21ª edición

POSTCROI

Hepatitis, tuberculosis y PrEP

Judit Villar García
Hospital del Mar, Barcelona

FLS SCIENCE FOSTERING LEARNING & SHARING

FUNDACIÓ LLUITA CONTRA LA SIDA I LES MALALTIES INFECCIOSES

21ª edición

POSTCROI

CONTENIDO:

- **Hepatitis**
- **Tuberculosis**
- **PrEP**

21ª edición

POSTCROI

CONTENIDO:

- **Hepatitis**
- **Tuberculosis**
- **PrEP**

Opening Session

Plenary Sessions

Oral Abstract Sessions

Interactive Sessions

Poster Sessions

Symposia

Workshops

21ª edición

POSTCROI

HEPATITIS

Preclinical Pharmacokinetic Assessment of a Hepatitis C Virus Long-Acting Injectable Formulation

Usman Arshad
University of Liverpool, Liverpool, UK

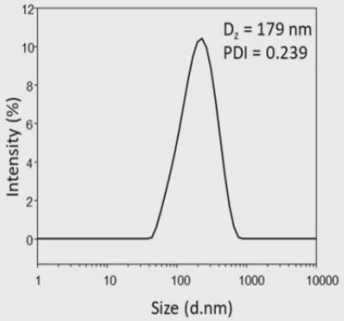
Methodology: LAI Formulation Strategy

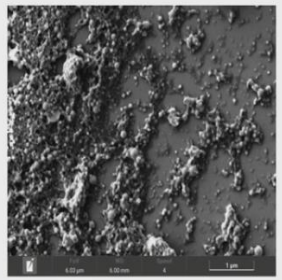
Active Pharmaceutical Ingredients dissolved in a water immiscible solvent and added to an aqueous solution of excipients

High energy agitation of the mixture with a sonicator probe forms an emulsion

the emulsion is spray dried to remove water and solvent, resulting in a dry powder containing solid drug nanoparticles (SDN)

onstitution of powder into eous vehicle forms particle suspension enabling amuscular / subcutaneous administration.



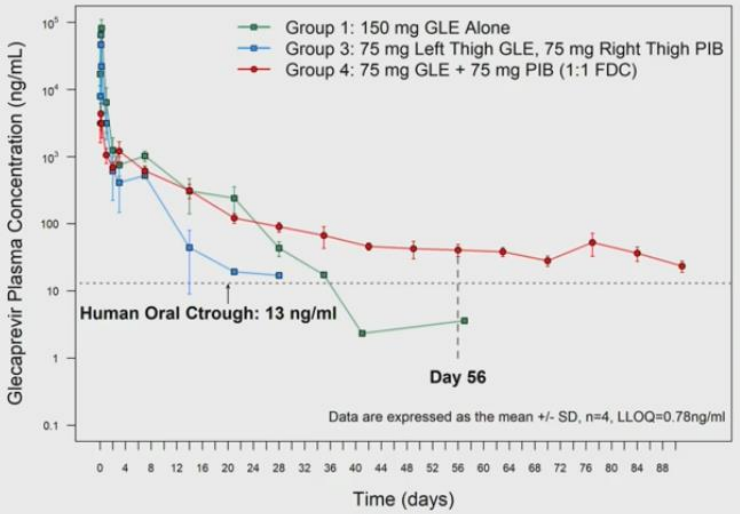


DOI: 10.1038/ncomms13184

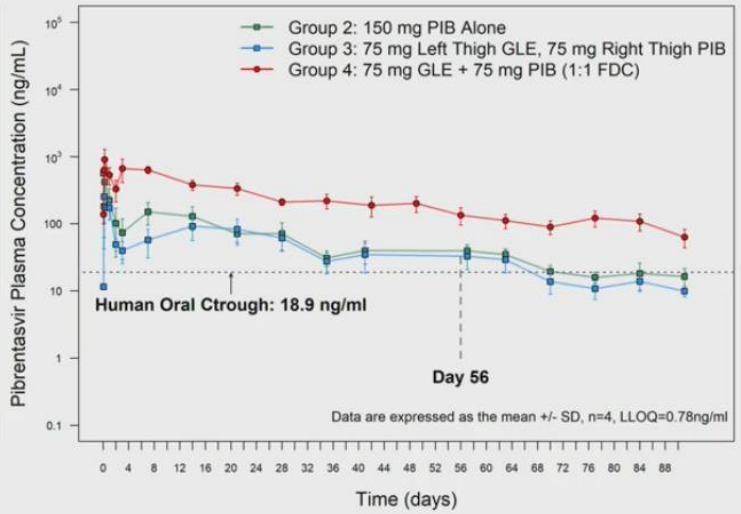
Pharmacokinetic Benefit for Co-formulation

Green – Either GLE or PIB alone in both thighs Blue – GLE to left thigh PIB to right thigh RED – GLE/PIB 1:1 FDC administered to both thighs

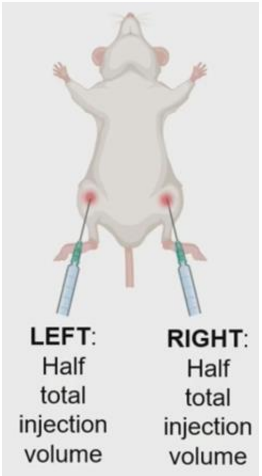
(a) Glecaprevir Intramuscular LAI Rat Plasma PK



(b) Pibrentasvir Intramuscular LAI Rat Plasma PK



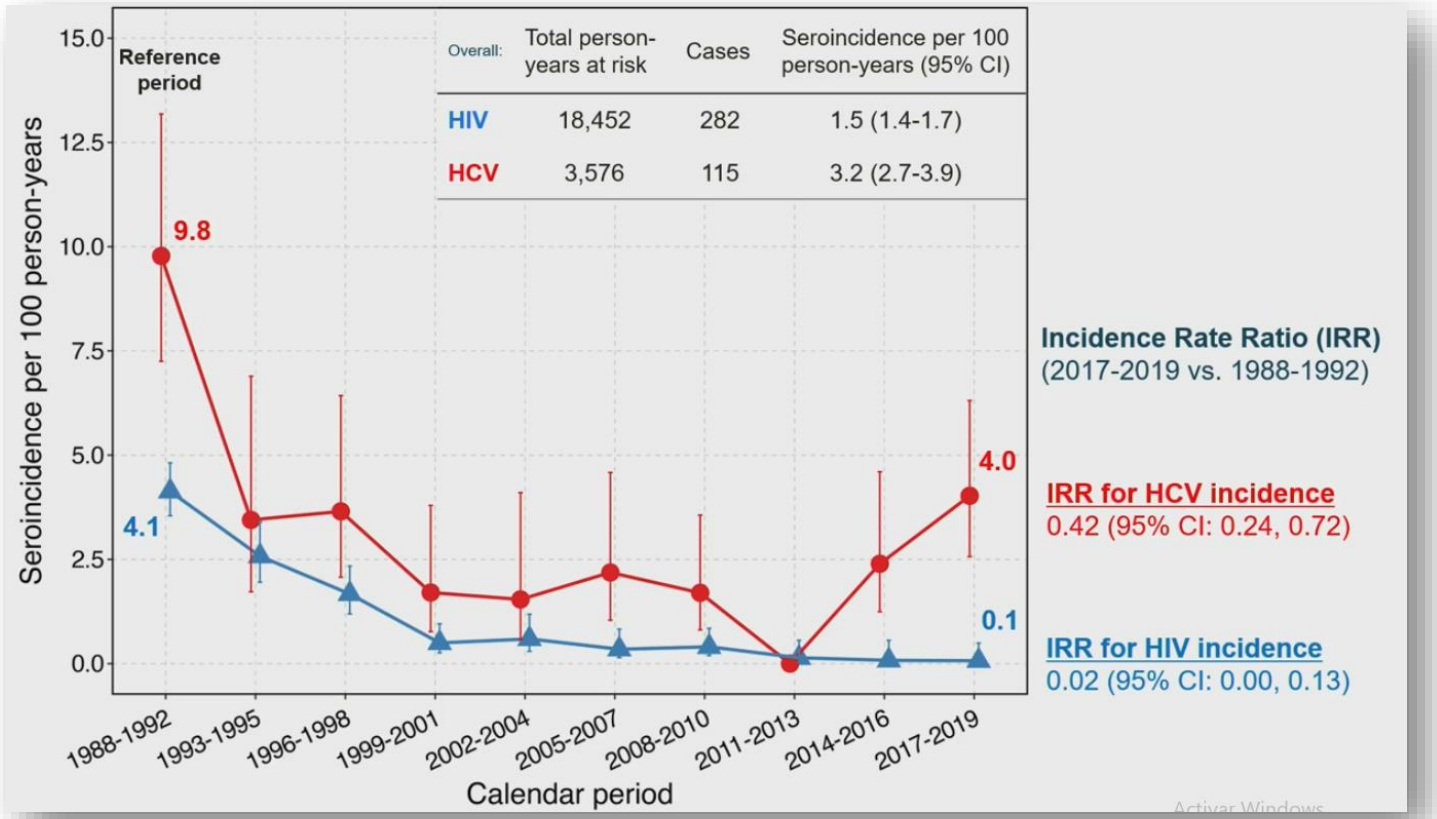
The combination of both drugs within an FDC maintains a longer terminal half-life for GLE and improves exposure for PIB, maintaining plasma concentrations **above the human oral C_{trough}**

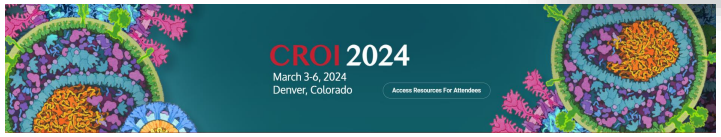


Trends in HIV and HCV Prevention Efforts and Incidence Among People Who Inject Drugs in Baltimore

AIDS Linked to the IntraVenous Experience study

- **Study design:** Community-based, prospective cohort study
- **Location:** Baltimore, Maryland [fixed study site]
- **Recruitment:** street-based, community outreach, word-of-mouth
- **Eligibility criteria:** Age ≥ 18 years and history of injection drug use
- **Enrollment periods:** 1988-1989, 1994-1995, 1998, 2005-2006, 2015-2018



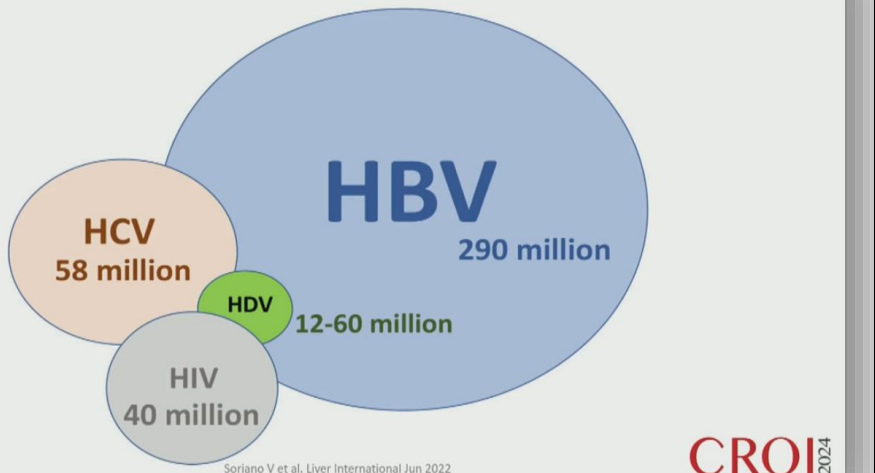


E.U. Patel

Hepatitis Delta: What to Know, What to Do?

