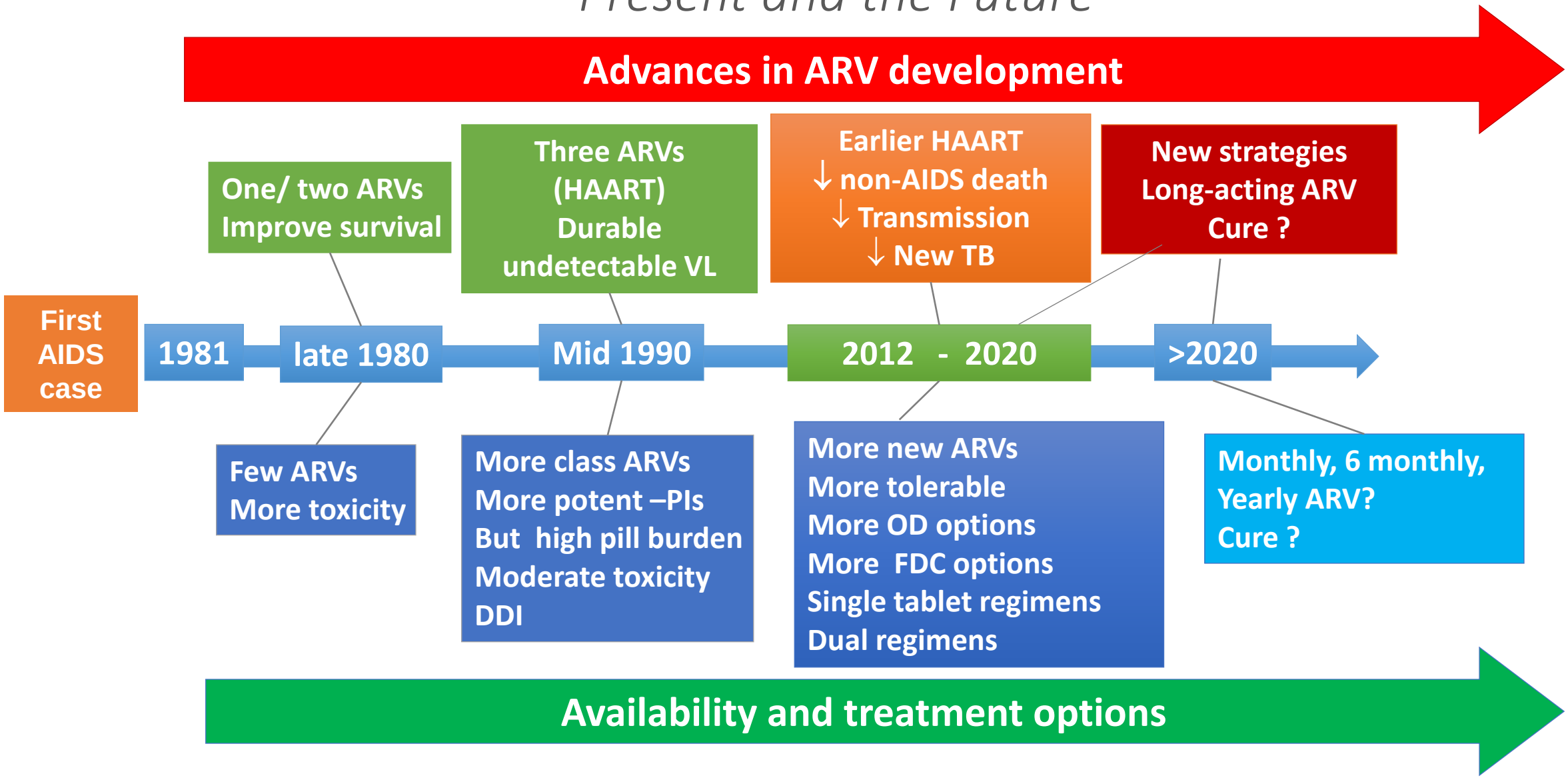

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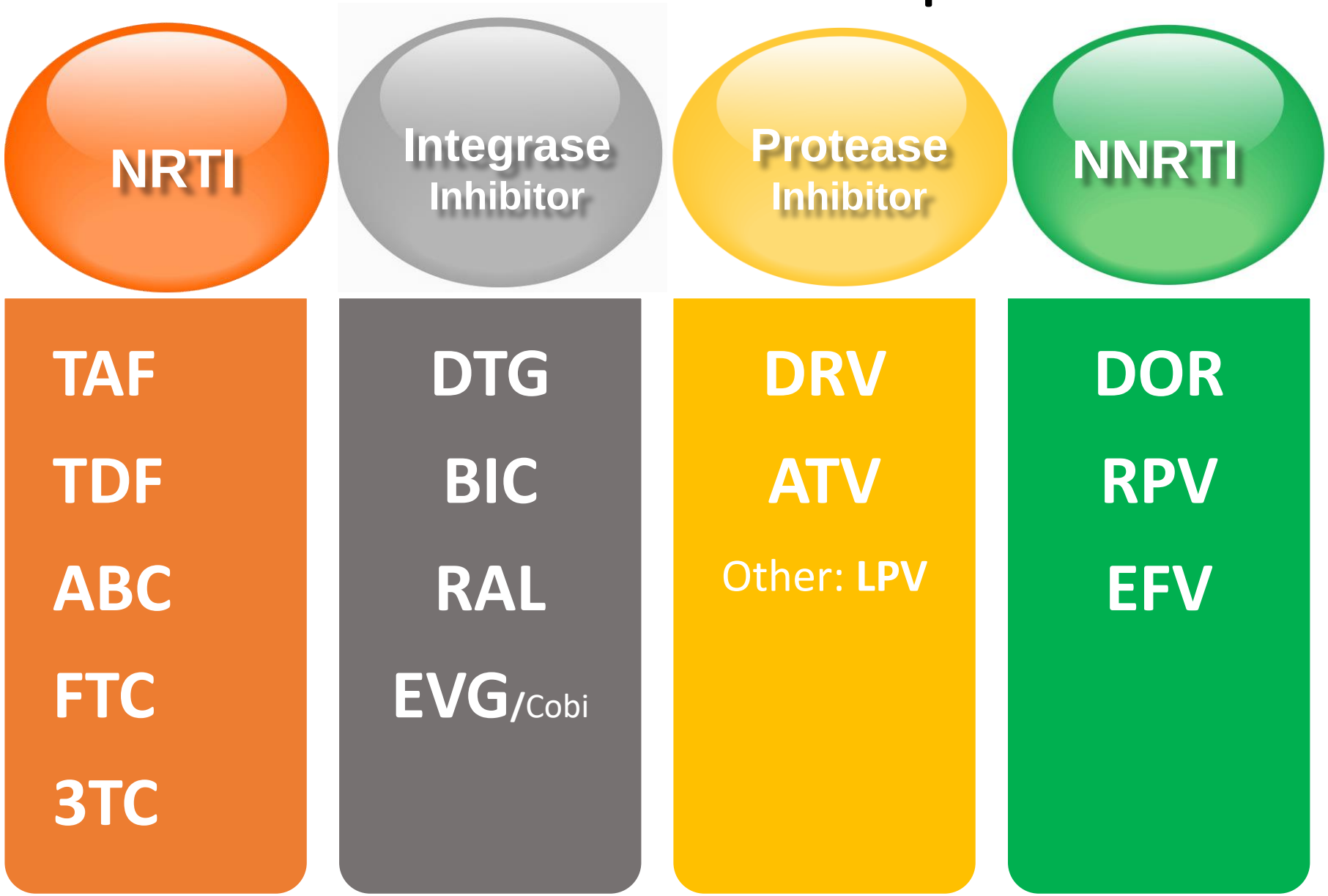
Current Oral ARV options



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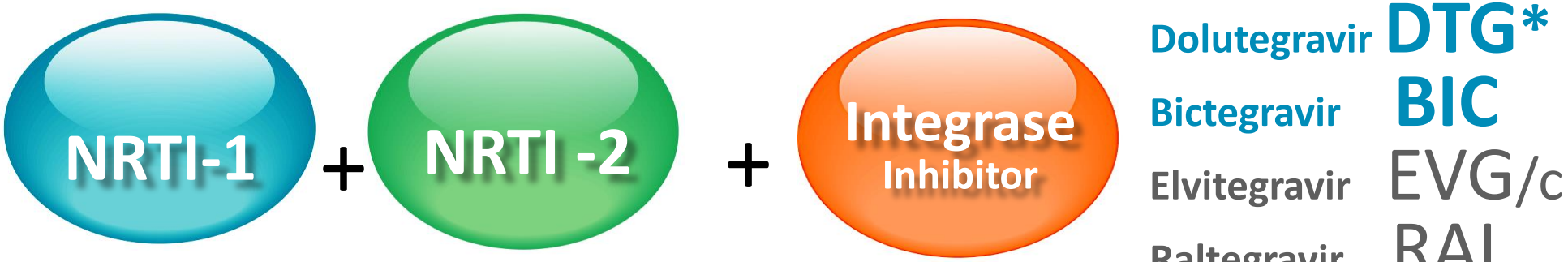
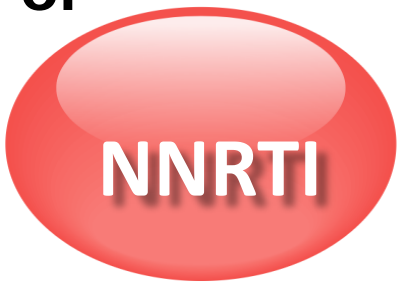


TAF
TDF
ABC*

FTC
3TC

Dolutegravir DTG*
Bictegravir BIC
Elvitegravir EVG/c
Raltegravir RAL

or



Rilpivirine RPV
Doravirine DOR
Efavirenz EFV

or

Darunavir DRV
Atazanavir ATV
(both need a booster RTV or Cobi)

Principle of
ART 3-drug Regimens

*ABC only for HLA-B*5701 negative person, *ABC+3CT combined with DTG as a STR,

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	Integrase Inhibitor	Protease Inhibitor	NNRTI
Tolerability	++++	+++	EFV ++ RPV ++++
Genetic Resistance Barrier	DTG, BIC – *High* RAL, EVG - *Low*	*High*	*Low*
Single pill regimen	DTG, EVG/c, BIC-*Yes*	*Only 1* *(only DRV/c/TAF/FTC)*	*Yes*
Drug-Drug interaction	*EVG/c - High* DTG, RAL, BIC - *Low*	*High*	*Low*

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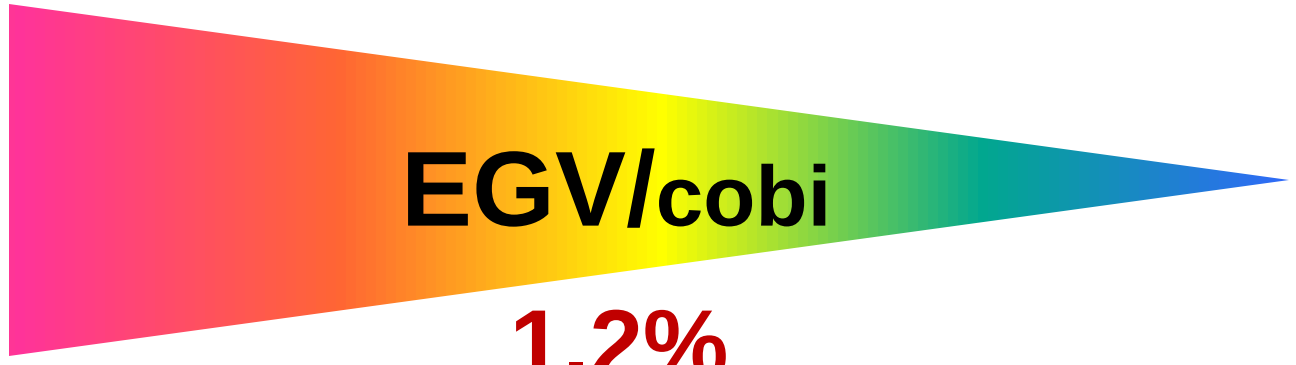
HIV Integrase Inhibitors

