

# HIV MID-YEAR MARKET MEMO



July 2024

Introducing the eighth edition of the Clinton Health Access Initiative's **HIV Mid-Year Market Memo**, a brief covering the latest trends in the HIV space in LMICs since the publication of the annual [HIV Market Report](#) in October 2023.

For questions, reach out to Jessica Fox ([jfox@clintonhealthaccess.org](mailto:jfox@clintonhealthaccess.org))

## Cross-Cutting Updates

### Climate Change and HIV



**11.6M to 16M** additional HIV infections by 2050 due to rising temperatures, according to [models](#) of data from 25 countries in SSA



**2x** higher [odds](#) of having recently acquired HIV among women in rural areas of SSA who had been exposed to drought

### Sustainability/Financing



**PEPFAR's 1-year reauthorization** until March 2025 reaffirms the commitment of the U.S. to ending HIV, though the long-term future of the program remains at risk

## Prevention

### General Updates



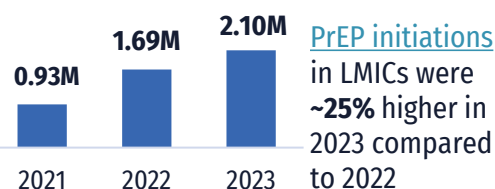
**Choice leads to more use** when clients are offered oral PrEP, PEP, and CAB-LA, according to findings in the SEARCH Dynamic Choice Prevention study



#### In the dynamic choice prevention arm:

- Proportion of time covered by a prevention product was **56.4 percentage points higher** (69.7% vs 13.3%)
- HIV incidence was **0%** compared to 1.8% in the SoC arm
- **CAB-LA** was the **most commonly used option**
- **28%** of participants used **more than one product**

### PrEP initiations in LMICs



### Product Pipeline Updates

#### LENACAPAVIR (LEN)

- **PURPOSE 1 trial data:** LEN (6-monthly injectable) for PrEP shows **100% efficacy and superiority over oral TDF+FTC** in African cisgender AGYW
- Gilead [announces access strategy](#) of dedicated Gilead supply and voluntary licensing for high-incidence, resource-limited countries

#### OTHER PIPELINE

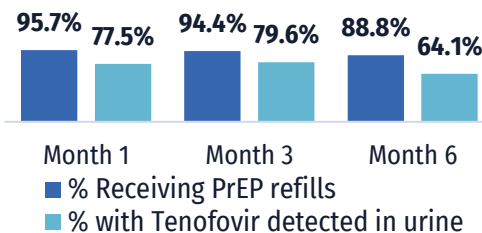
- **Acceptability study** conducted in Zimbabwe found **two-thirds of AGYW preferred combined oral PrEP and oral contraceptives (DPP)** over separate pills
- **Phase 1 trial** shows positive results for **Ultra Long-Acting CAB (CAB-ULA)** given intramuscularly every four months

### Oral PrEP

#### EFFICACY AND ADHERENCE IN CISGENDER WOMEN

- Studies by [Moore et al.](#), [Zhang et al.](#), and [Marazzo et al.](#):
- **4 doses** of oral PrEP/week **84-100%** effective at preventing HIV in cisgender women, similar to MSM
  - Findings suggest oral PrEP is **equally effective** for HIV exposure via vaginal or anal sex

**INSIGHT Cohort Study:** AGYW in 6 SSA countries show **higher levels of PrEP adherence than previously reported**



### Dapivirine Vaginal Ring (DVR)



South African firm Kiara Health signs [MOU](#) with Population Council to **locally manufacture and distribute the DVR**



**DELIVER Study** shows that DVR is **safe for use during pregnancy and breastfeeding**



**3-month DVR with contraception** under [development](#)

### Long-Acting Cabotegravir (CAB-LA)



CAB-LA **approved** in 50 countries including **16 LMICs as of June 2024**



**Prequalified by the WHO** Dec 2023



CAB 600mg/3ml **23.49 GBP** per vial



**955K** doses available for LMICs through 2025, with introductions underway in **Malawi, Zambia, and Zimbabwe**

### Vertical Transmission



**A modelling study** using data from Zambia found that **maternal peer support groups, HIV retesting during late antenatal care, and infant prophylaxis** were each most effective in reducing vertical transmission