Kathrin van Bremen
University of Bonn, Bonn, Germany

Overlapping epidemics



Soriano V et al. Liver International Jun 2022

CROI 2024

HDV prevalence data among European HIV/HBV cohorts in 2023

France

Dat'AIDs Cohort (2,406* HBsAg+ PWH)[1]

- ➢**15.6%** anti-HDV+ overall
- ➢**56.5%** anti-HDV+ in PWID
- ➢**38.2%** anti-HDV+ in patients from Eastern Europe
- ➢**42.4%** anti-HDV+ in HCV/HBV co-infected patients

Netherlands

ATHENA Cohort[4]

- **14.0%** HDV Test Rate (anti-HDV or HDV RNA) in PWH
  - **13.0%** in MSM
  - **23.5%** in PWID
  - **15.6%** in heterosexual/others
- ➢**7.2%** HDV+ (anti-HDV+ or HDV RNA+)

Italy

ICONA Cohort (1,028 HBsAg+ PWH)[2]

- **78.7%** Anti-HDV Screen Rate
  - ➢**18.8%** anti-HDV+
- **62.5%** HDV RNA Test Rate
  - ➢**66.3%** HDV RNA+

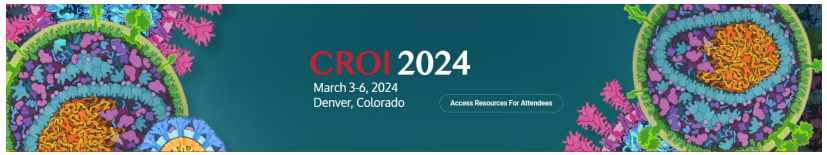
EuroSIDA and SHCS

Béguelin et al.[3]

- **56%** Anti-HDV Screen Rate in PWH
  - ➢**15.2%** anti-HDV+
  - ➢**50.5%** anti-HDV+ in PWID
  - ➢**4.7%** in non-PWID

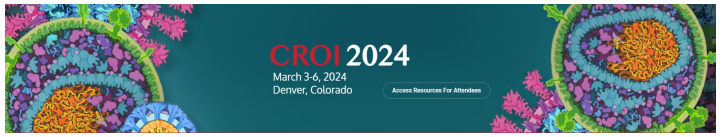
Alfaiate D, et al. EASL 2023. Poster #FRI-117. 2. Puoti M, et al. EASL 2023. Poster #WED-174. 3. Béguelin C, et al. *Liver Int*. 2023. 4. Boyd A, et al. EASL 2023. Poster #FRI-138

CROI 2024



Hepatitis Delta: What to Know, What to Do?

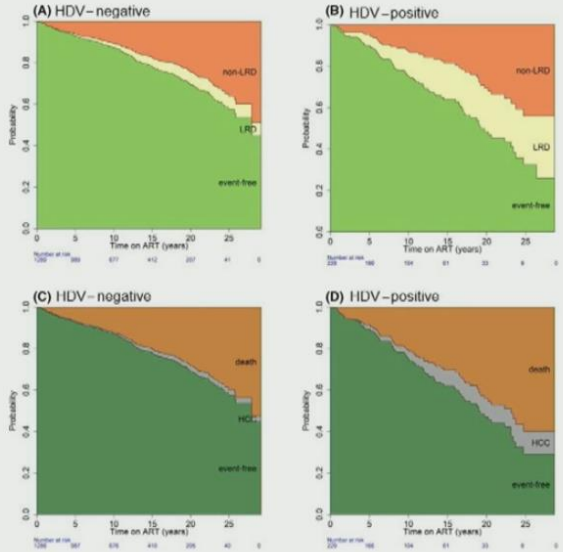
Kathrin van Bremen
University of Bonn, Bonn, Germany



Taking a closer look at EuroSIDA & SHCS

- HDV Co-infection prevalence 15.6%
- during follow-up of 10.8y 34.6% (HDV+) vs. 20.1% (HDV-) died
  - liver-related death 41.5% vs. 17.7%

HDV co-infection was **associated** with **overall mortality, liver-related death** and **HCC**



Beguelin C et al. Liv int 2023

CROI 2024

Current guideline testing recommendations for HDV

	Whom to test	Testing procedure
AASLD 2018	• HBsAg+ pos. patients with risk factors (PWH; IVDU; MSM; immigrants from high endemic countries) • Individuals with elevated ALT/AST with low/undectable HBV-DNA • In any uncertainity perform test. Re-testing if ongoing risk.	Anti-HDV; HDV-RNA if Anti-HDV+
EACS 2023	Every PWH with HBsAg+	Anti-HDV; HDV-RNA if Anti-HDV+
EASL 2023	• At least once in all HBsAg+ • Re-testing whenever clinically indicated (e.g. ALT/AST flares); repeat (yearly) if ongoing risk	Anti-HDV; HDV-RNA if Anti-HDV+

AASLD Hepatology 2018; EACS Guidelines 12.0 2023; EASL Journal of Hepatology 2023

CRO

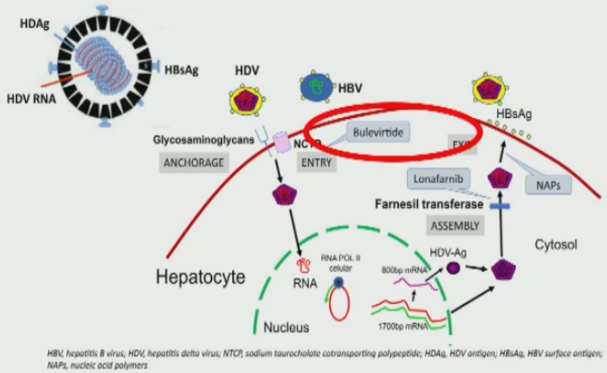
Repetir DNA-VHD porque es muy fluctuante

Hepatitis Delta: What to Know, What to Do?

Kathrin van Bremen
University of Bonn, Bonn, Germany

Bulevirtide, the new star on the horizon?

- Blocks the NTCP receptor for entry of HBV/HDV within hepatocytes
- 2mg s.c./d +TDF/TAF in PWH
- Approved in the EU
- Duration of treatment not known so far
- Costs: 6.500 USD/month



HBV, hepatitis B virus; HDV, hepatitis delta virus; NTCP, sodium taurocholate cotransporting polypeptide; HDAg, HDV antigen; HBsAg, HBV surface antigen; NAPs, nucleic acid polymers

CROI 2024

Current guidelines treatment recommendations

	Interferon	Bulevirtide
AASLD 2018	**Peg-IFN-α for 12 months is the recommended therapy for those with elevated HDV RNA levels and ALT elevation.**	**No recommendation yet.**
EACS 2023	**In persons with chronic HDV co-infection and significant liver fibrosis(≥ F2),** long-term (at least 12 months) treatment with **Peg-IFN might be considered in association with TDF-based ART.**	**BLV (2mg/s.c/d) in combination with TDF/TAF should be used where available** **Optimal duration of treatment remains unclear.**
EASL 2023	**All patients with CHD and compensated liver disease,** irrespective of whether they have cirrhosis or not, **should be considered** for treatment with **PegIFN-α.**	**All patients with CHD and compensated liver** disease **should be considered** for treatment with **BLV.** The optimal dose and duration of treatment not yet been defined. **Long-term treatment with BLV, 2 mg once daily, may be considered.**

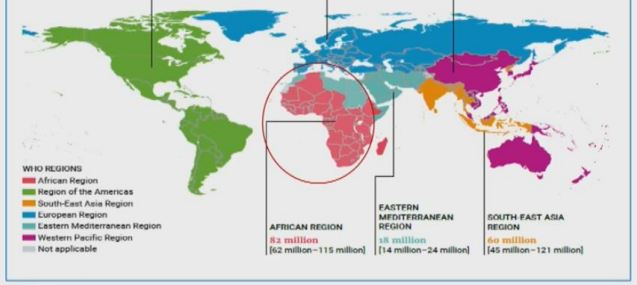
AASLD Hepatology 2018; EACS Guidelines 12.0 2023; EASL

How New WHO Guidance Can Transform Hepatitis B in Sub-Saharan Africa

Olufunmilayo ('Funmi) Lesi
World Health Organization, Geneva, Switzerland

Worldwide, an estimated 296 million people are chronic carriers of HBsAg

Fig. 1.1 Global status of chronic hepatitis B virus infection by WHO region, 2019 *(4)*



1.5M
# of new HBV infections/year

820k
deaths/year from HBV liver cirrhosis & Cancer

12M
Anti-HDV prevalence

World Health Organization

https://iris.who.int/bitstream/handle/10665/360348/9789240053779-eng.pdf?sequence=1 4

Stockdale AJ, et. al J Hepatol. 2020;73:523–32. doi: 10.1016/j.jhep.2020.04.008

Who to treat

NEW

Treatment is recommended for all adults and adolescents (aged ≥12 years) with CHB (including pregnant women and girls and women of reproductive age) with:

1. **Evidence of significant fibrosis** (≥F2) based on an **APRI score of >0.5 or transient elastography value of >7** kPa or evidence of cirrhosis (F4) (based on clinical criteria (an APRI score of >1 or transient elastography value of >12.5 kPa[c]), *regardless of HBV DNA or ALT levels.* *(Adults: Strong/Mod, Adolescents Strong/Low)*

OR

2. **HBV DNA >2000 IU/mL and an ALT level above the upper limit of normal** (ULN) (30 U/L for men and boys and 19 U/L for women and girls). For adolescents, this should be based on ALT>ULN on at least two occasions in a 6- to 12-month period. *(Adults: Strong/high; [HBV DNA >20 000 IU/mL] & Low [HBV DNA 2000–20 000]; Adolescents: Conditional/Low)*

OR

3. **Presence of coinfections** (such as HIV, hepatitis D or hepatitis C); **family history of liver cancer** cirrhosis; **immune suppression; comorbidities (such as diabetes); or extrahepatic manifestations**, *regardless of the APRI score or HBV DNA or ALT levels.* *(Adults: Strong/Mod; Adolescents: Conditional/Low)*

OR

4. **In the absence of access to an HBV DNA assay:**
Persistently abnormal ALT levels (defined as two ALT values above the ULN at unspecified intervals during a 6- to 12-month period), *regardless of APRI score.* *(Adults and adolescents: Conditional/very Low)*

World Health Organization

Monitor annually with HBV DNA, ALT and APRI score, with ongoing adherence support and retention in care

What to use for treatment

NEW

First line antiviral therapy

5. **Updated recommendation**
Tenofovir disoproxil fumarate (TDF) or entecavir (ETV) are recommended as **preferred regimens**
Or

TDF + lamivudine (3TC) and
TDF + emtricitabine (FTC) as **alternative regimens** (where TDF monotherapy is not available)
(strong recommendation, moderate-certainty evidence)

Rationale

- Systematic review comparing TDF monotherapy with dual therapy showed comparable outcomes in terms of DNA suppression and normalization of ALT levels.
- Use of dual therapy allows synergies with HIV programmes and may support expansion of treatment programmes in countries with limited availability of TDF monotherapy esp. in LMIC/SSA

World Health Organization

How New WHO Guidance Can Transform Hepatitis B in Sub-Saharan Africa

Olufunmilayo ('Funmi) Lesi
World Health Organization, Geneva, Switzerland

NEW

Preventing mother to child transmission of HBV using antiviral prophylaxis

Updated 2024 recommendation

6

In settings where HBV DNA or HBeAg testing is available,
*Prophylaxis with TDF is recommended for **all HBV-positive** (HBsAg-positive) pregnant women with HBV DNA ≥200 000 IU/mL or positive HBeAg
(strong recommendation, moderate-certainty evidence)

New 2024 recommendation

7

In settings where neither HBV DNA nor HBeAg testing is available,
*Prophylaxis with TDF for **all HBV-positive** (HBsAg-positive) pregnant women may be considered
(conditional recommendation, low-certainty evidence)

Rationale: HBV DNA or HBeAg Available

- TDF prophylaxis for HBsAg-positive pregnant women with high HBV DNA viraemia or positive HBeAg supported by most clinical trials

Not available

- Modelling analysis suggested that prophylaxis all strategy would have great impact with about 4.9 million (95% CI: 4.7 million–5.1 million) neonatal infections averted.

World Health Organization

*Preferably from the second trimester of pregnancy until at least delivery or completion of the infant HBV vaccination series), to prevent MTCT of HBV. All interventions should be given in addition to at least three doses of hepatitis B vaccination for all infants, including a timely birth dose.