Chance to develop drug resistance

Subgroup meta-analysis from clinical trials

You, PLoS One. 2016;11:e0160087

High *Chance to develop drug resistance* **Low**



RAL **EGV/cobi** **DTG**

3.9% **1.2%** **0.1%**

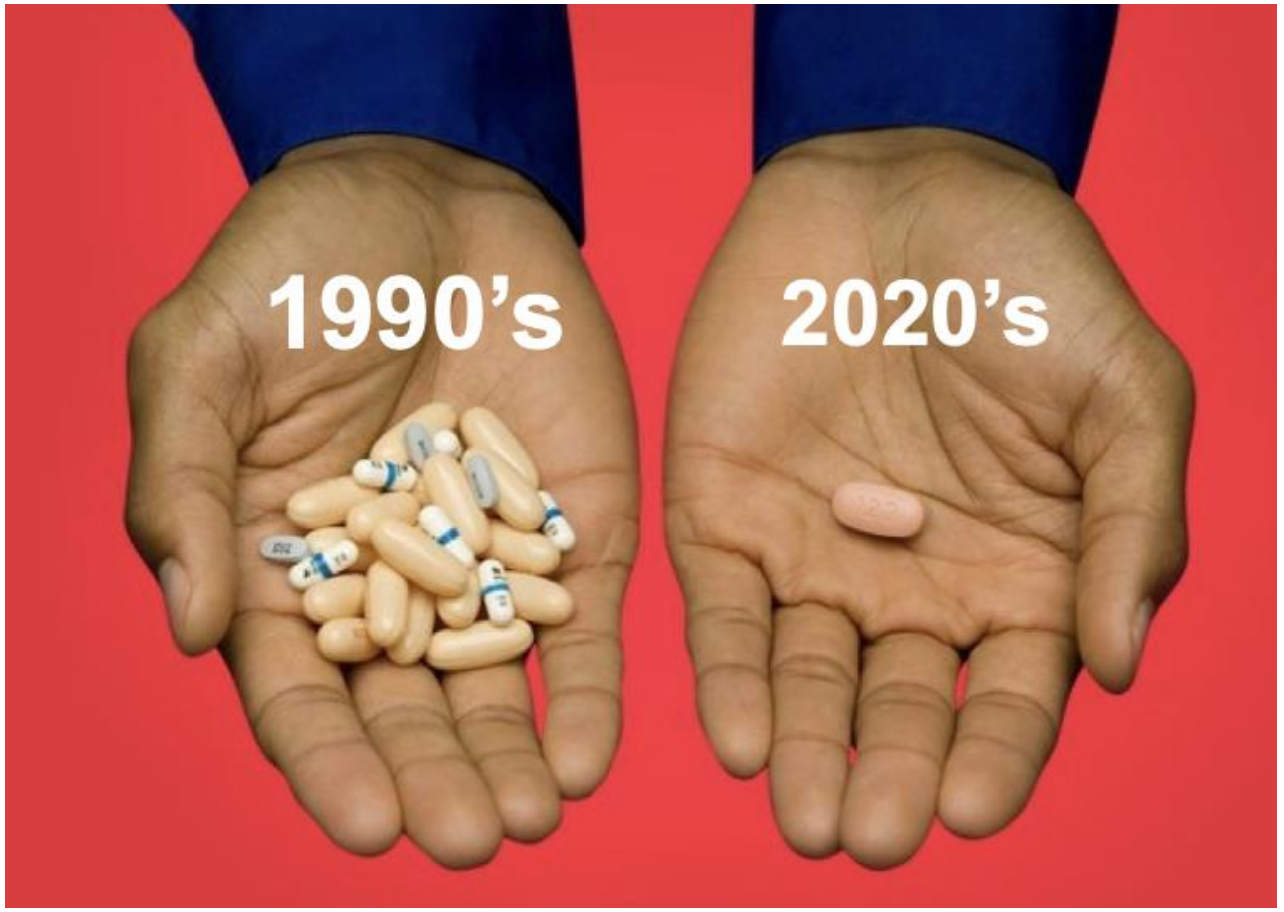
BIC*

RAL vs DTG – DR rate 3.9% vs 0.1% (40-fold higher)
RAL, EVG/c: 10 major integrase mutations (N155H, Y143C/R, Q148H/R, Y143Y/H, L74L/M, E92Q, E138E/A, Y143C, Q148Q and Y143S)
DTG 13 mutations (T97T/A, E138E/D, V151V/I, N155H, Q148, Y143C/H/R, T66A and E92Q).

* Acosta RK. AAC. 2019

DTG, BIC : Options for patients who plan to start ART before having resistance test results

HIV Treatment Evolution
More Friendly, More Accessible and Affordable



Q Abdool Karim. CAPRIS

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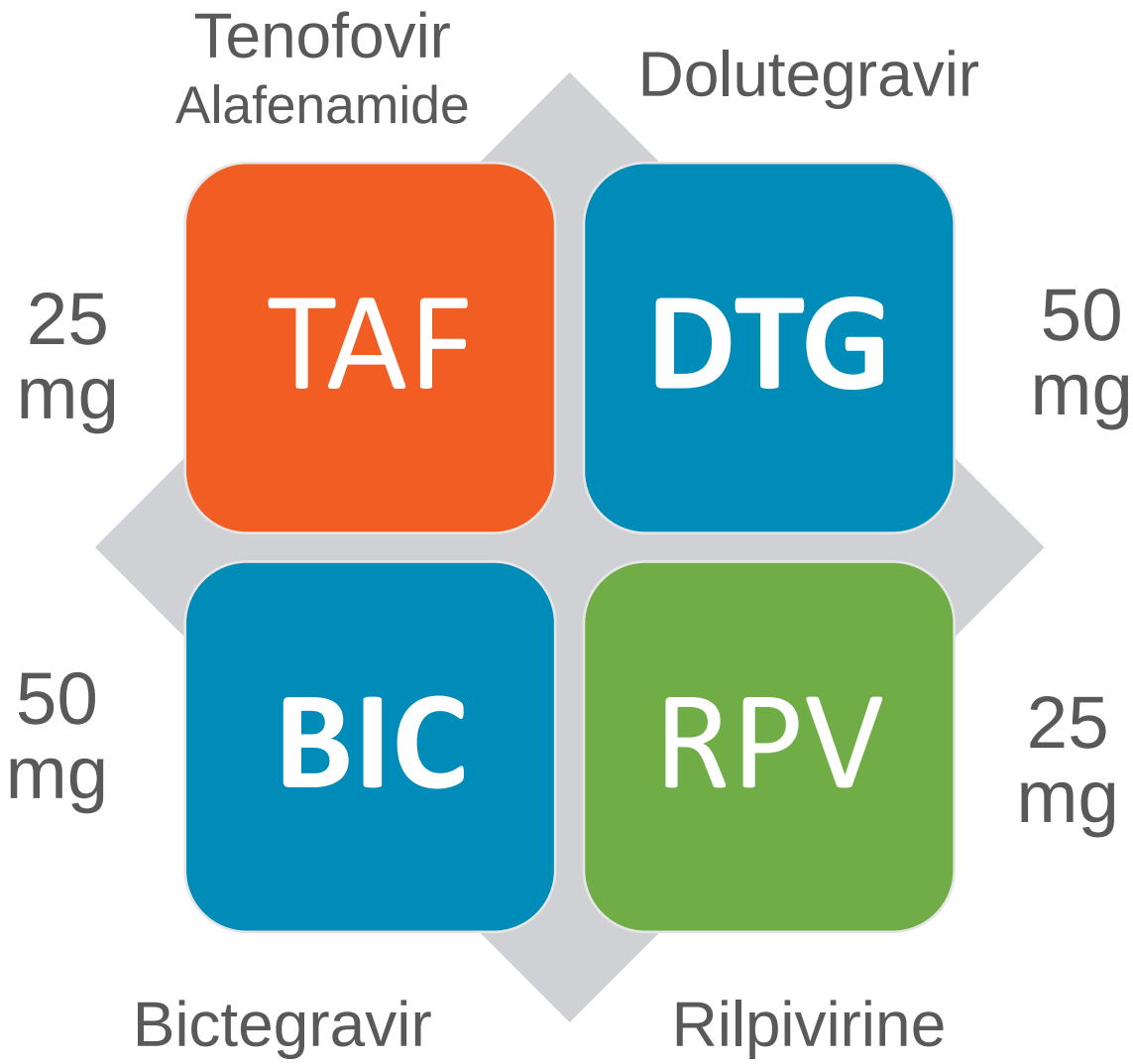
High potency ARVs lead to much **smaller doses** *and* **smaller pills**



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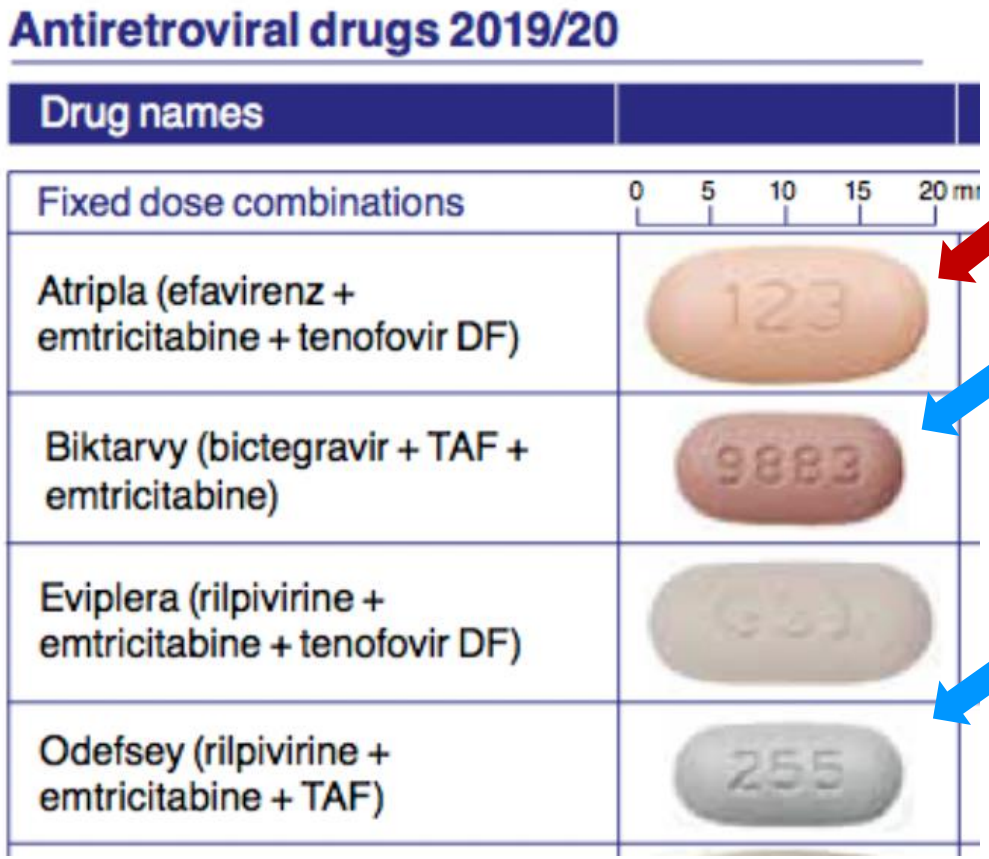
Pill Size of Single-Tablet Pill Getting Smaller