# Testing

## HIV Self-Tests (HIVST)



**Nigeria & Uganda** formally launched Wondfo's HIVST



**US \$1** per test under the MedAccess [volume guarantee](#) terms facilitated by CHAI

## Early Infant Diagnosis (EID)



- Xpert® HIV-1 Qual XC by Cepheid receives [WHO PQ](#)
- **Delivers results 7-10 days before seroconversion**
- Potential to replace legacy GX HIV-1 Qual cartridge
- **Doesn't require high-heat incineration**, simplifying waste management

## Triple Elimination Diagnostic Pipeline

- Safe, effective, and affordable **tools exist to prevent transmission** of hepatitis, HIV, and syphilis from mothers to children
- **Combination testing serves as an important entry point** to these services
- A triple combination RDT simplifies service delivery, saves on testing costs and time, and streamlines supply chain barriers

### Products under development for HBV, HIV, and syphilis combination testing (Not exhaustive, subject to change)

Manufacturer	Expected Sample Types			Test Type	
	Whole Blood	Serum	Plasma	Lateral Flow Assay	Flow-Through
Abbott <sup>1</sup>	x			x	
Accubio <sup>2</sup>	x	x	x	x	
BioLytical	x				x
CTK Biotech <sup>3</sup>	x	x	x	x	
InTech Products	x	x	x	x	
SD Biosensor	x	x	x	x	

<sup>1</sup>CE Marked, Under WHO PQ Review; <sup>2</sup>CE-mark pending for 4-product test (HBV, HCV, HIV, syphilis) by Accubio; <sup>3</sup>CTK Biotech 4-product test (HBV, HCV, HIV, syphilis) commercialized in select countries

# Pediatric Treatment

## Pediatric ABC/3TC/DTG (pALD)



**3 generic suppliers** are ready to receive orders with no supply issues expected



**180-count bottles preferred** by PEPFAR to support multi-month dispensing (MMD)



Generic supplier, Mylan/Viatris, will **convert existing pDTG orders to pALD**



**Zambia** received the **first shipment of pALD** and is beginning to transition CLHIV to this optimal product

pALD Procurement, via APWG Reporting as of H1 2024



- Orders Placed or Delivered
- Planned Orders
- No data

## Pediatric Dolutegravir (pDTG)



**87 countries** have placed or received orders for pDTG



**7.6M** packs of pDTG supplied

## Pediatric Darunavir/ Ritonavir (pDRV/r)

- **June 2024** Laurus Labs applied for US FDA tentative approval of pDRV/r (120/20 mg), a best-in-class PI for CLHIV that fail DTG
- For more information on this optimal pediatric product see CHAI's [HIV New Product Introduction Toolkit](#)

### **i** pALD INTRODUCTION RESOURCES

- [pALD Product Profile](#)
- [pALD FAQs](#)
- [GAP-f pALD Planning Considerations for National Programmes](#)

# Adult Treatment

## Adult HIV Treatment Trends

### RETAIN6 STUDY



- Most clients presenting for ART initiation were treatment-experienced
- A **cyclical pattern** of engagement and treatment interruptions was common in clients, **especially in the early treatment period**
- Emphasizes enhanced counseling, flexible service delivery, and good provider-client relationships to improve early treatment outcomes

## Lenacapavir (LEN)

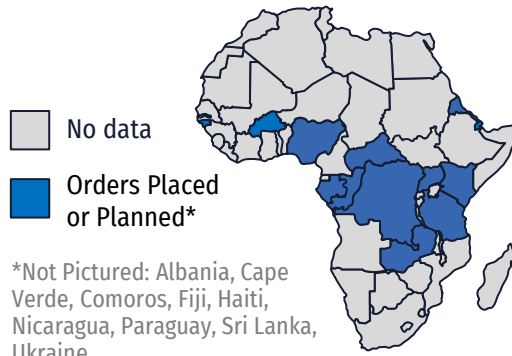
### CAPELLA TRIAL

#### Week 104 Results:

- LEN with an optimized background regimen (OBR) is associated with sustained VL suppression in heavily treatment experienced PLHIV with MDR HIV
- Development of resistance was **associated with poor adherence to OBR or absence of active ARVs in OBR**
- **50%** of participants with LEN resistance **resuppressed after adhering to or changing their optimized background regimen**
- LEN was **well tolerated** with no serious adverse events recorded