NEW

Diagnostics- Hepatitis Delta (HDV)Testing

Universal testing approach

10

Serological testing for anti-HDV antibodies may be performed **for all individuals** who are HBsAg positive, as the preferred approach to scale up access to HDV diagnosis and linkage to care
(conditional recommendation, very-low-certainty evidence)

11

In settings in which a universal anti-HDV antibody testing approach is not feasible because laboratory capacity or other resources are limited, testing for anti-HDV may be given priority in specific populations of HBsAg-positive individuals, including the following

- people born in HDV-**endemic** countries, regions and areas;
- people with **advanced liver disease**, those receiving hepB treatment and those with features suggesting HDV infection (such as low HBV DNA with high ALT levels); and
- people considered to have **increased risk** of HDV infection, including haemodialysis recipients, people living with HCV or HIV, people who inject drugs, sex workers and gay men and other men who have sex with men.

(conditional recommendation, very-low-certainty evidence)

Rationale
Observational data in several countries highlight the marked increase in case finding with the adoption of a universal testing approach.

World Health Organization

New Frontiers in Hepatitis B

Moderators

Background – Why do we need new biomarkers for the management of CHB therapy?

- **Current therapies**
  - HBsAg loss is unfrequent and delayed with slow kinetics of decline
  - Prediction of HBsAg loss during antiviral therapy
  - Prediction of outcome after treatment cessation

- **Multitude of new therapies under clinical development**
  - Goal: achieving **functional cure**, i.e. sustained HBsAg loss
  - **Several MoA:** direct acting antivirals & immune based therapies
  - Novel biomarkers needed to assist drug development
    - **Target engagement**
    - **Prediction of HBsAg loss (endpoint)**

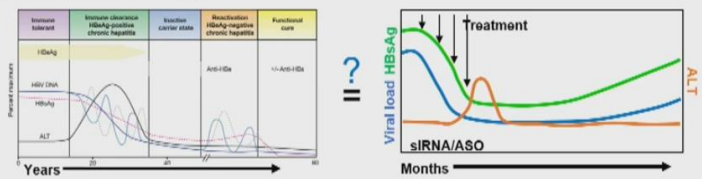
F. Zoulim

Do all patients need immunomodulatory therapy to achieve HBV cure?

Vast majority of patients who achieved cure received immunomodulatory therapy

Immunotherapy as monotherapy can capitalize on natural immunity in patients with naturally low HBsAg

- But not all low HBsAg patients – why?



Does shortening HBsAg decline from decades to months with DAAs achieve the same outcome?

Probably not,

- Still very limited data that antigen reduction enhances immunity
- The immune system does not take over HBsAg decline when therapy stopped – may help slow rebound?
- And, we don't want to wait years to find out

Encouraging data on antigen reduction + immunomodulation in combo trials – boosting

With functional cure now an expected outcome in studies, immunological biomarkers will be achievable.

A. Gehring

21ª edición

POSTCROI

TUBERCULOSIS

Plenary Lecture

Accelerating Tuberculosis Elimination: Short-Course Prevention and Treatment

Vidya Mave

Byramjee Jeejeebhoy Government Medical College – Johns Hopkins Research Program
Pune, India

CROI 2024

- Active TB treatment can be shortened for DS-TB
  - 4 months of HPMZ is non-inferior to the standard of care for adults with DS-TB, includir PLHIV
  - 2-month strategy with BDQ-LZD is non-inferior
  - 4 months of HRZE is effective for children with non-severe TB
- Active TB treatment for DR-TB
  - 6 months of BPaLM (or BPaL) is effective for MDR and XDR TB

Recommended Approach for Treating HIV in People with TB
Start within 8 weeks (2 weeks for CD4 <50)

- **NNRTI-based HAART (A I)**
  - EFV and rifampin (or rifapentine) – preferred regimen
  - EFV and rifabutin – increase RBT dose to 450-600 mg daily, but why use it?
- **Integrase inhibitor-based HAART – preferred regimens (A I-III)**
  - Rifampin + DTG 50 BID clinically effective (INSPIRING)
  - Rifampin + RAL 800 mg BID (REFLATE)
  - Rifabutin + RAL: 400 BID, 20% reduction in RAL Cmin
- **Boosted PI-based HAART**
  - Lopinavir/r + Rifabutin – 150 mg daily (B I)
  - Double-dose Lopinavir/r + Rifampin (B III)

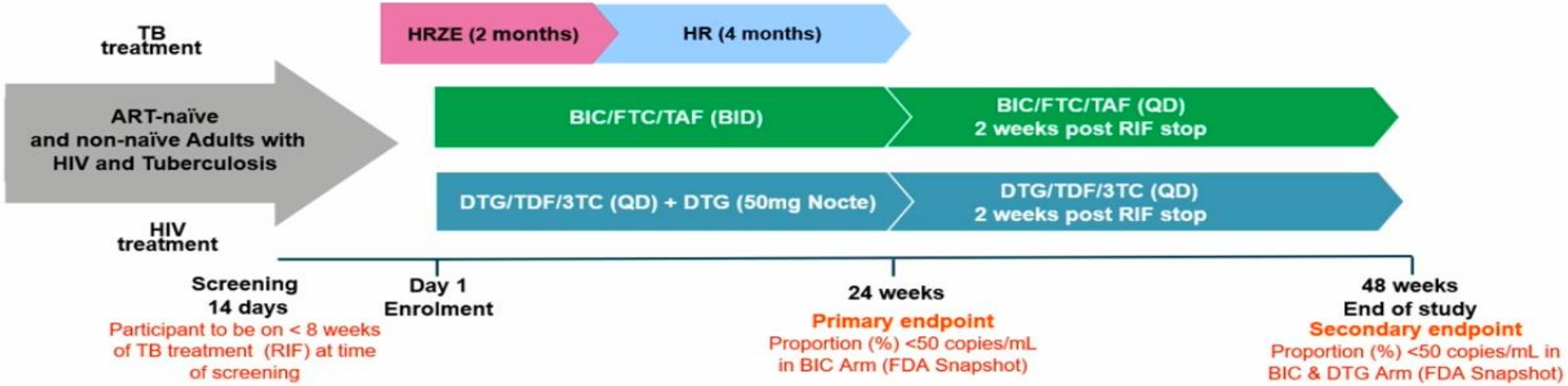
USPHS Guidelines, February 17, 2022. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/mycobacterium-tuberculosis-infection-and#_Recommendations_for_Treating

INSTI's FOR THE MANAGEMENT OF HIV-ASSOCIATED TB (INSIGHT STUDY)

EFFICACY, SAFETY, AND PK OF BIC/FTC/TAF IN ADULTS WITH HIV AND TUBERCULOSIS ON RIFAMPICIN AT WEEK 24

INSIGHT Study Design

Phase IIb open-label, non-comparative, randomized-controlled trial



Inclusion criteria

- ART-naïve OR ART non-naïve Adults with HIV (no exposure to ART at least ≥ 3 months at the time of enrolment)
- CD4+ ≥ 50 cells/µl; Females on contraception, HBsAg -ve
- Confirmed RIF-susceptible TB and/or on first-line RIF-based TB treatment (not > 8 weeks at the time of enrolment)
- eGFR ≥ 60 mL/min/1.73m^2, ALT ≤3 ULN, Total bilirubin ≤2.5 ULN
- Hb ≥ 7.0 g/dL/ ♀ ≥6.5g/dL, Platelet ≥ 50,000/mm^3, ANC ≥650/mm^3

Total Enrolled = 122
2:1 ratio
BIC (n=80) : DTG (n=42)

3TC-Lamivudine; ART- Antiretroviral therapy; BIC-Bictegravir; BID-Twice a day; DTG-Dolutegravir; FTC-Emtricitabine; HRZE- isoniazid + rifampicin + pyrazinamide + ethambutol regimen; HR-isoniazid + rifampicin regimen; mg-milligram; n-total number of individuals; Nocte-At night; TAF-Tenofovir Alafenamide; TB-Tuberculosis; TDF-Tenofovir Disoproxil Fumarate; QD-Once a day; ANC- Absolute neutrophil count; eGFR-estimated glomerular filtration rate; ALT- Alanine aminotransferase; Hb-Hemoglobin; HBsAg- Hepatitis B surface antigen; ULN-Upper limit of normal

CROI 2024

Demographic and Baseline Characteristics

	BIC (n=80)	DTG (n=42)	Total (N=122)
Age, median (range), years	35 (19-56)	35 (22-60)	35 (19-60)
Female, n (%)	25 (31)	18 (43)	43 (35)
Black, n (%)	80 (100)	42 (100)	122 (100)
HIV-1 RNA, median (Q1, Q3) copies/mL*	75649 (22784, 391299)	73735 (21242, 544830)	74692 (21475, 393703)
HIV-1 RNA ≥ 100000, n (%)	32 (42)	17 (41)	49 (42)
CD4+ cell count, median (Q1, Q3), cells/mm³	172 (108, 352)	139 (97, 237)	161 (101, 311)
50 - 100 cells/mm³, n (%)	18 (23)	13 (31)	31 (25)
101 - 199 cells/mm³, n (%)	26 (33)	16 (38)	42 (34)
≥ 200 cells/mm³, n (%)	36 (45)	13 (31)	49 (40)
Previous ART exposure, n (%)			
ART non-naïve	23 (29)	16 (38)	39 (32)
Time from start of TB treatment (RIF) to randomization day, median (range), days	15 (7-48)	16 (0-35)	15 (0-48)
Karnofsky score, n (%)			
70	21 (26)	10 (24)	31 (25)
80 - 100	59 (74)	32 (76)	91 (75)
WHO Stage 4, n (%)	7 (9)	0 (0)	7 (6)

CROI 2024

Primary Endpoint: Viral Suppression at Week 24

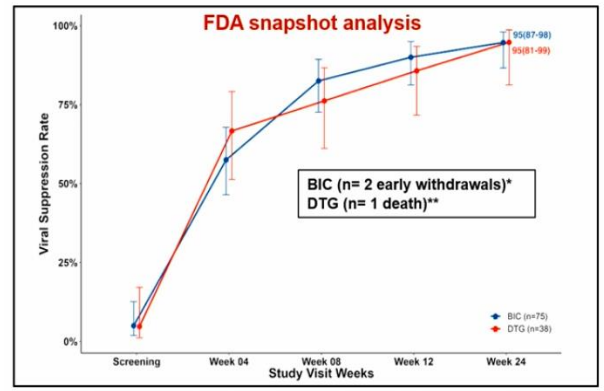


Figure 1: Viral Suppression Rate (FDA snapshot analysis) over study visits by Arm with two-sided 95% Confidence Interval

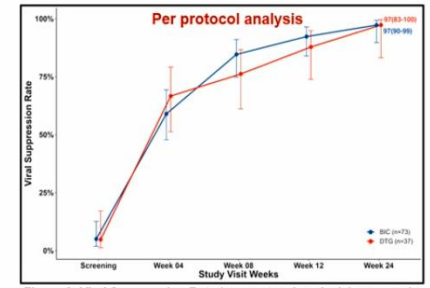


Figure 2: Viral Suppression Rate (per protocol analysis) over study visits by Arm with two-sided 95% Confidence Interval

- **Median CD4+ cell count** (Q1, Q3) cells/mm³ at Week 24
  - BIC: 259 (213, 505)
  - DTG: 231 (170, 311)
- **Median change in CD4+ cell count** (Q1, Q3) cells/mm³ at Week 24
  - BIC: 96 (35, 137)
  - DTG: 69 (27, 122)

Viral suppression rates were high and similar in participants receiving BIC/FTC/TAF vs DTG/3TC/TDF

CROI 2024

** two relocations; **hemoptysis*

Summary of Adverse Events

n (%)	BIC (n=80)	DTG (n=42)
Any AE	80 (100)	42 (100)
Most frequently occurring AEs in either group		
Increased Amylase	44 (55)	23 (55)
Arthralgia	31 (39)	18 (43)
Peripheral neuropathy	21 (26)	21 (50)
Hyperglycaemia	28 (35)	14 (33)
Proteinuria	26 (33)	13 (31)
Anaemia	23 (29)	14 (33)
Decreased creatinine clearance	22 (28)	13 (31)
Any serious AE (SAE)	**9 (11)**	**3 (7)**
Any Grade 3 and 4 AEs		
Grade 3	30 (38)	15 (36)
Grade 4	6 (8)	6 (14)
Grade 3 and 4 Liver Chemistry Abnormalities		
Grade 3	3 (4)	3 (7)
Grade 4	1 (1)	0 (0)

NO AE's leading to treatment discontinuations, withdrawals or drug switches

CROI 2024

BIC pharmacokinetic data

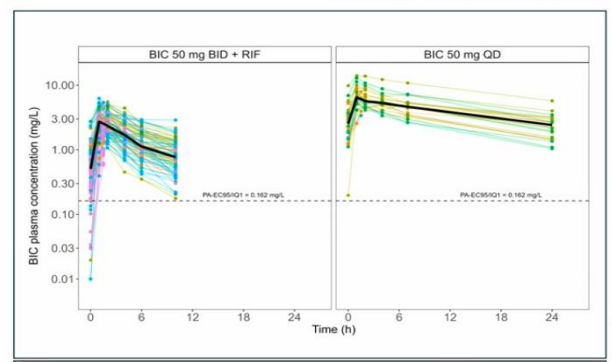


Figure: Plasma concentrations versus time for each individual stratified by dosing regimen (BIC dosed twice daily with BIC or once daily alone), at ALL timepoints including sparse sampling at week 8, 24 & 48 and subset with poor adherence. Each colored line represents a PK sampling visit for one individual. The solid black line connects median plasma concentrations for each scheduled timepoint. The dotted black line represents the PA-EC95 or IQ1 (0.162 mg/L).