EFV/TDF/FTC : 600/300/200 mg

BIC/TAF/FTC : 50/25/300 mg

RPV/TAF/FTC : 50/25/300

i-base.info

Food Effect

With Food

to improve absorption

- Rilpivirine
- EVG/c
- DRV or ATV,+rtv,c

Empty Stomach

to reduce AEs

- Efavirenz

No meal restriction

- Dolutegravir
- Bictegravirr
- Raltegravir
- Doravirine

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DTG-based vs other ART in Controlled Trials

First-line regimen

SPRING 2	**DTG** is ***non-inferior*** to **RAL** 96 weeks results. More DR was found in RAL, but none in DTG among those with VF
SPRING	**DTG** is ***superior*** to **EFV** **(ABC/3TC/DTG) at 48 and 144 weeks**
FLAMINGO	**DTG** is ***superior*** to **DRV/r** **at 48 and 96 weeks**
ARIA	**DTG** is ***superior*** to **ATV/r** **at 48 weeks**
GS-US-380-1490 & 1498	**DTG** is ***non-inferior*** to **BIC**

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Adult HIV Treatment Guidelines

DHHS[1]	IAS-USA[2]	EACS[3]	WHO[4]
▪ **BIC**/FTC/TAF ▪ **DTG**/3TC/ABC ▪ **DTG** + FTC/TAF or TDF ▪ **DTG**/3TC	▪ **BIC**/FTC/TAF ▪ **DTG**/3TC/ABC ▪ **DTG** + FTC/TAF ▪ **DTG**/3TC	▪ **BIC**/FTC/TAF ▪ **DTG**/3TC/ABC ▪ **DTG** + FTC/(TAF or TDF) ▪ **DTG**/3TC ▪ **RAL** + FTC/(TAF or TDF) ▪ **DRV**(COBI or RTV) + FTC/(TAF or TDF)	▪ **DTG** + (3TC or FTC)/TDF

- Recommendations may differ based on baseline HIV-1 RNA, CD4+ cell count, CrCl, eGFR, HLA-B*5701 status, HBsAg status, bone mineral density, and pregnancy status or intent

1. DHHS ART. Guidelines. October 2021. 2. Saag. JAMA. 2020. 3. EACS. 2021. 4. WHO ART. July 2021.

Modified from Slide credit: clinicaloptions.com

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Cost of ART in LMICs

a Key Driver for Wolrdwide Early Accessibiliy and Coverage

TDF/3TC/DTG

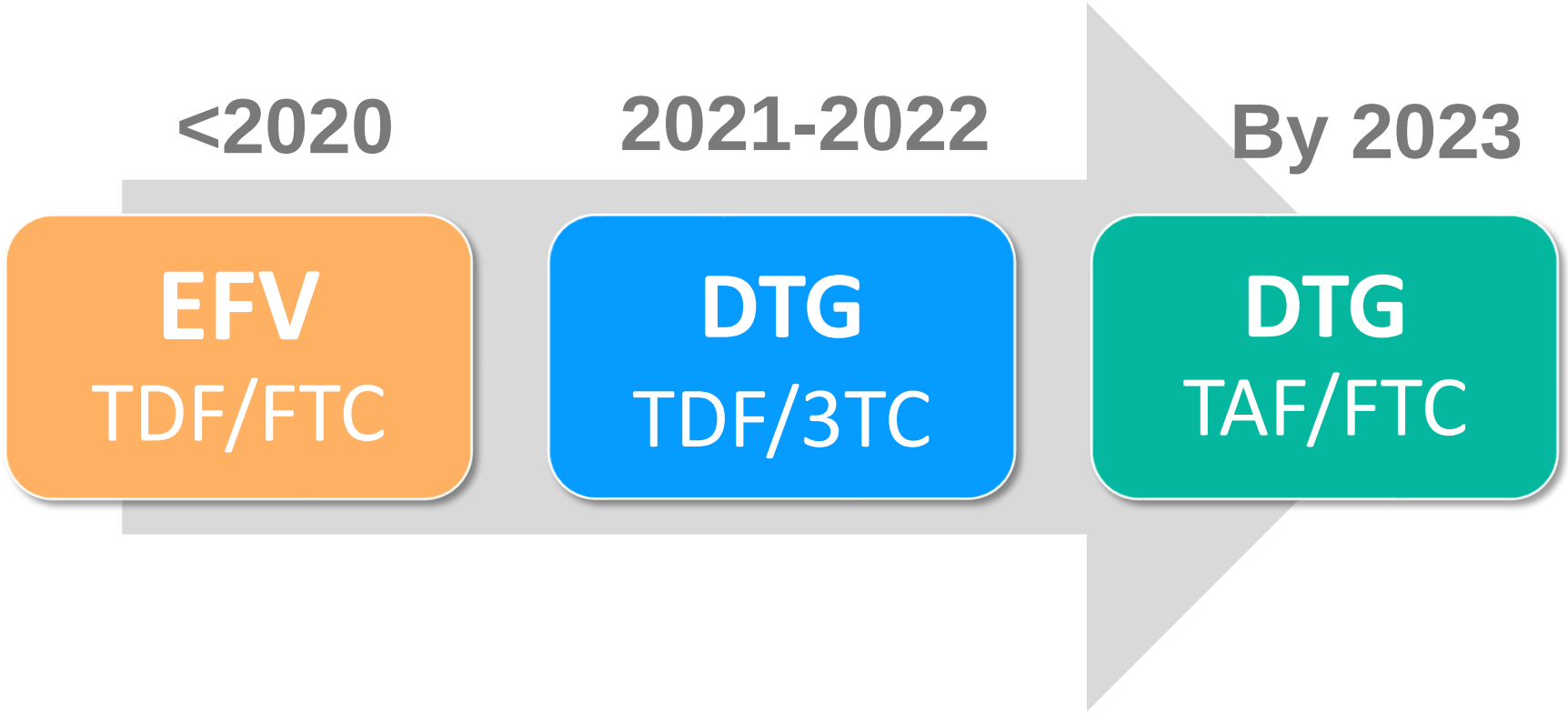
$75 per person-year (SA, Kenya)

$24 per month -Thailand

TAF/FTC/DTG

$35 per month -Thailand

Current *Preferred*-ART in Thailand



Higher Potency,
Rare DR failure
Lower toxicity
Low cost
Low DDI
Kidney/bone friendly

DTG (dolutegravir)

Recent Data on Adverse effects

1. **Neural Tube Defect (NTD)**: recent updated Tsepamo, Bosswana cohort:
   - **0.3%** DTG vs **0.1%** non-DTG ART
   - Should provide counseling and discussion with our female patient on this low risk NTD
2. **Weight gain** :
   - NAMSAL study in Cameroon:
     - DTG vs EFV: **5** vs **3** kg
   - ADVANCE study in South Africa:
     - DTG/TAF vs DTG/TDF vs EFV/TDF : **10** vs **5** vs **3** kg
   - should monitor patient's BW

Cristina Mussini, clinicaloptions.com. Zash. NEJM. 2019;[Epub];
ANRS 12313 Study Group. NEJM. 2019:[Epub]., Venter. NEJM. 2019;[Epub],

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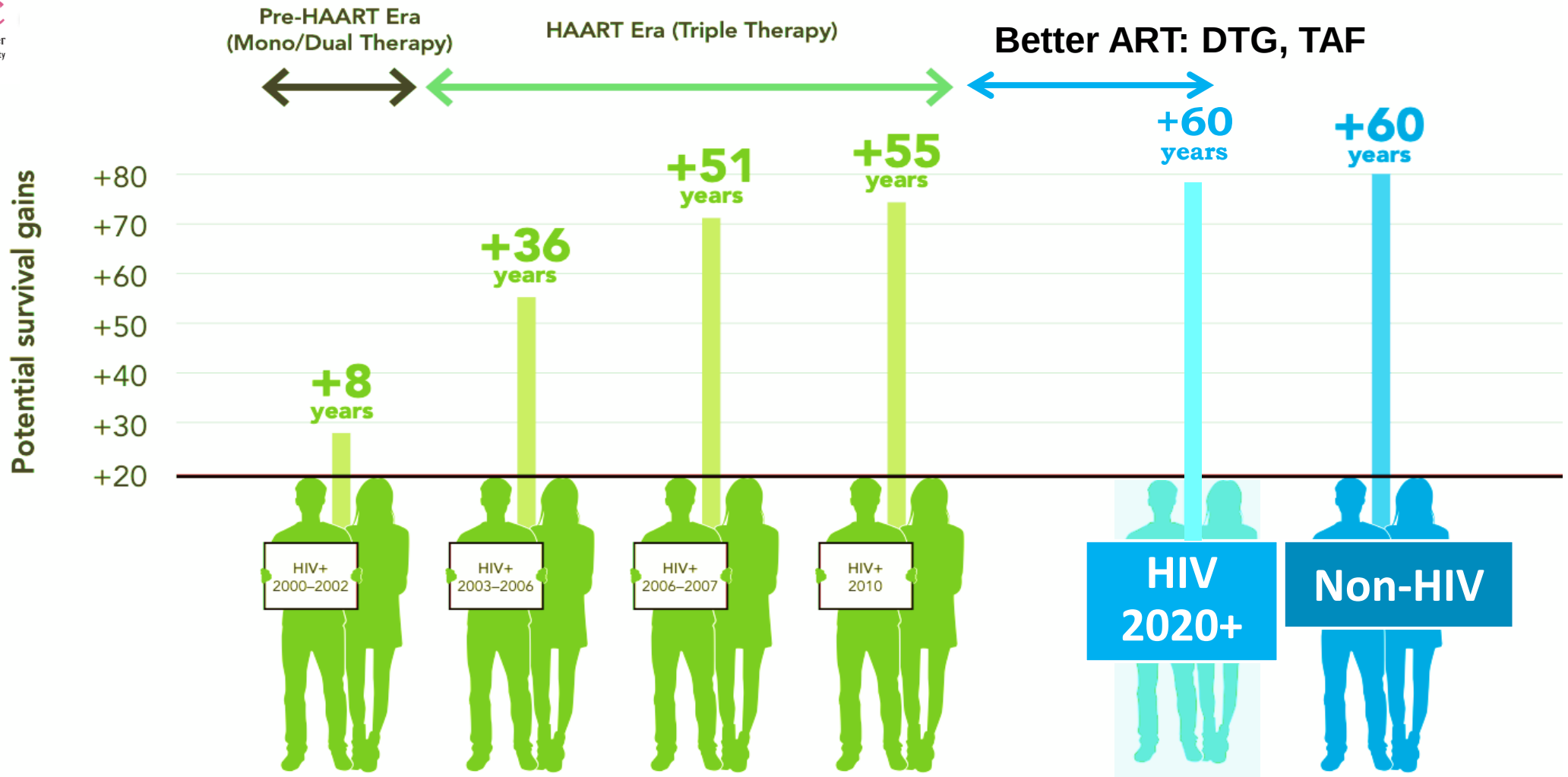
HIV Treatment Can Normalize Survival



Expected impact of HIV treatment in survival of a 20 years old person living with HIV in a high income setting (different periods)

Source: Samji H et al., PLoS ONE, 2013.