## Darunavir/Ritonavir (DRV/r) 400/50 mg

### DRV/r Procurement as of H1 2024



- **22 LMICs** are currently procuring or planning to procure DRV/r
- **US \$17.50** per pack



*For me, I've never experienced side effects with the drug [DRV/r]. So far, I would say this is the best drug for me.*

- [DRV/r client in Zambia with 17-year treatment history](#)

## Cabotegravir and Rilpivirine (CAB + RPV)

### CARES STUDY

- Phase 3b study: Long-acting CAB + RPV showed **non-inferiority to standard oral ART** in **African populations** at 48 weeks

### LATITUDE STUDY

- Phase 3 study conducted in the US: **Long-acting CAB + RPV** showed **superior efficacy** compared to daily oral ART in **PLHIV with adherence challenges**

## Weekly Oral Islatravir/Lenacapavir (ISL/LEN)

### Phase 2 Week 24 Results

- 104 participants randomized 1:1 to receive either daily oral Biktarvy (BIC/FTC/TAF) or investigational oral islatravir 2 mg and lenacapavir 300 mg once a week
- Both arms demonstrated **comparable rates of viral suppression at week 24** (94.2% vs 94.2%)
- 1 participant treated with ISL + LEN had viral load >50 copies/mL at week 24, but resuppressed at week 30

# Treatment Monitoring

## HIV Drug Resistance

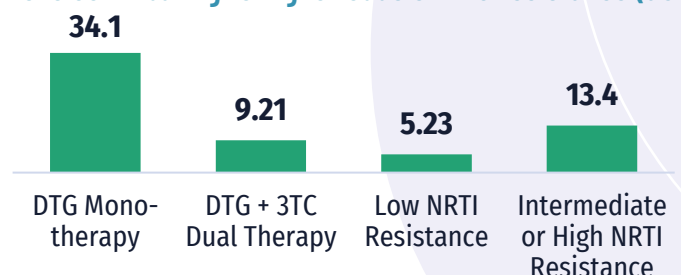
### WHO 2024 DRUG RESISTANCE REPORT

- Viral suppression (and re-suppression) on DTG is high**, and **drug resistance is still very low** as a proportion of the total number of PLHIV on DTG
- Most PLHIV on DTG-based regimens do not have resistance to DTG** at the time of failure to suppress viral load initially
- The management strategy for people with unsuppressed viral load on DTG-based regimens should stress **expanded access to high-quality and evidence-based adherence interventions**

### DTG-RESIST STUDY

Among 8 cohorts of PLHIV from North America, Europe, and South Africa who were **viremic** on DTG-based ART, **DTG resistance was rare**

### Risks contributing to higher odds of DTG resistance (aOR)



# Advanced HIV Disease

## CD4 Market Shifts

### POINT-OF-CARE TESTING

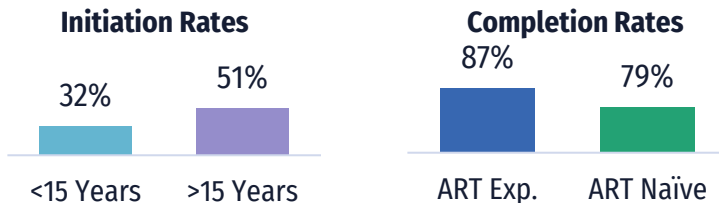
- **BD FACSCount and FACSPresto** analyzers and cartridges no longer available for procurement
- **Abbott is no longer manufacturing Pima analyzers**, but will continue to supply cartridges and bead standards as well as service and refurbish existing analyzers
  - **US \$7.60** per Pima cartridge, an increase from the previous price of US \$6.60
- **Extended 18-month** shelf-life for Accubio's VISITECT (previously 12 months) is currently under review by WHO PQ team

## Tuberculosis (TB)

**Pediatric 3HP** for TB prevention now available for children ≥2 years following Dec 2023 GF ERP [approval](#) of a child-friendly formulation of rifapentine (RPT)