***BIC Trough Concentration & AUC during and post-TB treatment**

Trough concentration (Ctau) and AUC 0-24:
BIC 50 mg BID **with RIF**

Time	n	BIC C_{tau} (mg/L) Geometric mean (CV%)	AUC 0-24 (mg*h/L) Geometric mean (CV%)
Weeks 4 and 12	75	0.397 (73.4%)	30.9 (42.2%)

Trough concentration (Ctau) and AUC 0-24:
BIC 50 mg QD **without RIF**

Time	n	BIC C_{tau} (mg/L) Geometric mean (CV%)	AUC 0-24 (mg*h/L) Geometric mean (CV%)
Week 32	22	2.29 (45.1%)	94.9 (35.9%)

*Noncompartmental analysis of semi-intensive sampling time points
PK sampling time was pre-dose, 1, 2, 4, 6-8, 8-12-, or 24-25-hours post-dose for BIC 50 mg BID + RIF and BIC 50mg QD without RIF, respectively. (Ctau) calculated by extrapolating up to 12 and 24 hours for BID and QD BIC 50 mg, respectively. 2 participants below limit of quantification (BLQ <0.01mg/L) due to known non-adherence were excluded from the week 12 analysis

CROI 2024

**TAF plasma & tenofovir diphosphate intracellular levels with and without RIF- coming soon!*

A. Naidoo

A 4-Month Regimen of Quabodepistat, Delamanid, and Bedaquiline for Pulmonary TB: Interim Results

Simbarashe Takuva
Otsuka Novel Products GmbH, Munchen, Germany

Tuberculosis Is a Major Global Health Problem

Tuberculosis (TB)

- TB is caused by infectious agent *Mycobacterium tuberculosis*
- In 2022, TB was the world's second leading cause of death from a single infectious agent[1] and remains the leading cause of death in people living with HIV globally

Treatment

- Standard treatment consists of a combination of **3 or 4 drugs for ≥6 months** to cure the disease and prevent drug resistance[1]
- There is **an urgent need** for **shorter duration**, **more potent**, and **safer** anti-TB agents effective against **drug-susceptible** and **drug-resistant strains**

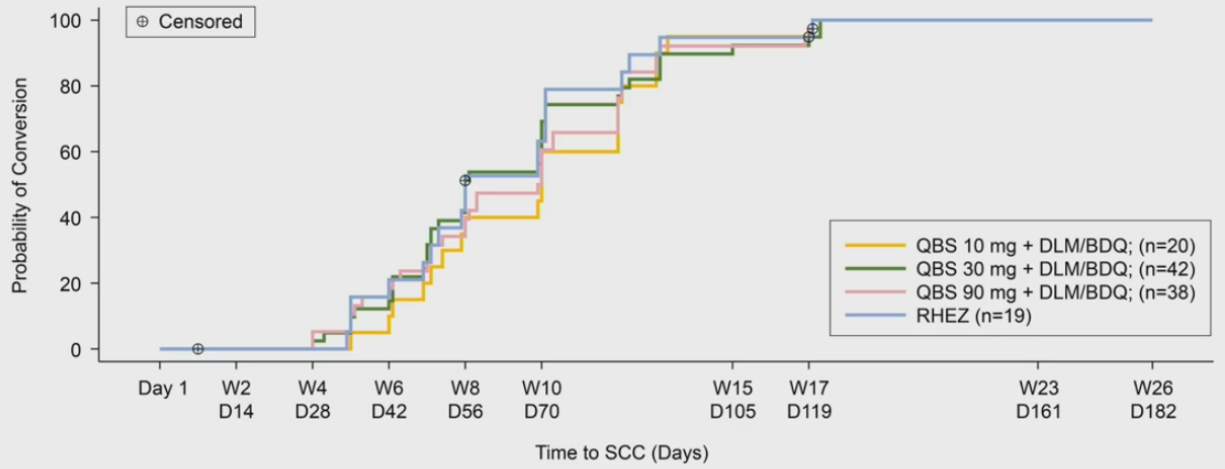
Quabodepistat (QBS)

- QBS (OPC-167832) is a **novel, oral anti-TB agent** that targets decaprenyl-phosphoryl-β-D-ribose-2′-epimerase (DprE1)[2]
- In a phase 2a study, QBS in combination with delamanid (DLM) and bedaquiline (BDQ) for 14 days was well tolerated and exhibited similar early bactericidal activity to RHEZ[3]

HEZ, rifampicin, isoniazid, ethambutol, and pyrazinamide.

World Health Organization. Global tuberculosis report 2023. Geneva, Switzerland: World Health Organization; 2023.
Hariguchi N, et al. *Antimicrob Agents Chemother*. 2020;64(6):e02020-19.
Dawson R, et al. Poster presented at the 33rd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID); April 15–18, 2023 (Copenhagen, Denmark and virtual).

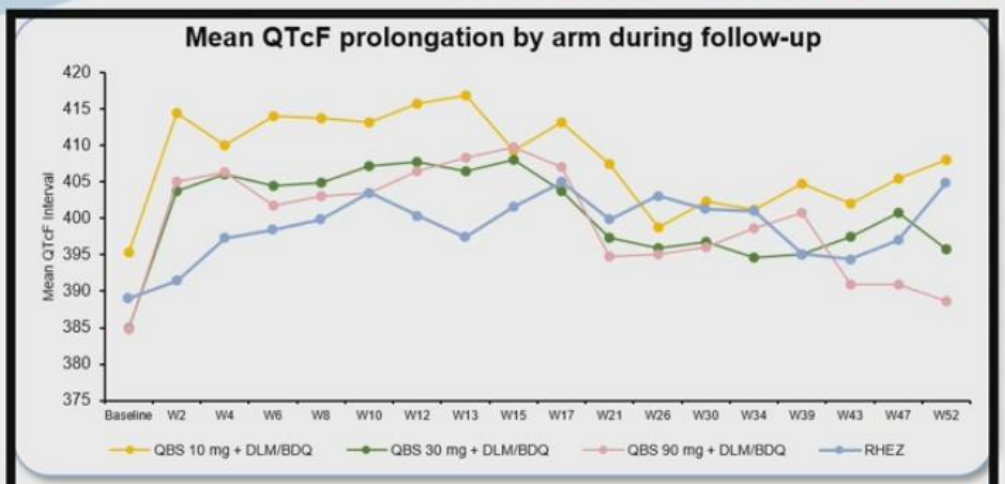
Kaplan-Meier Curve: Time to SCC by End of Treatment



- No clear differences in time to SCC between the experimental arms and RHEZ
- No clear dose-response relationship was observed for QBS

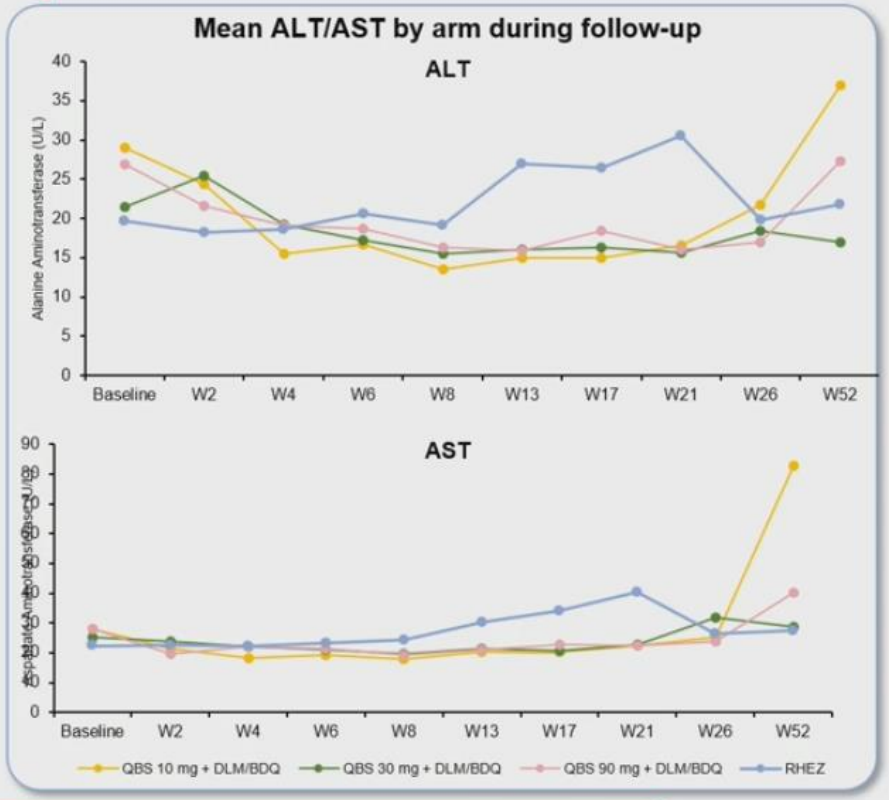
BDQ, bedaquiline; D, day; DLM, delamanid; QBS, quabodepistat; RHEZ, rifampicin, isoniazid, ethambutol, and pyrazinamide; SCC, sputum culture conversion; W, week.

Adverse Events of Special Interest



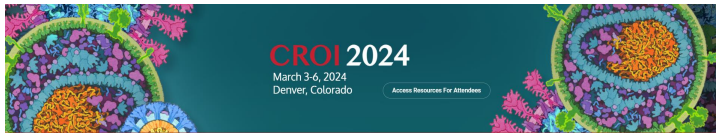
Severity of QTc prolongation by arm

Aggregate QT interval (msec)	QBS 10 mg + DLM/BDQ n=20	QBS 30 mg + DLM/BDQ n=42	QBS 90 mg + DLM/BDQ n=38	RHEZ n=21	Total N=121
QTcF >450	5 (25.0)	7 (16.7)	3 (7.9)	1 (4.8)	16 (13.2)
QTcF >480	0	0	0	0	0
QTcF >500	0	0	0	0	0
>60 increase from baseline	1 (5.0)	5 (11.9)	2 (5.3)	0	8 (6.6)



- No clinically significant QTc prolongation events or QTc prolongation events ≥500 ms
- In the QBS arms, mean ALT/AST did not increase during the treatment period
- No dose-related effects on QTc interval or liver enzymes observed

ALT; alanine transaminase; AST, aspartate aminotransferase; BDQ, bedaquiline; DAIDS, Division of AIDS; DLM, delamanid; QBS, quabodepistat; QT, time from the start of the Q wave to the end of the T wave, time taken for ventricular depolarization and repolarization; QTc, heart-rate corrected QT interval; QTcF, QT corrected for heart rate by Fridericia's cube root formula; RHEZ, rifampicin, isoniazid, ethambutol, and pyrazinamide.