Teeraananchai S, et al. Antivir Ther. 2017;22(5):393-402

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Why we do need more **new ART** options?

Current Preffered ART Regimens	Why Desire for more new options
• Highly Effective • Easy to take as once daily • High barrier to drug resistance • Well-tolerated and safe	• To improve adeherenc issue by having once a month or longer ART • Options for MDR patients • Concern of unanticipated long-term toxicities of current ARVs • Less drug-drug interaction

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Current and Future Trends

Simplify Treatment, Reduce number of drug exposure

1 Reduce to 2 drug-regimen (Daul ART)

DTG/3TC
DTG/RPV

CAB/RPV

2 Reduction in dose frequency

LA injectable ARVs
LA implantable ARVs

6 Monthly Shot

Implant Device

2-6 months or yearly interval

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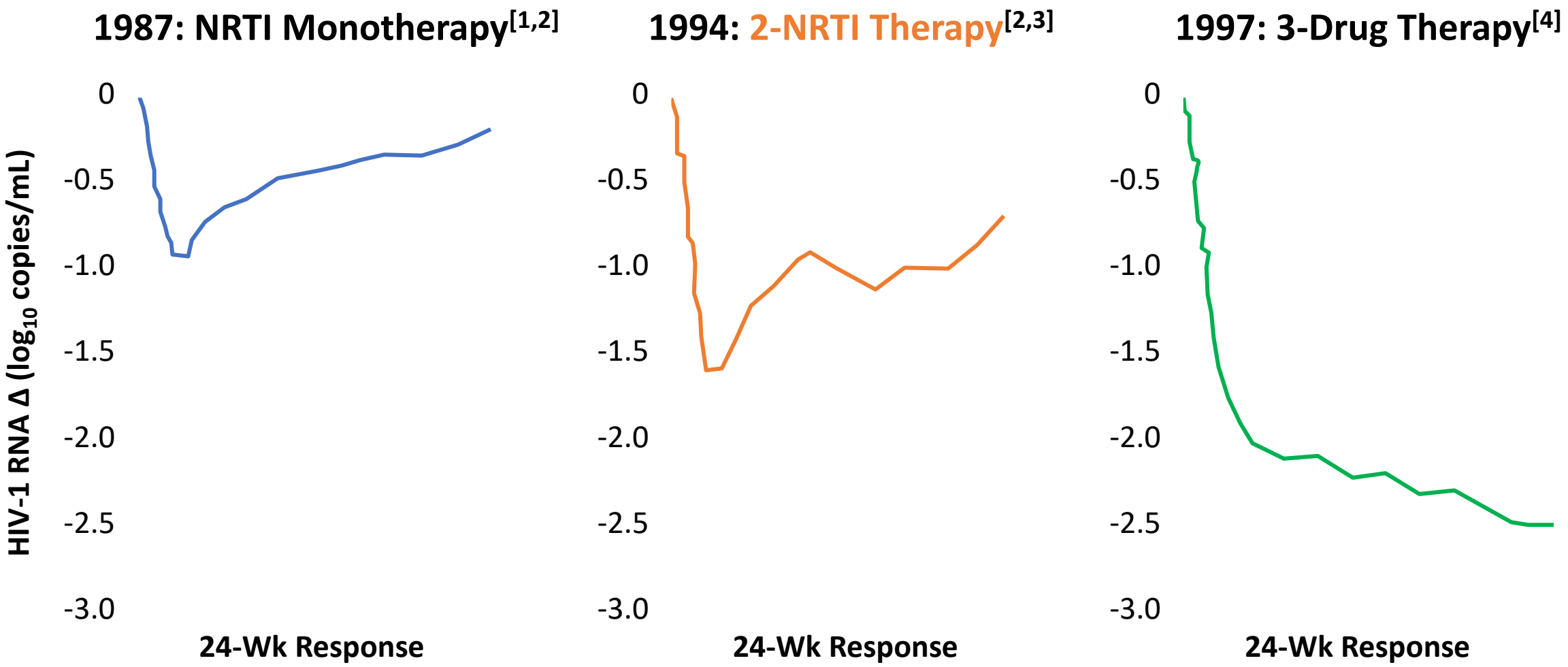
Evolution of ART: 1987-1997



1. Fischl. NEJM. 1987;317:185. 2. Harrigan. J Acquir Immune Defic Syndr Hum Retrovirol. 1995;10 Suppl 1:S34.
3. Eron. NEJM. 1995;333:1662. 4. Gulick. NEJM. 1997;337:734.

Slide credit: clinicaloptions.com

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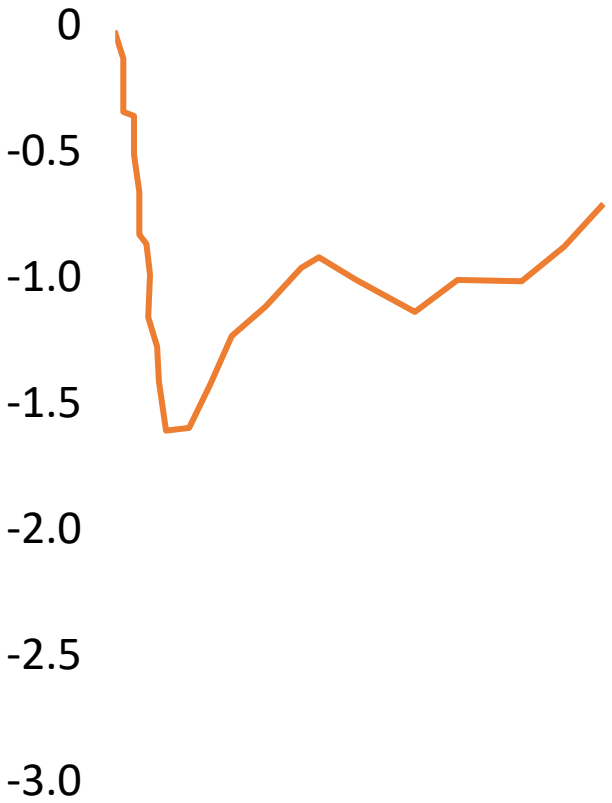
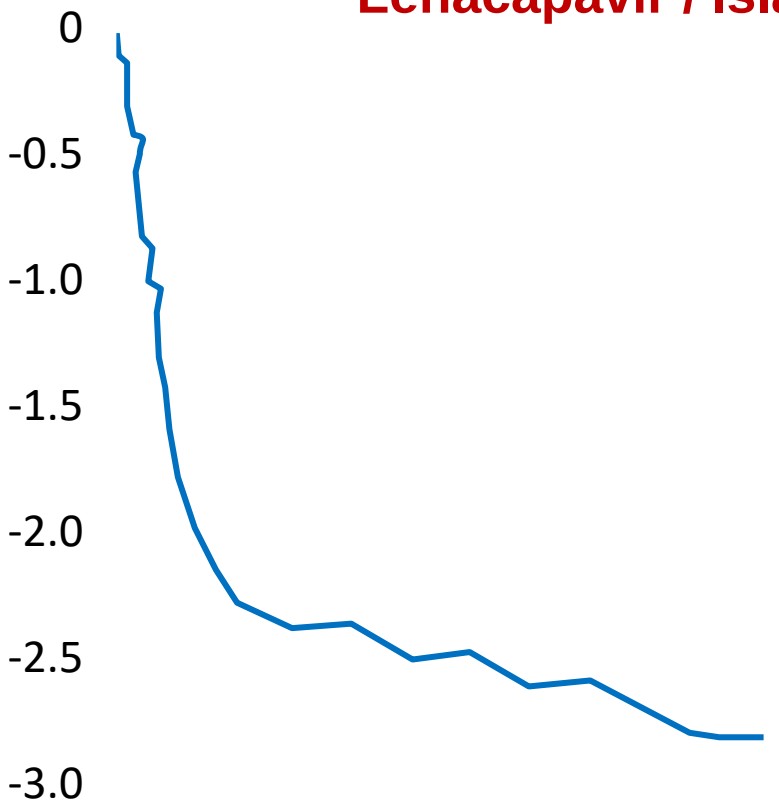
Past 2-drugs ≠ Current 2-drugs regimen

1994: 2-NRTI Therapy



24-Wk Response

>2020: 2-ARVs: DTG/3TC or LA CAB/RPV
Lenacapavir / Islatravie



24-Wk Response

2-Drug Regimens and Implementing in **Asia**

Two Drug Regimen	Hig-income countries	LMICs	Indication
Dolutegravir + lamivudine (**DTG / 3TC**) - STR	STR-Dovato	Not available	First-line, and switch option
Dolutegravir + rilpivirine (**DTG / RPV**) - STR	STR-Juluca	Not available	Switch in VL suppressed >6 mo
LA Cabotegravir + rilpivirine (**CAB/RPV-LA**) injectable	May be available	Not available	In VL suppressed patients, and an oral lead-in with CAB+RPV is needed

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Dual ART

in Treatment Naïve Patients

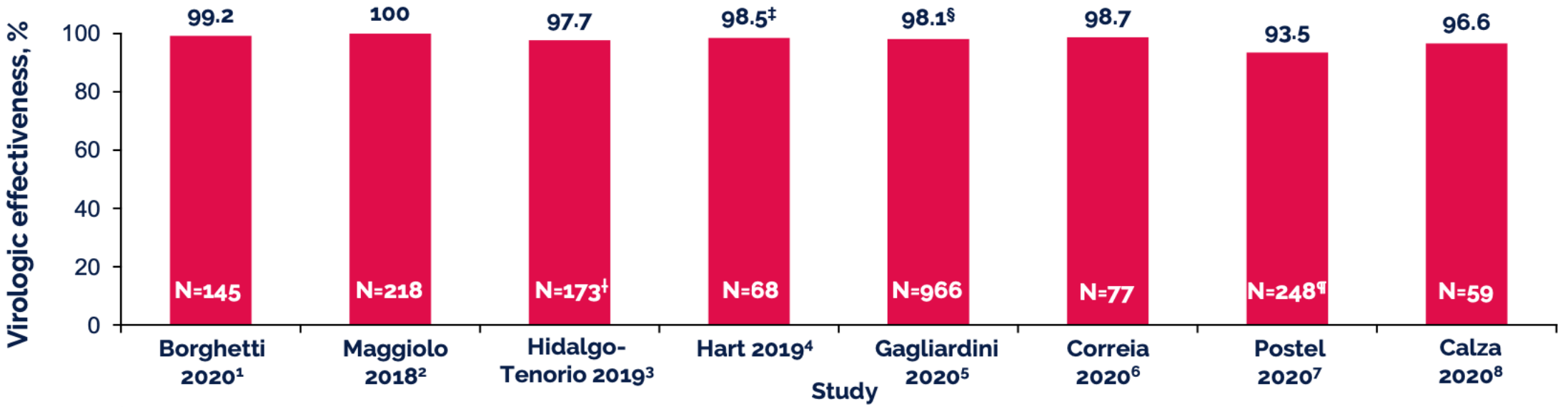
- **DTG+3TC** (Oral): FDA Approved
- **CAB+RPV**, (LA injectable) : Approval is pending
- **ISL+DOR** (Oral): Phase III Clinical development