- The **most affordable RPT-based TB prevention for children** in LMICs

### PEPFAR TPT in 36 Countries, as of March 2023



**Improving access to pediatric TPT formulations** may increase initiation rates among CLHIV



Ongoing need to ensure all ART-naïve clients receive adequate support to access and complete a full course of TPT - **increased access to short-course regimens** could help

## Opportunistic Infection Prophylaxis

- **Azithromycin 500mg** manufactured by ACI HealthCare Limited, is the first azithromycin [prequalified by WHO](#) - allowing for wider procurement of a WHO-listed product and increased access to this essential component of the AHD package of care

## CONVENTIONAL TESTING

- **Conventional suppliers remain committed to staying in the market** and have not made any changes to the supply of tests or analyzers

## CD4 MARKET EXPANSION EFFORTS

- **Feb 2024:** CHAI convened a CD4 roundtable with MOHs, civil society, IPs, and donors to discuss the most pressing challenges around CD4 access and align on a path forward
- **June 2024:** CHAI, Aurum Institute, Unitaid, and BMGF issued a call for expressions of interest from suppliers who can provide interventions to grow capacity and increase sustainable access to CD4 testing and opportunistic infection screening

## Cryptococcal Meningitis (CM)

### CrAg TESTING

- In H2 2024 IMMY expected to submit a new semi-quantitative (SQ) lateral flow CrAg assay to the US FDA
- SQ test has potential to **simplify linkage to care** by negating the need for confirmatory lumbar puncture in a subset of patients

- **25 pack** of existing IMMY CrAg lateral flow assay test now available in addition to 50 pack size

### L-AmB

- **US \$23.00** per vial access price for cryptococcal meningitis in 2024, an increase from US \$16.25
- Gilead is the **sole supplier** of L-AmB across LMICs, although CHAI, DNDi, and Unitaid are working accelerate generic development and access to L-AmB

## ACRONYMS USED

### DATA SOURCES

- 1 CHAI's annual data request to 25+ LMICs
- 2 Articles from journals and news outlets
- 3 Supplier and partner market intelligence
- 4 Major conferences and meetings
- 5 WHO guidelines and PEPFAR technical guidance

**3HP:** Three months of weekly RPT+INH for TPT

**AGYW:** Adolescent girls and young women

**AHD:** Advanced HIV disease

**APWG:** ARV Procurement Working Group

**ART:** Antiretroviral therapy

**BMGF:** Bill & Melinda Gates Foundation

**CAB-LA:** Long-Acting Cabotegravir

**CAB + RTV:** Cabotegravir + Rilpivirine

**CLHIV:** Children living with HIV

**CrAg:** Cryptococcal antigen

**DNDi:** Drugs for Neglected Diseases Initiative

**DPP:** Dual prevention pill

**DRV/r:** Darunavir/ritonavir

**DTG:** Dolutegravir

**DVR:** Dapivirine Vaginal ring

**EID:** Early infant diagnosis

**GBP:** British Pound Sterling

**GF ERP:** Global Fund Expert Review Panel

**HBV:** Hepatitis B virus

**HCV:** Hepatitis C virus

**HIVST:** HIV self-test

**IP:** Implementing partner

**ISL:** Islatravir

**L-AmB:** Liposomal amphotericin B

**LEN:** Lenacapavir

**LMIC:** Low- and middle-income country

**MMD:** Multi-month dispensing

**MOU:** Memorandum of understanding

**NRTII:** Nucleoside reverse transcriptase inhibitors

**pALD:** Pediatric ABC+3TC+DTG

**pDRV/r:** Pediatric darunavir/ritonavir

**pDTG:** Pediatric DTG (10 mg) scored, dispersible

**PEP:** Post-exposure prophylaxis

**PEPFAR:** President's Emergency Plan for AIDS Relief

**PLHIV:** People living with HIV

**PQ:** Prequalification

**PrEP:** Pre-exposure prophylaxis

**RDT:** Rapid diagnostic test

**RPT:** Rifapentine

**SSA:** Sub-Saharan Africa

**TB:** Tuberculosis

**TPT:** TB preventative treatment

**US FDA:** United States Food and Drug Administration

**WHO:** World Health Organization