S. Takuva

Provisional Results From a 3-month Clofazimine/Rifapentine-Containing Regimen for Drug-Sensitive TB

John Metcalfe
University of California San Francisco, San Francisco, CA, USA

A5362: A Phase IIc Trial of Clofazimine & Rifapentine Containing Treatment Shortening Regimens in Drug-Susceptible TB (CLOFAST)

- Phase IIC (N=185)
- Participants ≥18 years, with or without HIV, with DS TB

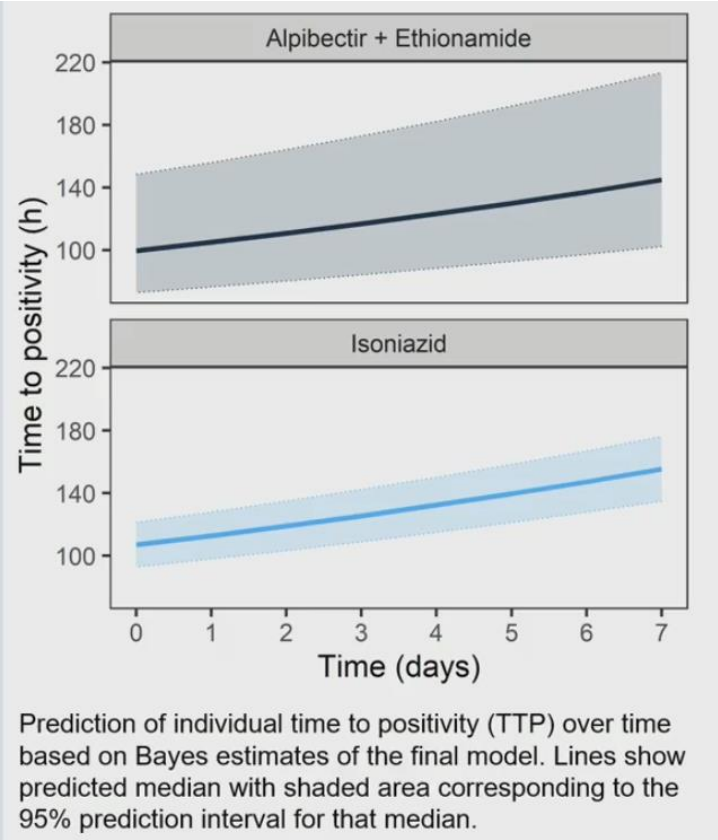
	Weeks					
	0-2	3-4	5-8	9-13	14-26	27-65
Arm 1 (Experimental) N=110	PHZE + CFZ 300 mg	PHZE + CFZ 100 mg	PHZE + CFZ 100 mg	PHZ + CFZ 100 mg	Follow up	Follow up
Arm 2 (Standard of Care) N=55	RHZE			RH		Follow up
Arm C (PK only subgroup) N=20	PHZE + CFZ 100 mg	PHZE + CFZ 100 mg	RHZE: On SOC treatment and study follow up	RH: On SOC treatment and study follow up		Follow up

CROI Oral abstract session 10-12am, March 5 2024

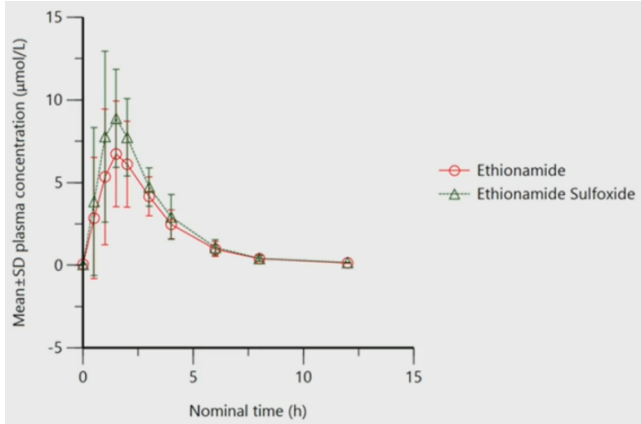
ACTG

Early Bactericidal Activity of the Alpibectir-Ethionamide (AlpE) Combination Against Tuberculosis

Jeantelle Du Preez
TASK Applied Science, Cape Town, South Africa

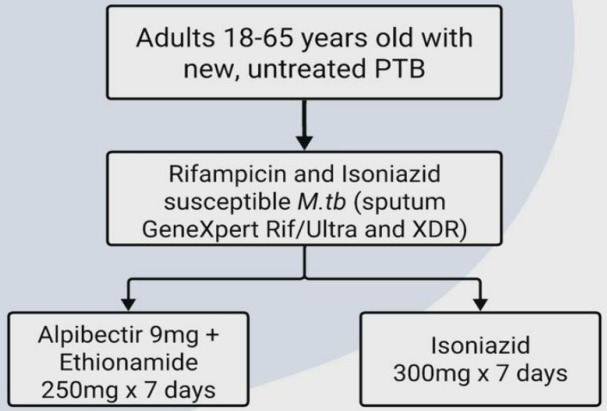


Prediction of individual time to positivity (TTP) over time based on Bayes estimates of the final model. Lines show predicted median with shaded area corresponding to the 95% prediction interval for that median.



Study Overview (Stage 1)

- Phase 2 trial to assess bactericidal activity, safety, and tolerability of the Alpibectir-Ethionamide (AlpE) combination
- Interim analysis performed after Stage 1



Safety &Tolerability

	All Participants n = 18 (%)	AlpE n = 15 (%)	INH n = 3 (%)
Number of TEAEs	**26**	**19**	**7**
Grade 1 (mild) TEAEs	20 (76.9%)	13 (68.4%)	7 (100.0%)
Grade 2 (moderate) TEAEs	6 (23.1 %)	6 (31.6%)	0 (0.0%)
Serious, Grade 3 and 4 TEAEs	0 (0.0%)	0 (0.0%)	0 (0.0%)

	All Participants n = 18 (%)	AlpE n = 15 (%)	INH n = 3 (%)
Participant with Potentially Drug Related Adverse Events	6 (33.3%)	4 (26.7%)	2 (66.7%)
Gastrointestinal disorders	3 (16.7%)	3 (20.0%)	0 (0.0%)
Diarrhoea	2 (11.1%)	2 (13.3%)	0 (0.0%)
Flatulence	1 (5.6 %)	1 (6.7%)	0 (0.0%)
Nervous System disorders	3 (16.7%)	1 (6.7%)	2 (66.7%)

ITBL en paciente VIH

Current options for TB Preventive Therapy

Drug(s)/Regimen	Guidelines	HIV Drug-Drug Interaction Issues
Isoniazid 9 months (9H)* Isoniazid 6 months (6H)* Isoniazid ≥ 36 months (36H)*	WHO, CDC	Efavirenz – increased exposure
Rifampin 3-4 months (3-4R)* Rifampin/isoniazid 3 months (3HR)*	WHO, CDC	EFV – safe to use NVP – do not use TAF – probably safe PIs – do not use RTG and DTG – safe to use BID
Rifapentine/isoniazid q wk x 12 (3HP)	WHO, CDC	EFV – safe to use TAF – unknown RTG and DTG – safe to use
Rifapentine/isoniazid daily x 1 month (1HP)	WHO, USPHS	EFV – safe to use TAF – unknown RTG and DTG – safe to use BID

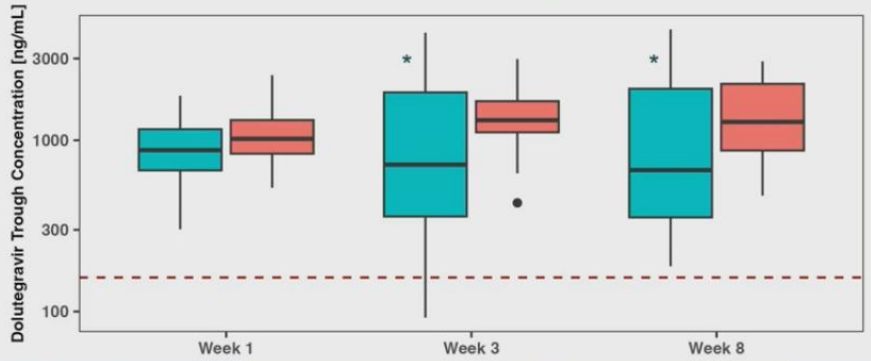
*can be used in pregnancy and in young children

I. Mave

Simultaneous Initiation in ART-Naive PWH of DTG-Based ART & 3HP Maintains Efficacious DTG Levels

Ethel D. Weld
The Johns Hopkins University, Baltimore, MD, USA

Dolutegravir Trough over Time



3HP 6H

Nonlinear mixed-effects modeling showed a **72% induction effect** of rifapentine on DTG clearance, from 0.954 L/hr to 1.64 L/hr

← 158 ng/mL (5th %ile C_{min} w/ 10 mg daily DTG in SPRING-1 Trial[1])

* Wilcoxon rank sum p-value <0.01

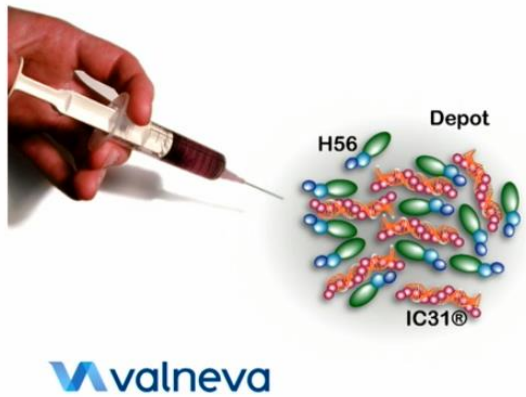
DTG troughs (ng/mL)	3HP (N=50)			6H (N=25)		
Sampling Time	Day 1	Day 21	Day 56	Day 1	Day 21	Day 56
n (# samples)	50	49	44	25	23	24
Median (5th, 95th %ile)	875 (411, 1580)	720 (219, 3325)	669 (208, 2593)	1020 (546, 2292)	1310 (642, 2915)	1344 (595, 2615)
Below 300 (#)	-	5	8	-	-	-
Below 158 (#)	-	2	-	-	-	-
Below 64 ($PA\text{-}IC_{90}$) (#)	-	-	-	-	-	-
%Target attainment (<158)	100%	96%	100%	100%	100%	100%

[1]Stellbrink HJ, AIDS 2013;Jul;17;27(11):1771-1778

Efficacy, Safety, and Immunogenicity of H56:IC31 Vaccine for Prevention of Recurrent TB

Alvaro Borges
Statens Serum, Institut, Copenhagen, Denmark

The H56:IC31 vaccine – developed by Statens Serum Institut



valneva

The H56:IC31 multistage vaccine candidate was designed to boost BCG and introduce ESAT-6 specific immunity.
H56 consists of a fusion protein of three antigens expressed at different stages of Mtb infection and a T helper type 1 cell stimulating adjuvant, IC31® (Valneva).