DOVATO: VIROLOGIC EFFECTIVENESS IS HIGH ACROSS REAL-WORLD STUDIES*

Reported effectiveness outcomes vary between studies

Effectiveness : 93.5- 100 %

FU range: 0.5 to 3 yea



Endpoint or time of follow-up	144 weeks	2 years	48 weeks	Mean: 0.5 years	Median: 15 months	48 weeks	6 months	12 months
Effectiveness outcome of patients on treatment with DTG + 3TC at endpoint/time of follow-up	Estimated probability of remaining free from VF	Proportion of patients without VF	Proportion of patients without VF	HIV-1 RNA <40 c/ml	Proportion of patients without virological rebound	Proportion of patients without VF	HIV-1 RNA <50 c/mL or 50–200 c/mL with subsequent HIV-1 RNA <50 c/mL	Proportion of patients without VF

Available data show real-world effectiveness is consistent with that seen in Phase III studies

*Includes studies reporting applicable effectiveness outcomes for >50 patients receiving DTG + 3TC; †Full study population=177; however, 4 patients have been excluded here; ‡At least 67/68 patients on DTG + 3TC remained free of virologic failure; 1 patient experienced virologic failure in the study (total population = 96), treatment regimen was not reported; §18 virological rebound events (calculation assumes ≤1 virological rebound event per patient); ¶Effectiveness analysis set (missing=excluded). **VF,** virologic failure

1. Borghetti A, et al. Clin Infect Dis 2020;cia313; **2.** Maggiolo F, et al. HIV Glasgow 2018. Poster P104; **3.** Hidalgo-Tenorio C, et al. Medicine 2019;98:1–7; **4.** Hart J, et al. BHIVA 2019. Poster P9; **5.** Gagliardini R, et al. CROI 2020. Poster 486; **6.** Correia RMA & Carvalho AC. AIDS 2020. Poster PEB0235; **7.** Postel N, et al. HIV Glasgow 2020; Virtual. Poster P044; **8.** Calza L, et al. J Antimicrob Chemother 2020;75:3327–33

DTG/3TC dual regimen
Confirmed Virological Withdrawal (CVW)

Study	DTG/3TC	DTG/TDF or TAF/FTC
GEMINI (3 years)	2 %	1 %
TANGO (2 years)	0 %	0 %
Real-World (0.5-3 yrs) 16 studies	0 %	0 %

Some Pracrtical Considerations

for DTG/3TC, DTG/RPV vs TAF-based ARTs

Study	DTG/3TC	DTG/RPV	TAF/FTC/DTG or BIC
HBV	+ anti-HBV	+ anti-HBV	√
CKD with dialysis	Adjust 3TC dose	√	Adjust FTC dose
Food-restriction	no	yes	no
PPI co-admister	√	X	√
Anticid Al, Mg, +/- Ca-	2 hrs before or 6 hrs after DTG	2 hrs before or 6 hrs after DTG	2 hrs before or 6 hrs after DTG, BIC
Obesity	May gain weight	May gain weight	Gain more weight

In virological suppressed individuals

LA-Injectable Dual Therapy

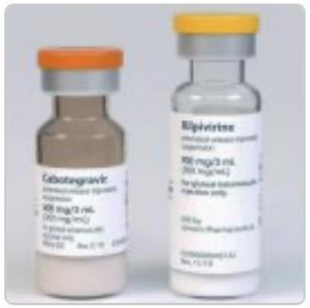
Cabotegravir / Rilpivirine

Oral Lead-in at least 1 month

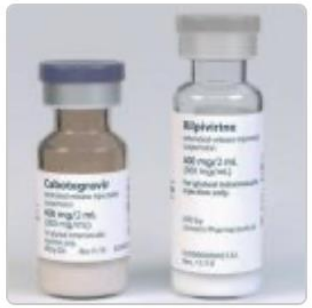
Cabotegravir 30 mg (Vocabria®)

Rilpivirine 25 mg (Edurant®)

Extended Release Injectable Suspensions



Cabotegravir 600 mg/3mL - Rilpivirine 900 mg/3mL



Cabotegravir 400 mg/2mL - Rilpivirine 600 mg/2mL

q 2 months

q 1 months

LA IM CAB + RPV: FDA and EMA Prescribing Information

- **Indication:** As complete regimen for treatment of HIV-1 infection in adults who are virologically suppressed on a stable ART regimen; no history of treatment failure and no known or suspected resistance to either CAB or RPV (EMA: or agents of the NNRTI and INSTI class)

Dosing for Q1M Regimen			
Drug	*Optional* Oral Lead-in	IM (Gluteal) Initiation Injections (1-Time Dosing)	IM (Gluteal) Continuation Injections (Once-Monthly Dosing)
	~1 Mo	On Last Day of Oral Lead-in or Current ART Dosing	Begin 1 Mo After Initiation Injections
CAB	30 mg once daily with meal	600 mg (3 mL)	400 mg (2 mL)
RPV	25 mg once daily with meal	900 mg (3 mL)	600 mg (2 mL)

Dosing for Q2M Regimen			
Drug	*Optional* Oral Lead-in	IM (Gluteal) Initiation Injections (2-Time Dosing)	IM (Gluteal) Continuation Injections (Every-2-Mo Dosing)
	~1 Mo	On Last Day of Oral Lead-in or Current ART Dosing and 1 Mo Later	Begin 2 Mo After Second Initiation Injections
CAB	30 mg once daily with meal	600 mg (3 mL)	600 mg (3 mL)
RPV	25 mg once daily with meal	900 mg (3 mL)	900 mg (3 mL)

Slide credit: clinicaloptions.com

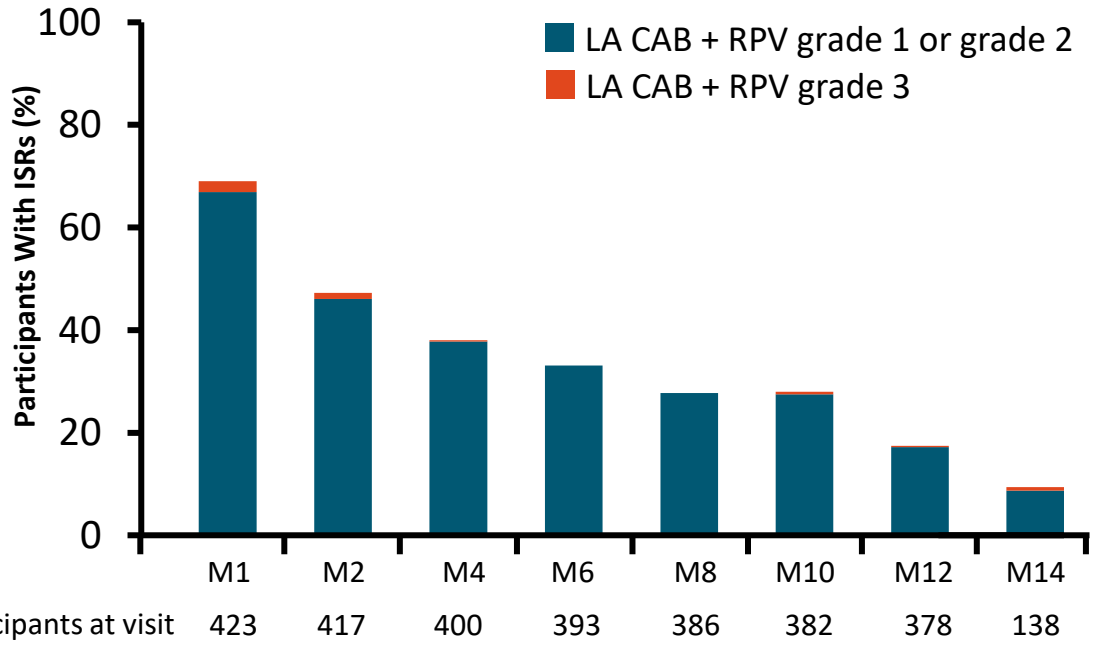
FDA extended-release CAB + RPV injections. EMA prolonged-release CAB injection. EMA prolonged-release RPV injection.

CARISEL: Safety Summary and Injection Site Reactions

Phase IIIb Implementation Study: Long-Acting CAB + RPV for ART in Europe

- **Injection site reactions** reported in **86%** of patients
- **98%** with mild or moderate severity
- Median ISR duration: **3** days; **82%** resolved within 7 days

Injection-Related Parameter	LA CAB + RPV (N = 430)
No. of patients who received ≥1 injection	423
No. of injections	5844
▪ ISR events, n	1867
Pain, n (% of injections)	1540 (26)
Discomfort, n (% of injections)	94 (2)
Induration, n (% of injections)	74 (1)
Grade 3, n (% of ISR events)	32 (2)
Patients withdrawing for injection-related reasons, n (% of participants with injections)	25 (6)



Jonsson-Oldenbüttel. AIDS 2022. Abstr EPLBB05.

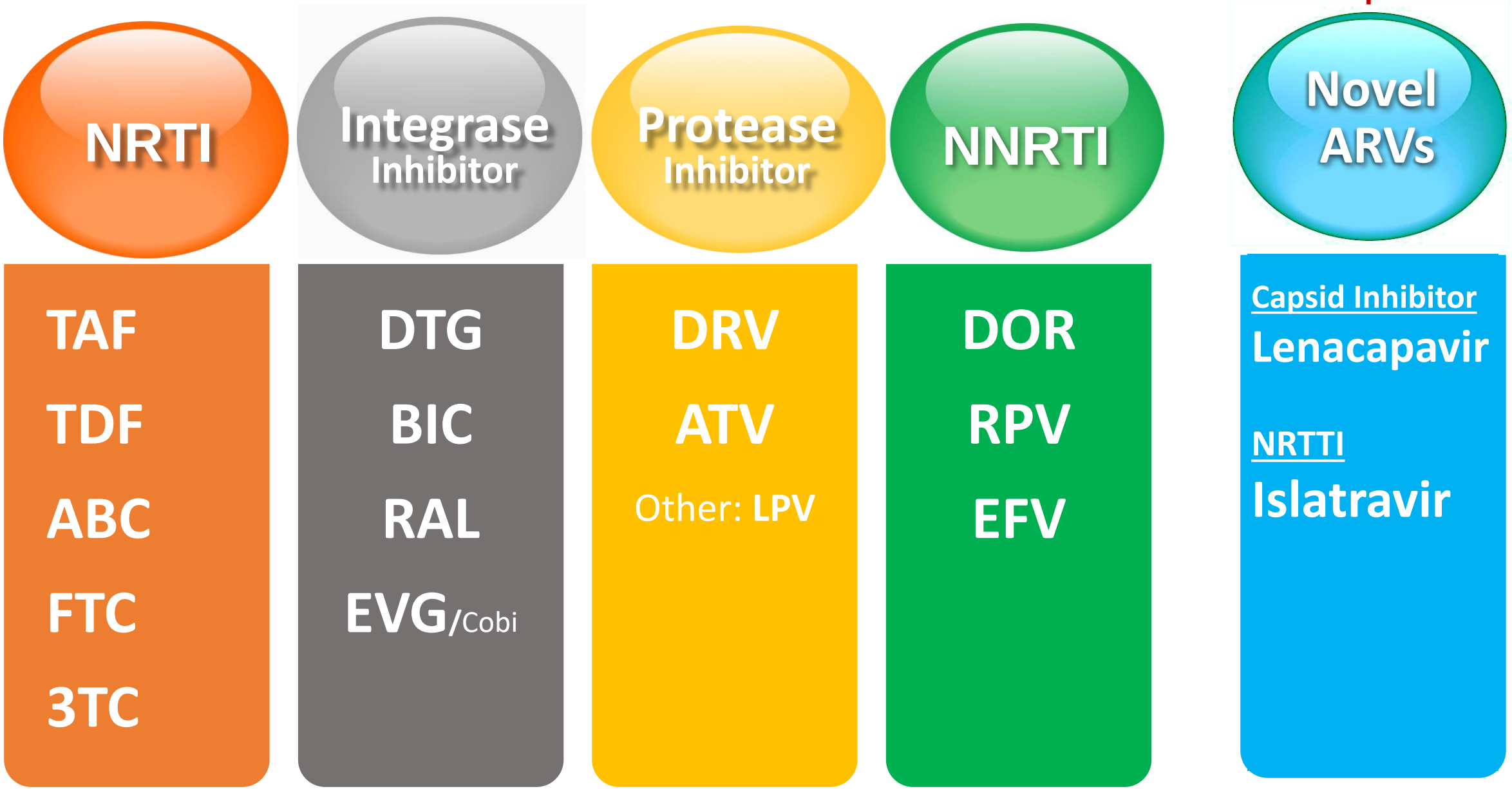
Slide credit: clinicaloptions.com

Patients for Whom **CAB/RPV LA** Is **Not Recommended**

- **Active HBV coinfection** without concurrent oral therapy for HBV
- **Known or suspected INSTI or NNRTI RAMs**, excluding the K103N mutation in isolation, at baseline

cdn.hivguidelines.org

Current and Future ARV options



New Option for HIV-MDR Patients

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Capsid Inhibitor: **Lenacapavir** - *a First-in-Class*

Lenacapavir

1. **Inhibits HIV-1 capsid function**
   Inhibits viral replication at both early and late stages of the life cycle
2. **Antiviral activity**
   Against viral mutations that are resistant to major antiretroviral classes
3. **Administration**
   - Subcutaneously up to q 6 months, or
   - Orally weekly

Side Effects : 63% Injection site reactions

Most were mild/moderate severe, lasted in days

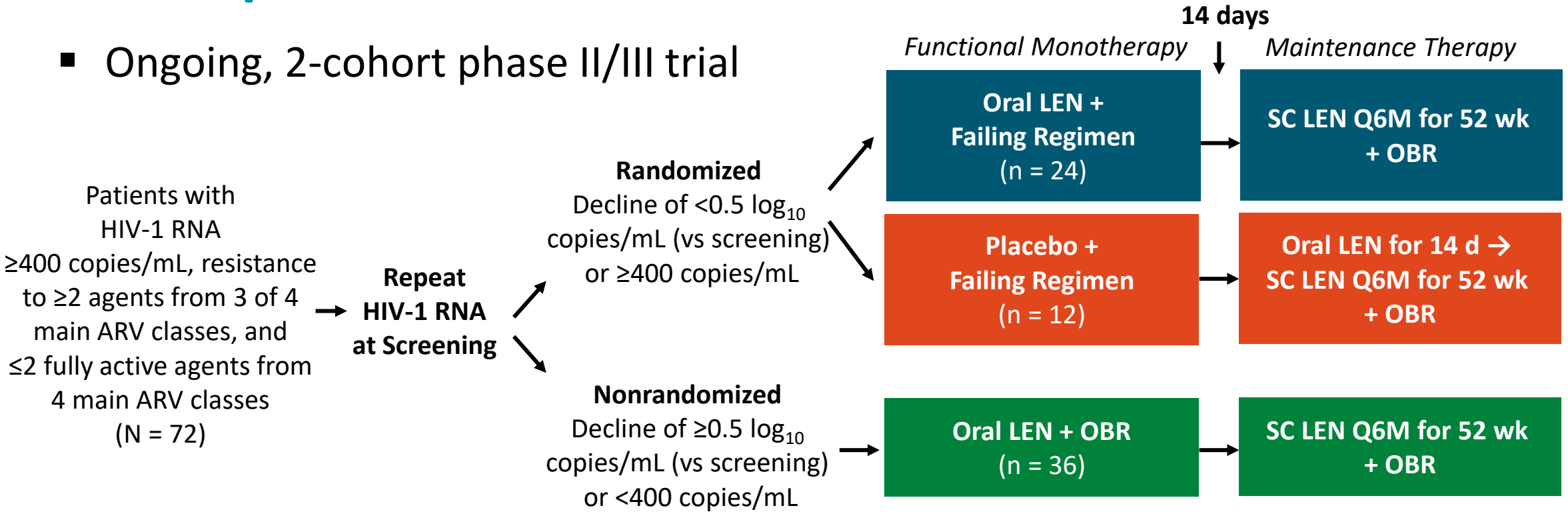
Nodules and induration lasted several months.

Segal-Maurer et al. N Engl J Med 2022;386:1793-803.

CAPELLA: Study Design

Lenacapavir q6M + OBR in MDR patients

- Ongoing, 2-cohort phase II/III trial



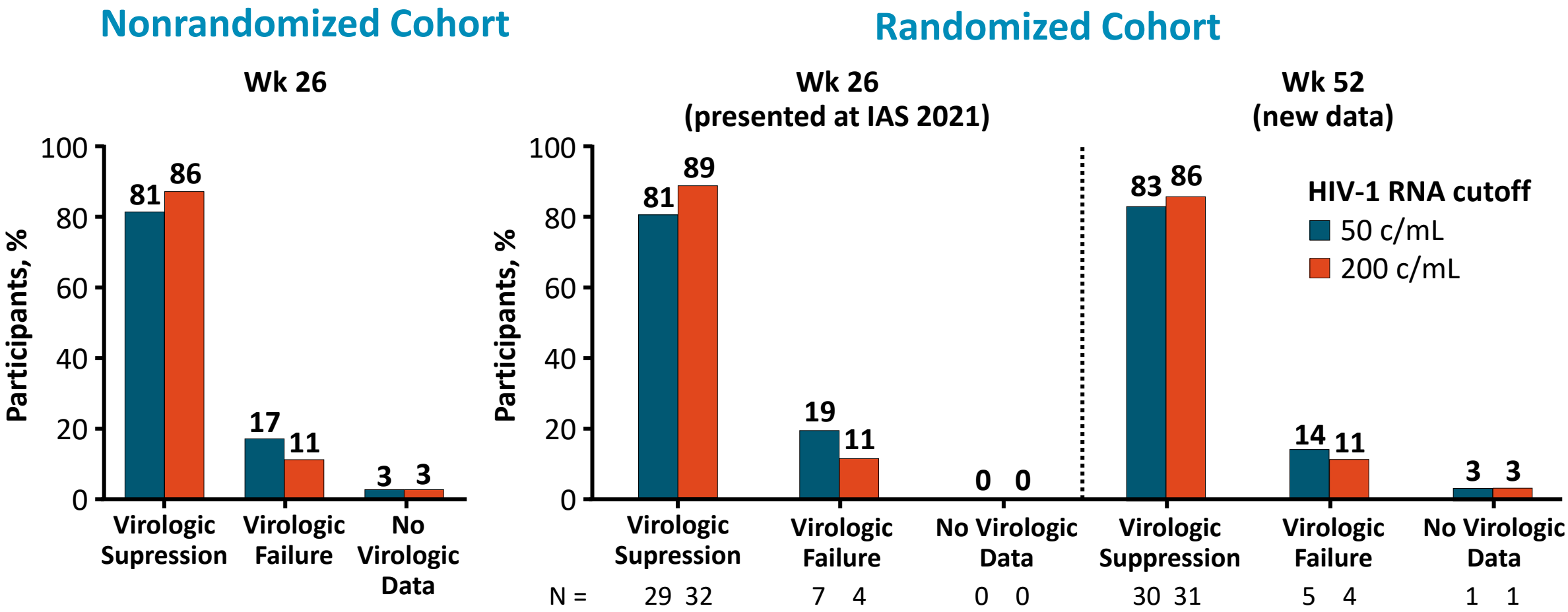
Oral LEN administered as 600 mg on Days 1 and 2, 300 mg on Day 8; SC LEN administered as 927 mg (2 x 1.5 mL) in the abdomen on Day 15 and Q6M thereafter.

- Current analysis: safety and efficacy (FDA Snapshot) of LEN + OBR at Wk 26 and 52

Ogbuagu. CROI 2022. Abstr 491.

Slide credit: clinicaloptions.com

CAPELLA: Lenacapavir Efficacy at Wk 26 and 52



- CD4+ count increased by 83 cells/mm³ at Wk 52 in randomized cohort

Ogbuagu. CROI 2022. Abstr 491. Reproduced with permission.

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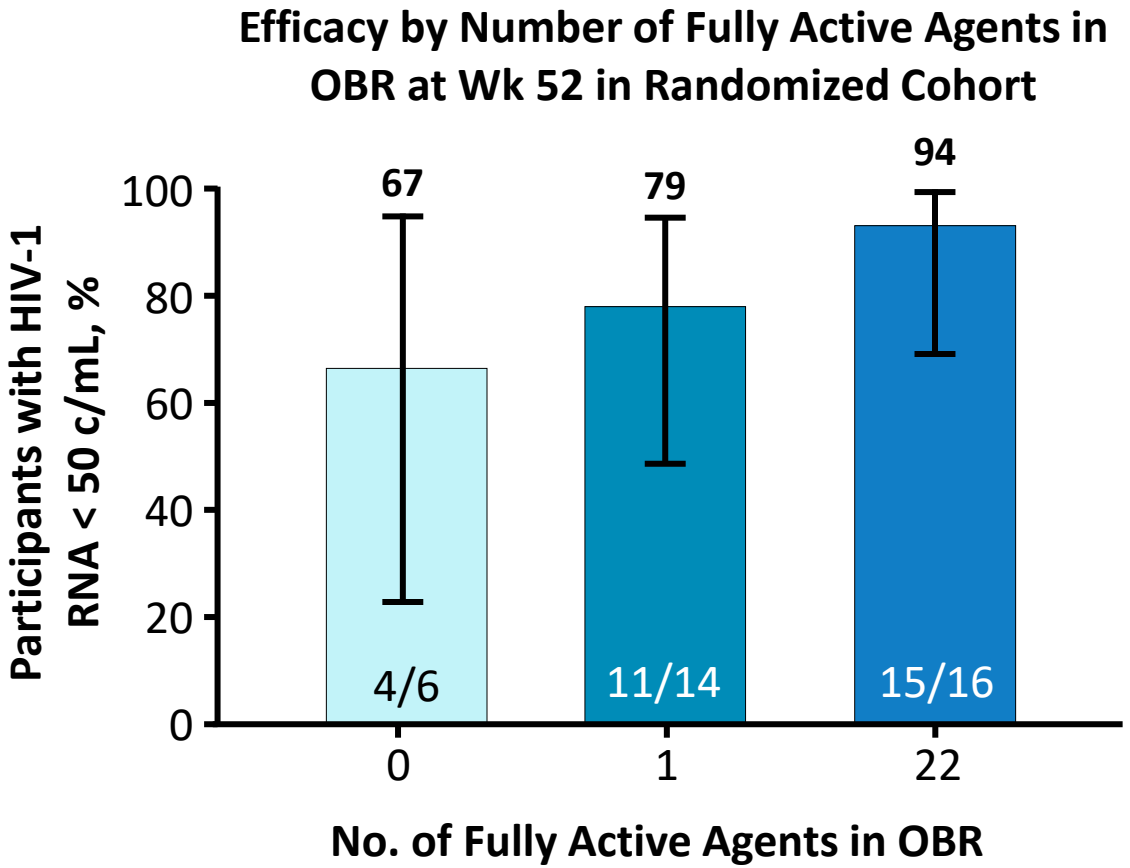
CAPELLA: Lenacapavir Efficacy
by Fully Active Agents and Emergent Resistance