H56 fusion protein:
Ag85B: An immunodominant antigen secreted in the acute phase of infection
ESAT-6: A premier virulence-associated antigen highly expressed throughout all stages of infection
Rv2660c: A stress-induced antigen, the expression of which is strongly associated with latent TB infection

IC31® adjuvant:
A 2-component adjuvant comprised of an oligodeoxynucleotide ODN1a and a polypeptide KLK, signalling through TLR9

→ **Long-lived immunity**

Primary analysis of efficacy (mITT) - TB recurrence from d70 – culture of sputum

	H56:IC31 N (%)	Placebo N (%)
mITT analysis set (N)	414	413
TB recurrence		
Number of participants contributing to analysis	400	406
TB recurrence n (rate)	23 (5.8)	14 (3.4)
Relapses	12	6
Re-infections	8	7
Indeterminate	3	1
Censored without TB recurrence	377 (94.3)	392 (96.6)

Time to TB recurrence is estimated using the Kaplan-Meier method and compared between treatment groups stratified by trial site.
The objective of the trial is considered met if H56:IC31 reduces the rate of TB compared to placebo and the p-value of the one-sided log-rank test is below 0.10

Schellack Vaccine 2006, Aagaard Nat Med 2011, Lin J Clin Invest 2012

21ª edición

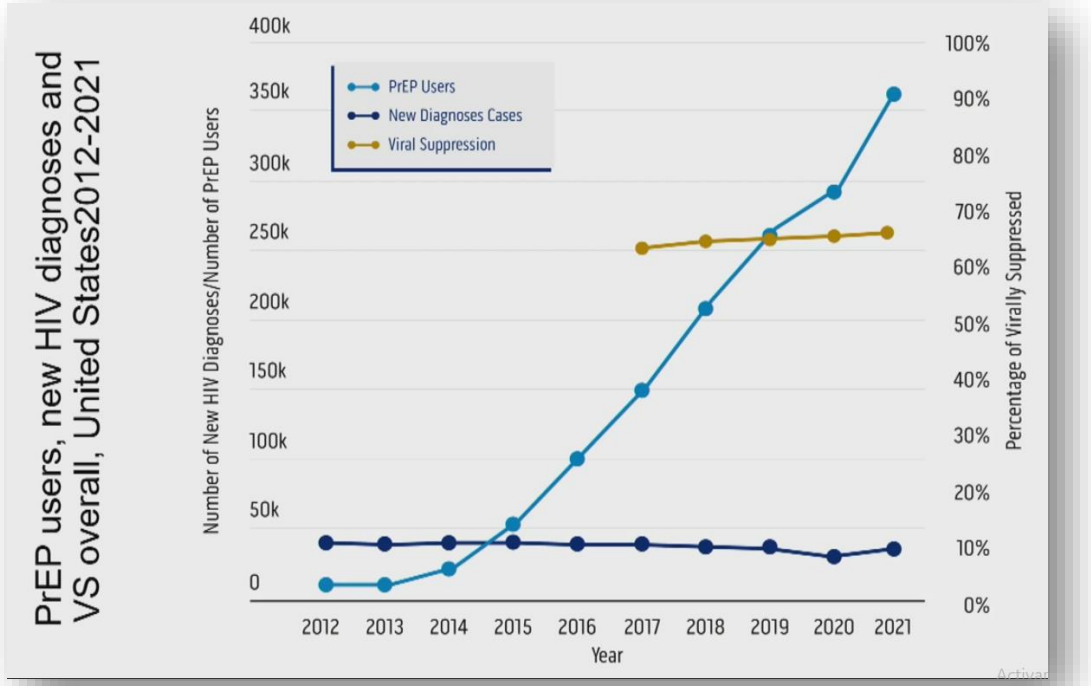
POSTCROI

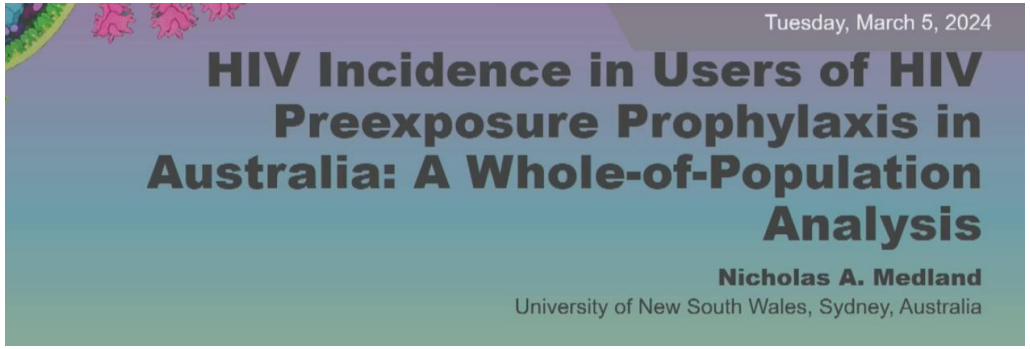
PrEP

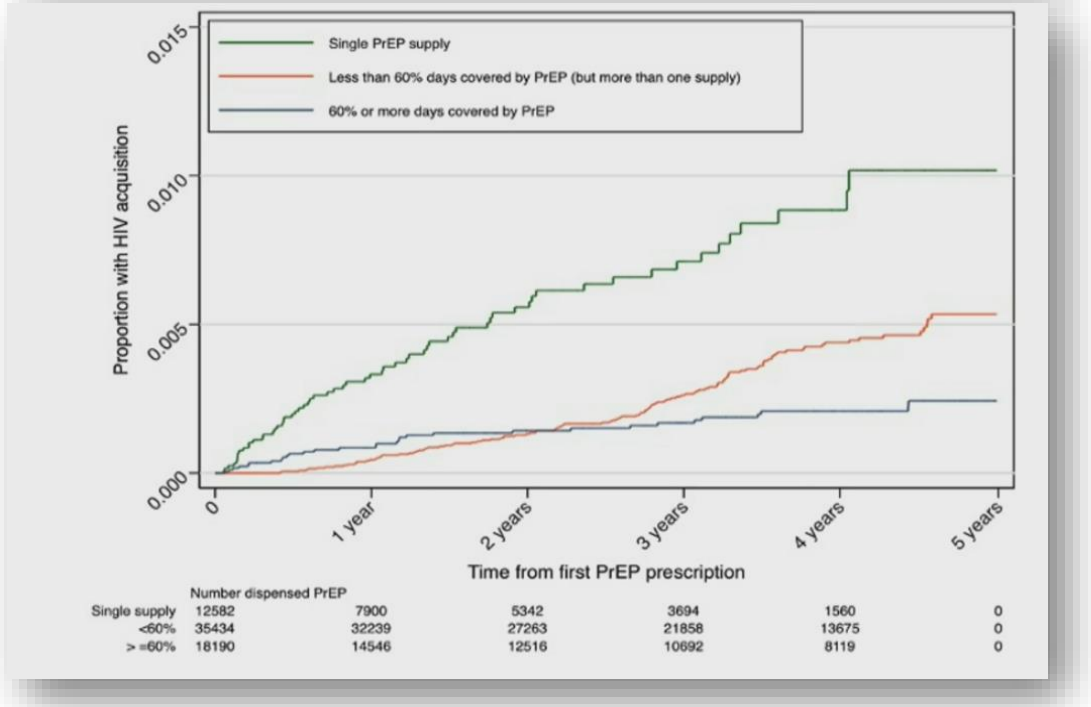
Higher State-level PrEP Coverage is Associated with Larger Declines in Population-level HIV Diagnoses, United States, 2012-2021

Patrick Sullivan, DVM, PhD[1]; Marta Juhasz, MPH[2]; Gordon Le, MPH[1]; Kamaria Brisco, MPH[1]; Stephanie DuBose, MPH[1]

1. Emory University
Rollins School of Public Health
Atlanta, Georgia
2. Saluda Analytics, Budapest, Hungary





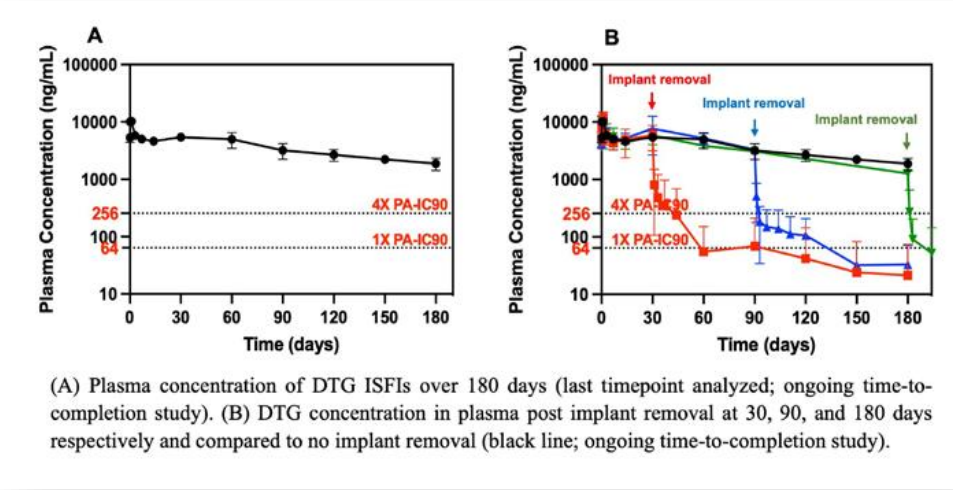


Safety of Dapivirine Vaginal Ring and Oral PrEP for HIV Prevention in the Second Trimester

Felix Mhlanga. *University of Zimbabwe, Harare, Zimbabwe*

Safety and Pharmacokinetics of Ultra-Long-Acting Dolutegravir In-Situ Forming Implant

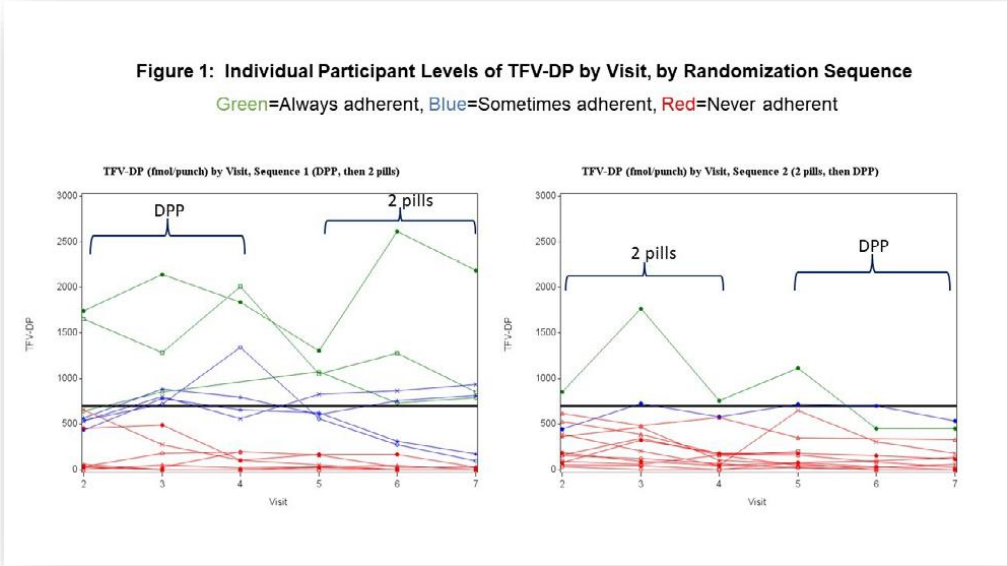
Thy Le, Isabella C. Young, S. Rahima Benhabbour
University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
Ratones, N:6



(A) Plasma concentration of DTG ISFIs over 180 days (last timepoint analyzed; ongoing time-to-completion study). (B) DTG concentration in plasma post implant removal at 30, 90, and 180 days respectively and compared to no implant removal (black line; ongoing time-to-completion study).

A Dual Prevention Pill for HIV and Pregnancy Prevention: A Pilot Study Among Young Women in Zimbabwe

Barbara A. Friedland
Population Council, New York, NY, USA,
University of Zimbabwe, Harare, Zimbabwe
N:30



Implante de TAF

Annual tenofovir alafenamide (TAF) implant

- Silicone implant: ±40mm (length), ±2.5mm (OD), 2 delivery channels
- With ±110mg TAF free-base micro-tablets; target release ±0.25mg/day

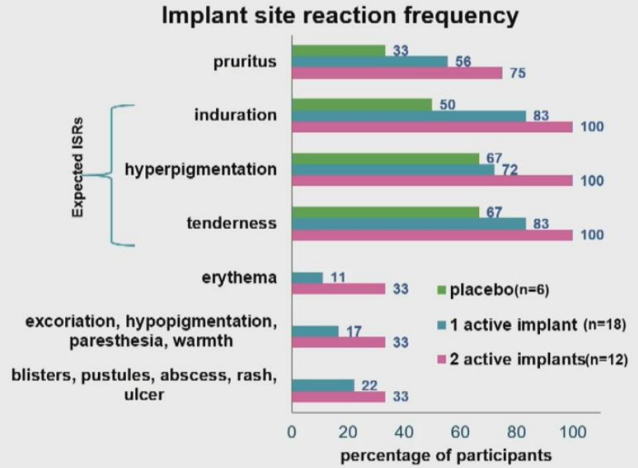
Systemic and local insertion site adverse events

5 most frequent systemic adverse events	N (36)	%
↓Creatinine clearance – all changes within the normal range	27	75%
Vitamin D deficiency	23	64%
↑Parathyroid hormone	20	56%
Haematuria	19	53%
Bacterial vaginosis	16	44%

Systemic AE severity:
Grade 1: 55.3 %
Grade 2: 42.5%
Grade 3: 2.2%

Implant local site reaction severity:
Grade 1: 90.9%
Grade 2: 8.3%
Grade 3: 0.8%*