Emergent LEN Resistance, n (%)	Randomized Cohort (n=36)	Nonrandomized Cohort (n =36)
Participants meeting criteria for resistance testing	11 (31%)	10 (28%)
Emergent LEN resistance	4 (**11%**)	4 (**11%**)
▪ M661	4	2
▪ Q67H/K/N	1	2
▪ K70H/N/R/S	1	3
▪ N74D/H/S	3	0
▪ A105S/T	3	1
▪ T107A/C/N	1	3

All 8 with LEN-R were high risk for resistance
- 0 active drugs in OBR, n = 4;
- inadequate adherence to OBR, n = 4)

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The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection

Segal-Maurer S et al. DOI: 10.1056/NEJMoa2115542

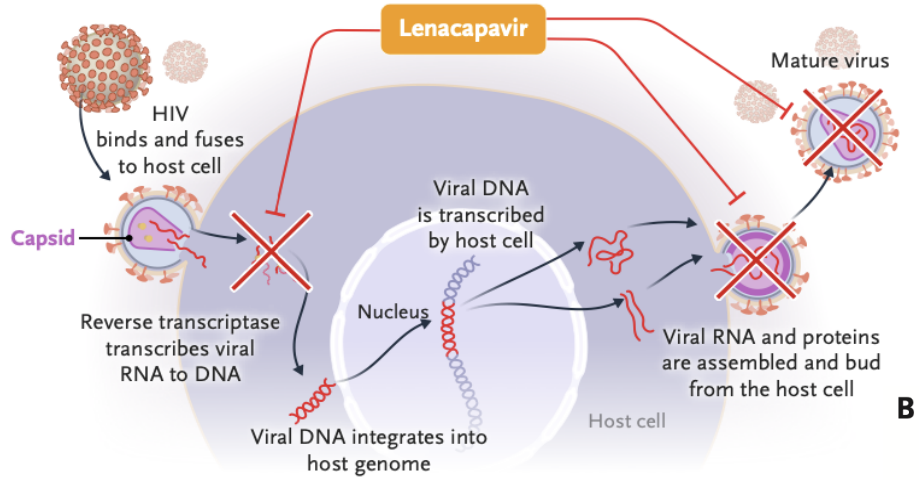
CLINICAL PROBLEM

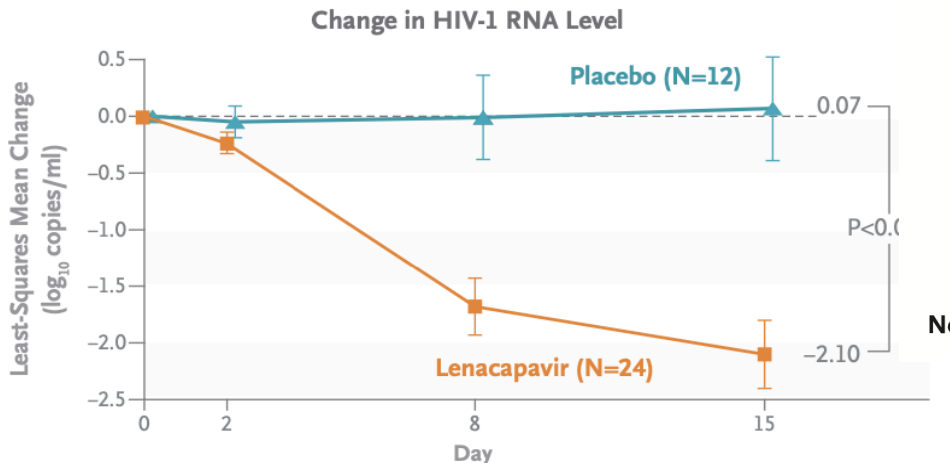
Treatment options are limited for patients with multidrug-resistant HIV-1 infection. Lenacapavir, a first-in-class HIV-1 capsid inhibitor, showed substantial antiviral activity in a phase 1b trial, but additional research is needed.

CLINICAL TRIAL

Design: A multinational, phase 3 trial examined the efficacy and safety of lenacapavir in patients with multidrug-resistant HIV-1 infection.

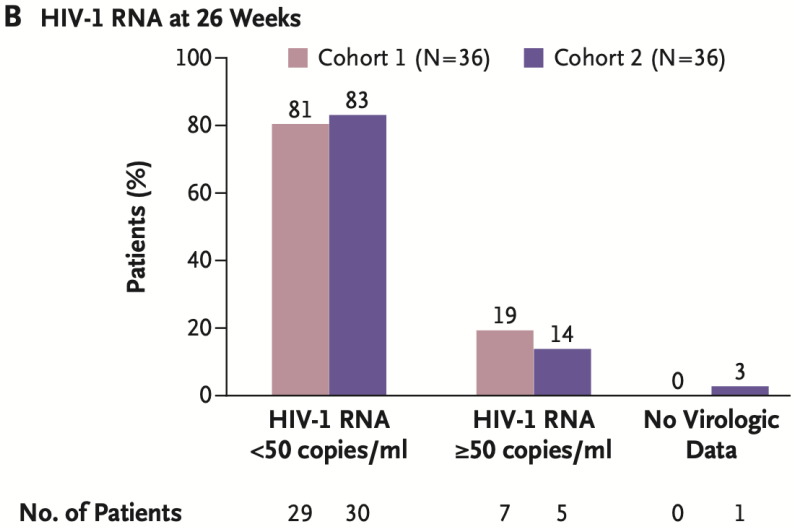
Intervention: In the randomized cohort, 36 patients 12 years of age or older were assigned in a 2:1 ratio to receive oral lenacapavir or placebo on days 1, 2, and 8 in addition to continuing their failing therapy for 14 days; on day 15, patients in the lenacapavir group began subcutaneous lenacapavir, given once every 6 months, and those in the placebo group began lenacapavir; both groups received optimized background therapy. In the nonrandomized cohort, 36 patients received lenacapavir plus optimized background therapy. The primary efficacy end point, assessed in the randomized cohort, was a reduction of ≥0.5 $\log_{10}$ copies per milliliter in HIV-1 RNA viral load by day 15.





Phase 3
N= 36, 2:1. 2 cohorts

81-83% VL <50 c/mL at 26 Weeks



MENU

GILEAD
Creating Possible

Press Releases

August 22, 2022

Gilead Announces First Global Regulatory Approval of Sunlenca® (Lenacapavir), the Only Twice-Yearly HIV Treatment Option

– European Commission Grants Marketing Authorization for Sunlenca

Helping to Address a Critical Unmet Clinical Need for People with Mul

Drug-Resistant HIV Who Have Very Limited Treatment Choices –

HIV Prevention with ARV

PrEP Study

LA-IM Cabotegravir q 2 Months ***vs*** **TDF/FTC** Oral Daily

HPTN 083

- N= 4,566 MSM, TGW
- **LA-IM CAB** was **66% >** effective than oral daily **TDF/FTC** in preventing HIV infection

Landovitz et al NEJM 2021; 385:595

HPTN 084

- N=3,224, Women in sub-Saharan Africa
- **LA-IM CAB** was **88% >** effective than oral daily **TDF/FTC** in preventing HIV infection

Deleny-Monetlwe Lancet 2022; 399:1779

Modified from clinicaloptions.com

December 20, 2021

FDA NEWS RELEASE

FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

Drug Given Every Two Months Rather Than Daily Pill is Important Tool in Effort to End the HIV Epidemic

December 20, 2021

- the U.S. Food and Drug Administration approved **Apretude** (**cabotegravir extended-release injectable suspension**) for use in at-risk adults and adolescents weighing at least 35 kilograms for **PrEP** to reduce the risk of sexually acquired HIV.
- **Apretude** is given **first as 2 initiation injections** administered **1 month apart**, and then **every 2 months** thereafter.
- Patients can either start with Apretude or take **oral cabotegravir** (Vocabria) for **4 weeks** to assess how well they tolerate the drug.

Islatravir (EFdA, MK-8591)

Nucleoside Reverse Transcriptase ***Translocation Inhibitors***

a First-in-Class NRTTI

Drugs

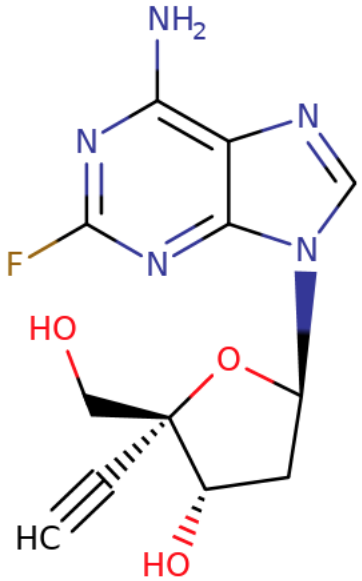
Home > Drugs > Islatravir

Enter Search Term(s)

+ Patient Version

− Health Professional

- Drug Information
  - Pharmacology
  - Clinical Trials
  - Adverse Events
  - Drug Interactions



Islatravir

Other Names: EFdA, ISL, MK-8591

Drug Class: Nucleoside Reverse Transcriptase Translocation Inhibitors

Molecular Formula: C_{12} H_{12} F N_5 O_3

Registry Number: 865363-93-5 (CAS)

Chemical Name: 4′-Ethynyl-2-fluoro-2′-deoxyadenosine

Chemical Class: Purine Nucleosides

Organization: Merck Sharp & Dohme Corp.

Phase of Development: Islatravir is in Phase 2b development for HIV treatment. Islatravir is also being developed for HIV prevention.

Oral can be dosed q weekly

HEALTH

A teeny-tiny arm implant could, one day, prevent HIV for a full year

Morgan Hines USA TODAY
Published 4:27 p.m. ET Jul. 26, 2019

A model holds the Nexplanon hormonal implant for birth control- the same implant device would be used to administer Islatravir for HIV prevention. *Merck Via AP*

NEXT-GENERATION ISLATRAVIR IMPLANTS PROJECTED TO PROVIDE YEARLY HIV PROPHYLAXIS

Islatravir (MK-8591, EFdA) Implant NNRTTI

Abstract Body

Preexposure prophylaxis (PrEP) with antiretroviral drugs has demonstrated efficacy in reducing new HIV infections, although efficacy is tightly linked to good adherence, especially in women. Islatravir (MK-8591) is a nucleoside reverse transcriptase translocation inhibitor with high potency and long t1/2, currently in development for PrEP as an oral monthly pill. In addition, prototype islatravir implants (containing only polymer and islatravir) have demonstrated the potential for yearly administration for PrEP.

Radiopaque next-generation islatravir-eluting implants were studied preclinically to establish general tolerability and assess pharmacokinetics (PK) of islatravir parent and active islatravir-TP (triphosphate). These data, along with data from an SIV challenge study and from previous Phase 1 trials, formed the basis for establishing a threshold islatravir-TP concentration of 0.05 pmol/million cells in PBMCs. In this double-blind placebo-controlled multicenter Phase 1 trial, a single islatravir-eluting (48 mg, 52 mg or 56 mg) or placebo implant was placed in participants at low risk of HIV infection for 12 weeks. Safety and tolerability, as well as PK for islatravir parent and islatravir-TP from plasma and PBMCs, was collected throughout placement and for 8 weeks post removal.

Implants were generally well tolerated, and there was no clear dose-dependent difference in implant-related adverse events (Table 1A). Active islatravir-TP levels were above target for all implants throughout implant placement (Table 1B). Data from this trial and from in vitro assessments of the ISL implants suggest that implants of >52 mg will achieve mean ISL-TP concentrations above the PK threshold at 52 weeks.

Advantages of Long-acting Implantable ARV

- Can be dose once or twice a year
- If there is a side effect to the drug(s), or become pregnant, the implant can be easily removed
- Can avoid non-adherence issues

MERCK

13 Dec 2021

Islatravir Trials

Merck Announces Clinical Holds on Studies Evaluating Islatravir for the Treatment and Prevention of HIV-1 Infection

Merck (NYSE: MRK), announced that the U.S. Food and Drug Administration (FDA) has placed clinical holds on the investigational new drug applications (INDs) for the oral and implant formulations of **islatravir** (MK-8591) for HIV-1 pre-exposure prophylaxis (PrEP); the injectable formulation of islatravir for HIV-1 treatment and prophylaxis; and the oral doravirine/islatravir (DOR/ISL) HIV-1 once-daily treatment.

The FDA's clinical hold is based on previously announced observations of decreases in total lymphocyte and CD4+ T-cell counts in some participants receiving islatravir in clinical studies.

Remaining
Major Challenges

School of Global Health
Faculty of Medicine
Chulalongkorn University

HIV-NAT

Equity to access to new ARV options

Current ARV Option

DTG-based regimen

Access for all is feasible

Future ARV Options

LA Injectable Implant ARV Yearly

Access for all is unlikely

Older PLWH

Too often abandoned population

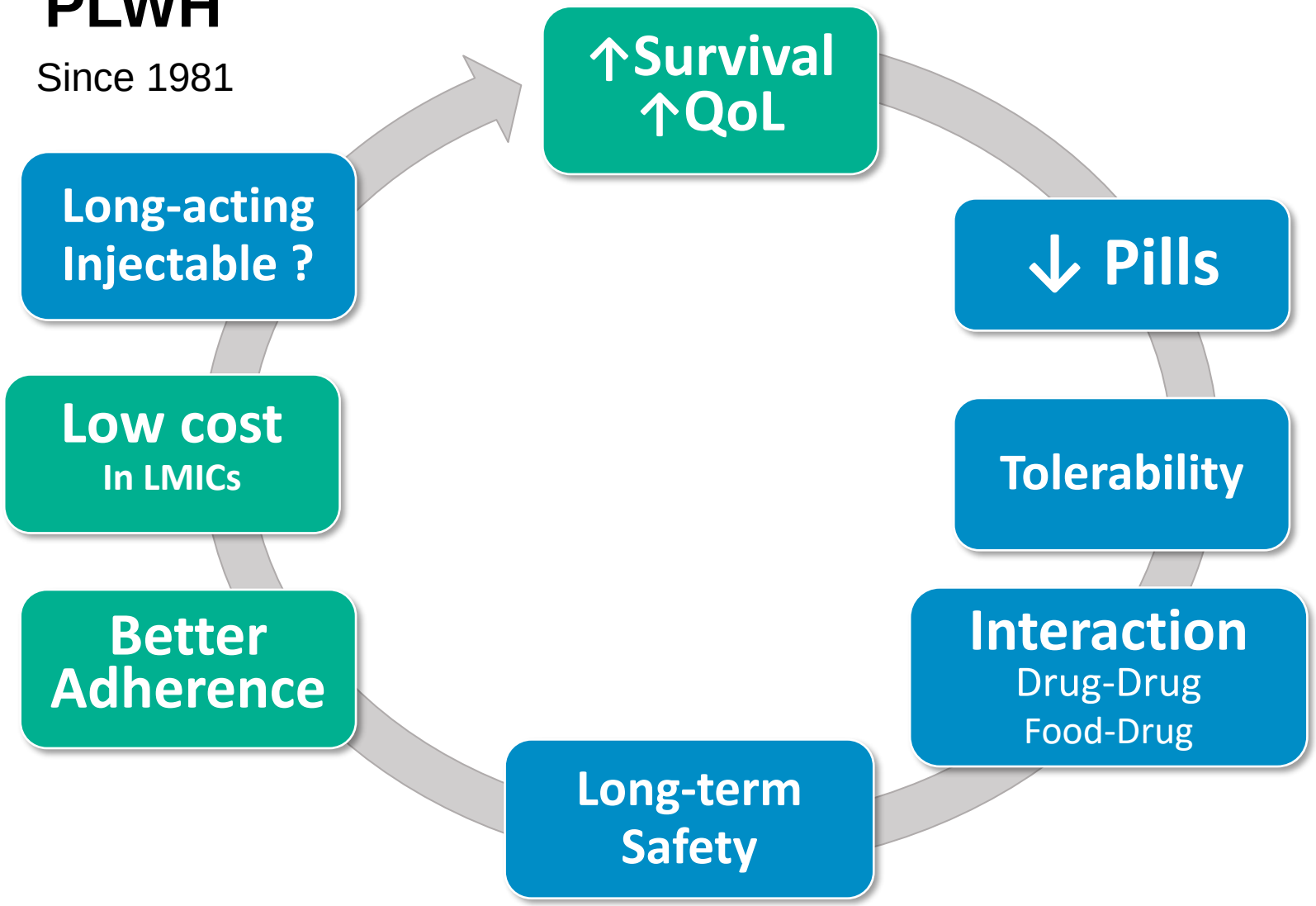
- Comorbidities
- Multimorbidity
- Polypharmacy
- Geriatric syndromes
- Psychosocial issues

Jonathan Appelbaum, MD, clinicaloptions.com

HIV Treatment Evolution to Ending AIDS

PLWH

Since 1981



↓ New Cases

Since 2015: ART early, TasP

- **Treat Early** — ART at any CD4
- **SD ART** — ART as Prevention
- **PrEP** — Pre-exposure

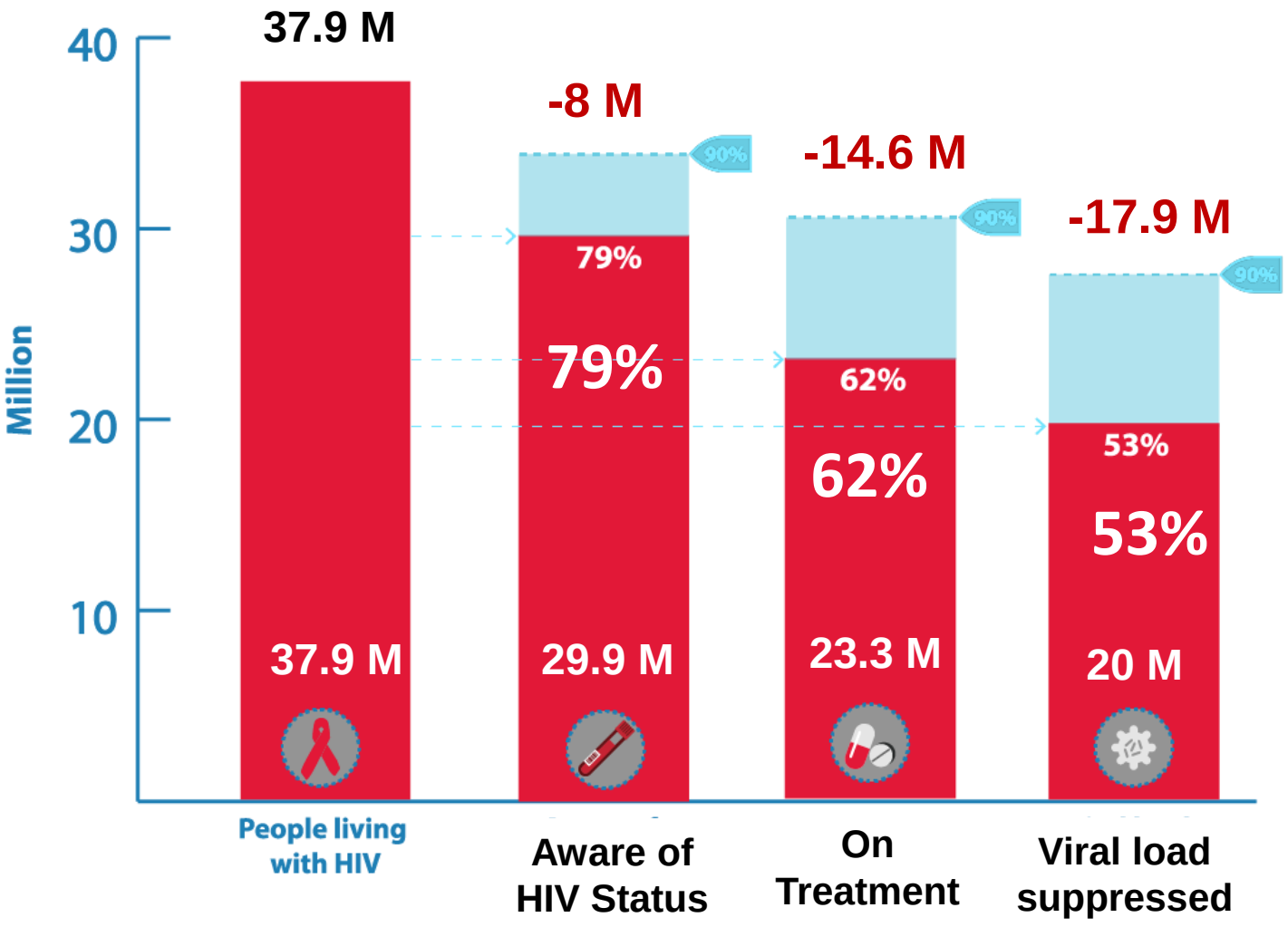
School of Global Health
Faculty of Medicine
Chulalongkorn University

HIV/AIDS remains **our challe**

Ending AIDS 2030 !

- **Transmission** : sexual, blood
- **Vaccine** : unlikely up-to-now
- **Effective treament : ART at any CD4**
- **Effective Prevention**: Condom use, **PrEP, Same-day or Rapid ART**
- **Global, country impact** : high

HIV testing and care continuum, global (2018)



Source: UNAIDS/WHO estimates

UNAIDS

WHO WE ARE

TURNING THE TIDE OF THE HIV EPIDEMIC IN THAILAND

17 JANUARY 2020

Prof. Praphan Phanuphak

"The region cannot achieve the 90–90–90 targets by 2020 at the current pace. "We need to think out of the box and do thing differently not as usually"

CHULALONGKORN
UNIVERSITY

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Thank You