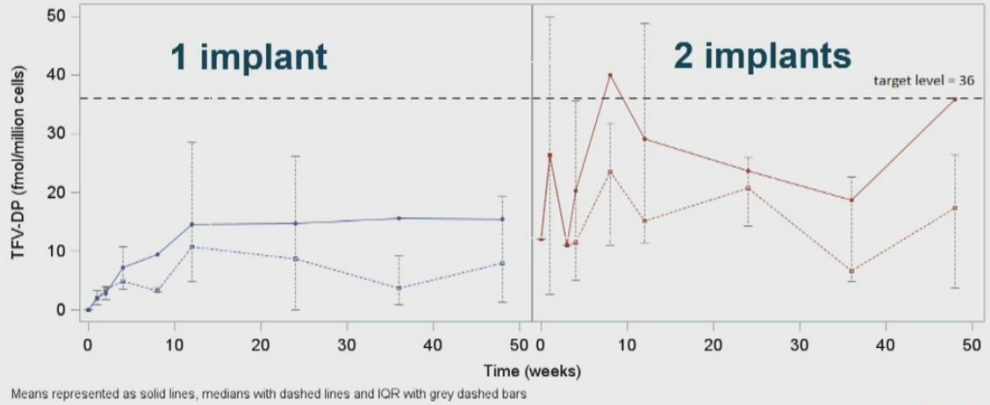
*2 of the 36 women had grade 3 local reactions: both had implant site abscesses → early removal



CAPRISA CROI 2024

Pharmacokinetics: Tenofovir Diphosphate Concentrations

- Median [IQR] TFV-DP concentrations*:
  - 3.9 [1.7-13.3] fmol/10^6 cells (1 implant) 14.8 [6.0-29.1] fmol/10^6 cells (2 implants)
  - 15% of samples reached or exceeded the target concentration TFV-DP of 36 fmol/10^6 cells



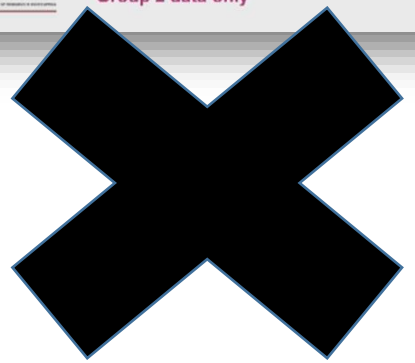
Means represented as solid lines, medians with dashed lines and IQR with grey dashed bars

CAPRISA Group 2 data only* CROI 2024

Tolerability

Implants removed prior to scheduled study end: 31% (11/36)

- Median time (weeks) to early removal: 19 (range: 2 - 27)
- 55% (6/11) were participant-initiated, other 5 were clinician-initiated
- 33% (10/30) of TAF implants & 17% (1/6) of placebo implants removed early
- 22% (4/18) of single & 50% (6/12) of double TAF implants removed early
- Implant site reaction incidence (95%CI) per person-month:
  2.1 (1.8 -2.6) in early removals vs **0.8** (0.6-0.9) in scheduled removals



T.N.Gengiah

Inhibidor del traslocación

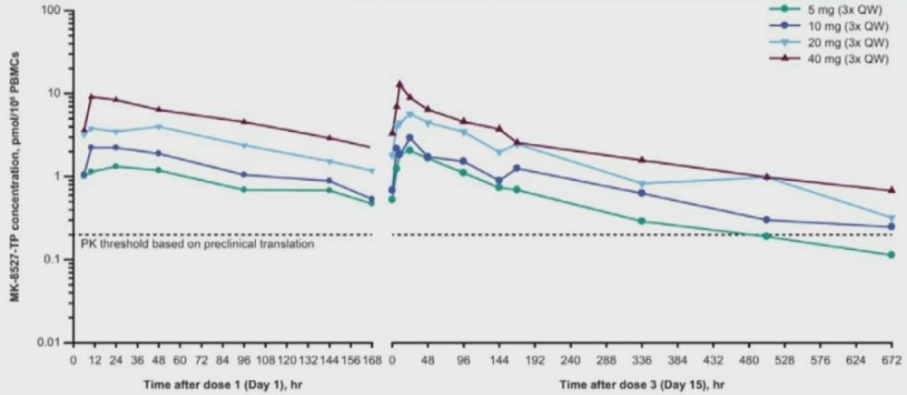
Oral Abstract Session-04

Monday, March 4, 2024

Safety and Pharmacokinetics of MK-8527, a Novel nRTTI, in Adults Without HIV

Gillian Gillespie

Mean MK-8527-TP concentrations after ascending multiple doses of MK-8527 (trial B)

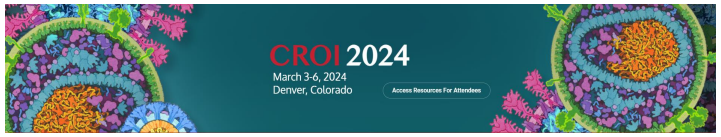


- After multiple doses of MK-8527 (3x QW), the true geometric mean C_{168} of MK-8527-TP was >0.2 pmol/10^6 PBMCs for all dose levels
- Accumulation of intracellular MK-8527-TP was modest (range of C_{max} and AUC_{0-168} ratios was 1.1–1.6)
- Across all dose levels, the range of MK-8527-TP apparent terminal half-life was 216–291 hours

C_{168}, concentration at 168 hours post dose.

Safety and tolerability

- In both trials, MK-8527 was generally well tolerated
- In trial A, AEs were reported in 27 of 34 participants (79.4%)
  - The most common AEs (>2 participants) were headache and influenza-like illness
  - 5 participants (14.7%) reported drug-related AEs; all were mild and resolved by end of study
- In trial B, AEs were reported in 29 of 32 participants (90.6%)
  - The most common AEs (>2 participants) were headache, oropharyngeal pain, cough, nausea, abdominal pain
  - 11 participants (34.4%) reported drug-related AEs; all were mild/moderate and resolved by end of study
- In both trials, there were no dose-related changes in vital signs, laboratory safety test results, or 12-lead ECGs
- In both trials, there were no serious AEs, no events of clinical interest, and no deaths



Cabotegravir sc y cada 4 meses

Oral Abstract Session-04

Monday, March 4, 2024

Phase I Study of Cabotegravir Long-Acting Injectable Formulations Supports ≥4-Monthly Dose Interval

Kelong Han

Study Design

Ongoing, open-label, single-dose, dose-escalation, phase 1 study (NCT05418868) evaluating CAB200 SC + rHuPH20 and CAB-ULA[a] SC or IM without rHuPH20

Part A	CAB200 dose (+ rHuPH20 10,000 IU)	Route	N
A1	800 mg (4 mL)	SC[b]	10
A2	1600 mg (8 mL)	SC[b]	10
A3	3200 mg (16 mL)	SC[b]	2
Part B	Not conducted – candidate formulation not progressed		
Part C	**CAB-ULA dose**	**Route**	**N**
C1	800 mg (2 mL)	SC[b]	8
C2	800 mg (2 mL)	IM[c]	8
C3	1200 mg (3 mL)	SC[b]	8
C4	1200 mg (3 mL)	IM[c]	8
C5	1600 mg (3 mL)	IM[c]	16

Inclusion criteria
- Aged 18-55 years
- HIV-negative
- Body weight ≥40 kg
- BMI 18-32 kg/m²

Monitoring of
- PK parameters
- Adverse events, including ISRs
- Vital signs
- Clinical laboratory values

- To evaluate potential CAB-ULA dosing regimens, CAB PK profiles were simulated using an established CAB200 IM population PK model modified based on observed PK data in Part C

Day 1 — Week 52[d]

BMI, body mass index; CAB, cabotegravir; IM, intramuscular; ISR, injection site reaction; PK, pharmacokinetics; rHuPH20, recombinant human hyaluronidase PH20; SC, subcutaneous; ULA, ultra-long-acting
[a]CAB ULA is a new formulation with higher CAB concentration than approved CAB200. [b]Abdominal. [c]Gluteus medius. [d]The study has been extended to Week 78 for C1 and C3.

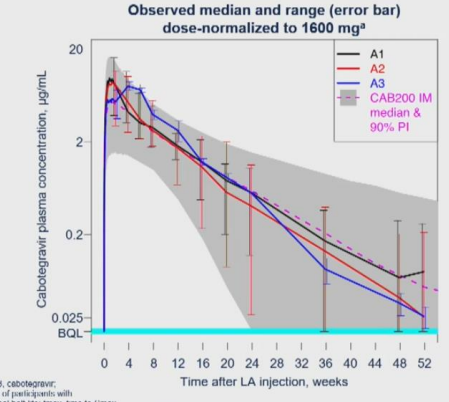
Conference on Retroviruses and Opportunistic Infections; March 3-6, 2024; Denver, CO

Han et al. CROI 2024; Denver, CO. Oral Presentation 130.

Part A: Pharmacokinetics of CAB200 + rHuPH20

Parameter, geometric mean (%CVb)	Part A: CAB200 SC + rHuPH20 A1: 800 mg (4 mL) (n=10)	A2: 1600 mg (8 mL) (n=9)	A3: 3200 mg (16 mL) (n=2)
$AUC_{0-\infty}$, mg·h/mL	6.1 (27.9)	11.5 (28.7)	26.6 (8.9)
Cmax, µg/mL	4.7 (47.4)	7.7 (46.2)	16.2 (10.1)
$t_{1/2}$, days	54.6 (57.9)	47.9 (68.5)	42.3 (5.3)
tmax, hours	164 (40.0)	316 (62.6)	755 (39.4)

- $t_{1/2}$ was similar to CAB200 IM, indicating similar overall absorption rate[1,2]
- Cmax was higher than CAB200 IM, indicating faster initial absorption[2]
- Exposure increased with dose proportionally
- $AUC_{0-\infty}$ was higher than CAB200 IM, indicating potentially increased bioavailability[2]



$AUC_{0-\infty}$, area under the plasma concentration–time curve from 0 to infinity; BQL, below quantification limit of 0.025 µg/mL; CAB, cabotegravir; Cmax, maximum observed plasma concentration; %CVb, coefficient of variation, IM, intramuscular; LA, long-acting; n, number of participants with valid PK parameters; PI, prediction interval; rHuPH20, recombinant human hyaluronidase PH20; SC, subcutaneous; $t_{1/2}$, terminal half life; tmax, time to Cmax.
[a]Error bars before Week 2 are not displayed for visibility. 1. Han et al. *Br J Clin Pharmacol* 2023;89:4607-4622. 2. Cabenuva [prescribing information]. ViiV Healthcare; 2023.

Conference on Retroviruses and Opportunistic Infections; March 3-6, 2024; Denver, CO

Han et al. CROI 2024; Denver, CO. Oral Presentation 130.

Part A: Safety of CAB200 + rHuPH20

The overall tolerability/safety profile, along with PK considerations, led to a decision not to progress this dosing strategy:

- Non-ISR drug-related AEs were infrequent
- ISRs occurred in all participants (22/22); ISR grade increased with increasing CAB dose
  - Most common ISRs were injection site pain, erythema, swelling, and warmth
- A single drug-related SAE was reported: 1 participant who received CAB 3200 mg (16 mL) SC + rHuPH20 experienced injection site erythema with necrosis requiring wound care; the wound completely healed, and the erythema resolved by Day 105

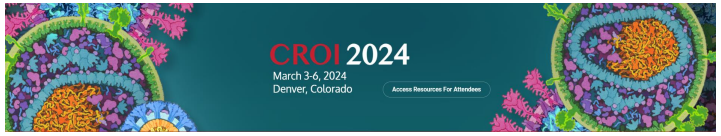
Parameter	Part A: CAB200 SC + rHuPH20 A1: 800 mg (4 mL) (N=10)	A2: 1600 mg (8 mL) (N=10)	A3: 3200 mg (16 mL) (N=2)
Any ISR, n (%)	10 (100)	10 (100)	2 (100)
Total ISR events, n	45	48	11
Maximum grade 1, n (% of ISRs)	25 (56)	29 (60)	5 (45)
Maximum grade 2, n (% of ISRs)	20 (44)	16 (33)	1 (9)
Maximum grade ≥3, n (% of ISRs)	0	3 (6)	5 (45)[a,b]
Duration, median (IQR), days[c]	9 (7-37)	24 (7-138)	28 (15-105)

AE, adverse event; CAB, cabotegravir; IQR, interquartile range; ISR, injection site reaction; PK, pharmacokinetics; rHuPH20, recombinant human hyaluronidase PH20; SAE, serious AE; SC, subcutaneous
[a]1 drug related SAE of injection site erythema with necrosis. [b]No further participants were dosed in A3 due to the safety findings from these 2 sentinel participants. [c]Only calculated for events that have resolved (A1: 10/10 [100%]; A2: 10/10 [91%]; A3: 11/11 [100%])

Conference on Retroviruses and Opportunistic Infections; March 3-6, 2024; Denver, CO

Han et al. CROI 2024; Denver, CO. Oral Presentation 130.

rHuPH: hialuronidasa recombinante humana que permite aumentar el volumen de la inyección subcutánea



Part C: PK of New Ultra-Long-Acting Formulation CAB-ULA

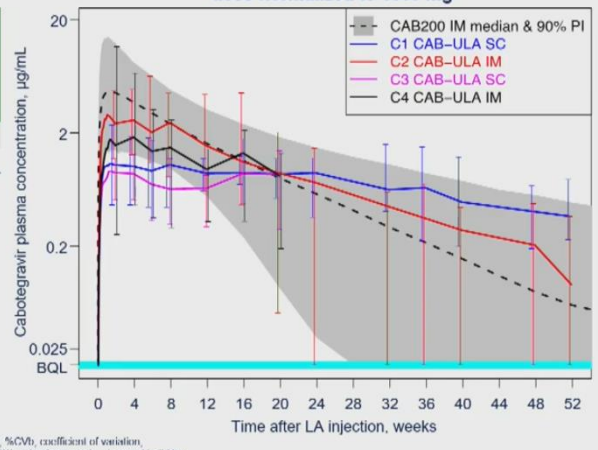
Part C: CAB-ULA

Parameter, geometric mean (%CVb)	SC C1 800 mg (2 mL) (n=8)	SC C3 1200 mg (3 mL) (n=8)	IM C2 800 mg (2 mL) (n=8)	IM C4 1200 mg (3 mL) (n=8)
Cmax, µg/mL	0.7 (35.5)	0.8 (39.0)	1.8 (53.5)	1.8 (148)
tmax, hours	570 (158)	349 (147)	298 (136)	383 (107)

CAB-ULA has slower absorption and longer $t_{1/2}$ than CAB200 IM

- PK profiles were flatter than CAB200 IM
- CAB-ULA Cmax was lower with SC than IM; both were lower than CAB200 IM[1]
- tmax was longer than CAB200 IM[1]
- **CAB-ULA $t_{1/2}$ for SC and IM was predicted to be >6x and >2x the $t_{1/2}$ of CAB200 IM, respectively[1,a]**

Observed median and range (error bar) dose-normalized to 1600 mg[b]



BQL, below quantification limit of 0.025 µg/mL; CAB, cabotegravir; Cmax, maximum observed plasma concentration; %CVb, coefficient of variation; IM, intramuscular; n, number of participants with valid PK parameters; PI, prediction interval; PK, pharmacokinetics; SC, subcutaneous; $t_{1/2}$, terminal half life; tmax, time to Cmax; ULA, ultra-long-acting. [a]Current follow-up time is insufficient to calculate final $t_{1/2}$ value for CAB-ULA. [b]PI not bars before Week 2 are not displayed for visibility. 1. Cabenuva [prescribing information]. ViiV Healthcare; 2023.

Part C: Safety of CAB-ULA

- Non-ISR drug-related AEs were infrequent
- CAB-ULA IM was better tolerated than SC
  - SC: ISRs occurred in 100% (16/16) of participants; most common SC ISRs were erythema, nodule, and pain
  - IM: ISRs occurred in 69% (22/32) of participants; most common IM ISR was pain and except for 1, all were mild (grade 1)
- CAB-ULA IM ISR profile appears comparable to established CAB200 IM ISR profile despite higher single doses of CAB-ULA

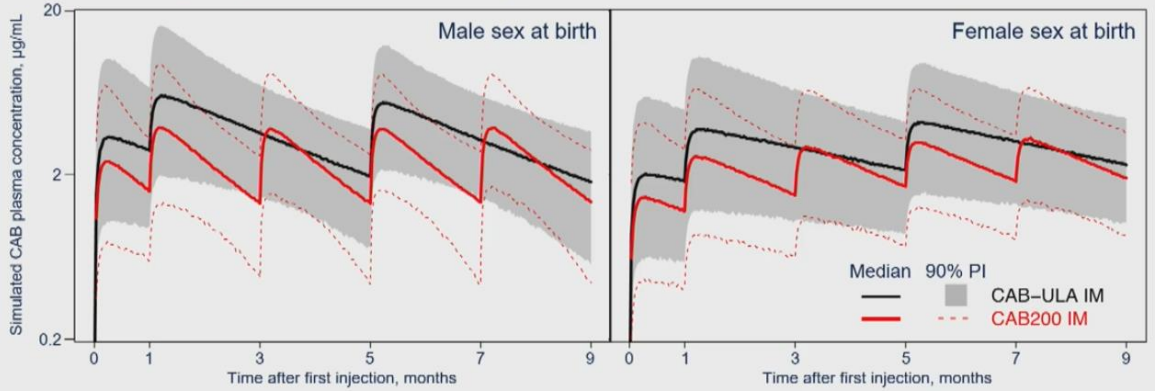
Part C: CAB-ULA

Parameter	SC C1: 800 mg (2 mL) (N=8)	SC C3: 1200 mg (3 mL) (N=8)	IM C2: 800 mg (2 mL) (N=8)	IM C4: 1200 mg (3 mL) (N=8)	IM C5: 1600 mg (3 mL) (N=16)
Any ISR, n (%)	8 (100)	8 (100)	3 (38)	8 (100)	11 (69)
Total ISR events, n	21	24	5	9	15
Maximum grade 1, n (% of ISRs)	19 (90)	22 (92)	4 (80)	9 (100)	14 (93)
Maximum grade 2, n (% of ISRs)	2 (10)	2 (8)	1 (20)	0	1 (7)
Maximum grade ≥3, n (% of ISRs)	0	0	0	0	0
Duration, median (IQR), days[a]	15 (6-41)	13 (6-21)	5 (5-8)	4 (3-5)	6 (4-8)

AE, adverse event; CAB, cabotegravir; IM, intramuscular; IQR, interquartile range; ISR, injection site reaction; SC, subcutaneous; ULA, ultra-long-acting. [a]Only calculated for events that have resolved (C1: 15/21 [71%]; C3: 17/24 [71%]; C2: 5/5 [100%]; C4: 9/9 [100%]; C5: 12/15 [80%]).

Pharmacokinetic Simulations of CAB-ULA Q4M Dosing

- PK simulations[a] predict a CAB-ULA IM dose interval of ≥4 months achieves higher exposure than approved CAB200 IM at intervals of 2 months
- CAB-ULA IM $t_{1/2}$ was predicted to be >2x the $t_{1/2}$ of CAB200 IM



CAB, cabotegravir; IM, intramuscular; PI, prediction interval; PK, pharmacokinetics; Q4M, every 4 months; SC, subcutaneous; $t_{1/2}$, terminal half life; ULA, ultra long acting. [a]1600 mg (3 mL) CAB ULA per injection.

K. Han

Oral Abstract Session-04

Monday, March 4, 2024

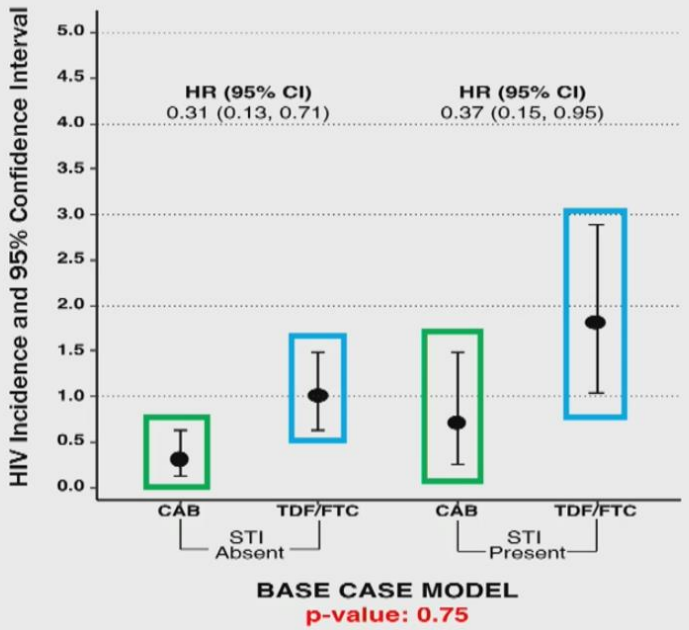
Cabotegravir Maintains Protective Efficacy in the Setting of Bacterial STIs: HPTN 083

Meredith Clement

Results: STI Incidence Rates, n= 3859 participants

	# Positive Tests	IR (per 100 PY)
Any STI	2819	50.7
Syphilis	923	16.7
Urogenital Gonorrhea	134	2.4
Urogenital Chlamydia	249	4.5
Rectal Gonorrhea	600	11.0
Rectal Chlamydia	913	16.7

Results: Maintenance of Efficacy

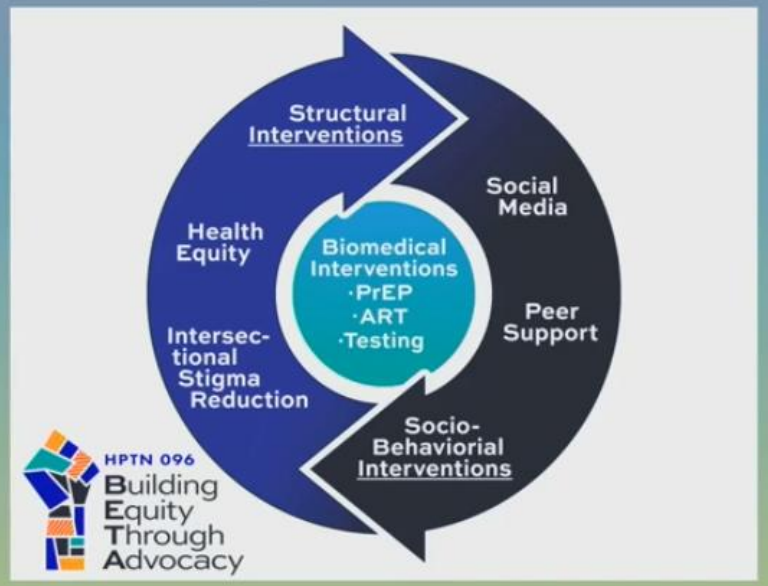


CROI 2024

IMPLEMENTACIÓN

Multi-Level Integrated Strategies

Learning from Social & Behavioral Science how to remove obstacles to impact



CROI 2024

LaRon E Nelson, CROI 2024

Themed Discussion-12

Wednesday, March 6, 2024

Persistence on Contraception and PrEP in Hair Salons in South Africa

Ingrid V. Bassett
Massachusetts General Hospital, Boston, MA, USA

Methods: Pilot RCT salon-based contraception/PrEP

- Stylist introduces study
- Nurse/RA facilitates questionnaires, provides testing, offers contraception/PrEP/STI screening, risk-reduction counseling
- Nurse dispenses PrEP (TDF/FTC) and/or contraception (oral or injectable); participant can renew, accept, or decline at later visits
- Study staff shares study nurse contact info, sends SMS reminders, follows up re: side effects, operates WhatsApp group

Conclusions

- Women in urban salons persisted on family planning and HIV prevention services (1 additional visit within 6 mo. with continued use), with 69% persisting on contraception and 42% on PrEP
- Age ≥25y, intimate partner violence, and persistence on contraceptives associated with PrEP persistence
- Hair salons are a novel venue for family planning and HIV prevention services
- A menu of PrEP delivery methods and supports may facilitate PrEP persistence


Gracias!
jvillar@psmar.cat