PILLAR Month 12 Clinical Results: Zero HIV Acquisition and High Persistence With CAB LA for PrEP

Taimur Khan,[1] Alison Gaudion,[2] Bo Li,[3] Julian A. Torres,[4] William Valenti,[5] Dima Dandachi,[6] Hadrian Holder,[7] Riya Moodley,[2] Todd McKeon,[8] Deanna Merrill,[8] Michael Aboud,[8] Kimberley Brown,[8] Maggie Czarnogorski,[8] Nanlesta Pilgrim,[8] Sonia Patel[8]*

[1]Fenway Health, Boston, MA, USA; [2]ViiV Healthcare, London, UK; [3]GSK, Collegeville, PA, USA; [4]Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA; [5]Trillium Health Rochester, Rochester, NY, USA; [6]University of Missouri–Columbia, Columbia, MO, USA; [7]Southwest Community Health Center, Bridgeport, CT, USA; [8]ViiV Healthcare, Durham, NC, USA

**Presenting on behalf of the authors.*

Key Takeaways

- **Real-world data from a diverse, gender-aligned population in the United States support long-acting cabotegravir (CAB LA) as an effective option for pre-exposure prophylaxis (PrEP) associated with high persistence**
- **No HIV acquisitions were observed through 12 months, irrespective of HIV testing methods used**
- **PILLAR reinforces the safety and effectiveness of CAB LA across diverse populations and clinical settings in the real world**

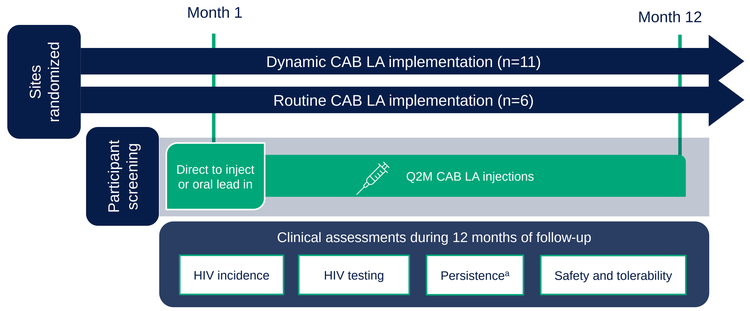
Introduction

- In 2022, men who have sex with men and transgender men accounted for 67% and <1% of new HIV diagnoses in the United States (US), respectively[1]
- Long-acting cabotegravir (CAB LA) administered every 2 months (Q2M) is the first and only approved LA medication for HIV-1 pre-exposure prophylaxis (PrEP) in adults and adolescents[2,3] and has demonstrated superiority to daily oral PrEP with tenofovir disoproxil fumarate plus emtricitabine for the prevention of new HIV acquisitions[4,5]
- CAB LA has demonstrated consistent effectiveness for HIV prevention and has been well tolerated across numerous implementation studies and diverse real-world studies[6-11]
- Here, we present clinical outcomes through Month 12 with CAB LA in the PILLAR study

Methods

- PILLAR is a phase 4, real-world, implementation science trial evaluating integration of CAB LA for men who have sex with men and transgender men (Figure 1)
  - Overall, 71% (12/17) of sites were in Ending the HIV Epidemic in the US (EHE) initiative regions
- PILLAR is the first industry-led implementation science trial to gender align participants per community request
- Semi-structured qualitative interviews at baseline (n=52) and Month 12 (n=49) assessed perceptions of CAB LA utilization, and interviews were analyzed by a framework analysis approach

Figure 1. PILLAR Study Design



[a]Persistence defined as duration for which an individual continued to receive injections.

Acknowledgments: This study was funded by ViiV Healthcare. The authors thank everyone who has contributed to the success of the PILLAR study; all study participants and their families; and the clinical investigators and their staff. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by Fingerpaint Medical (formerly MedThink SciCom) and funded by ViiV Healthcare. Data included in this poster have previously been presented in full at Conference on Retroviruses and Opportunistic Infections; March 9-12, 2025; San Francisco, CA; Oral presentation 196; and British HIV Association Spring Conference; April 23-25, 2025; Brighton, UK; Poster A043.

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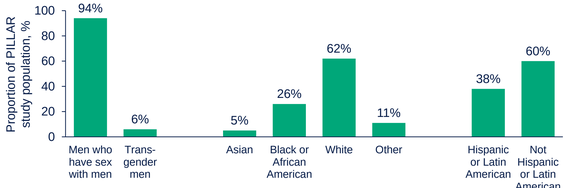
Results

Participant Demographics

- PILLAR enrollment reflected US national HIV demographics[12]
- 201 diverse participants enrolled and initiated CAB LA; median (IQR) age was 35 (29-44) years, 6% were transgender men, 26% were Black, and 38% were Hispanic (Figure 2)
  - Enrollment exceeded protocol-defined diversity targets
- In total, 22% of participants had not received oral PrEP in the last 6 months before receiving CAB LA

Figure 2. Participant Demographics



Protocol-defined enrollment targets exceeded:

	Target	Achieved
Black or Latin American participants[a]	50%	60%
Transgender men	2%-4%	6%

[a]8 participants were both Hispanic or Latin American and Black or African American.

Persistence and HIV Acquisition

- Through Month 12, persistence using CAB LA was high, and no HIV acquisitions occurred (Figure 3)
- A total of 72% (n=144/201) of participants completed all injections within the study; 6 (3%) participants missed an injection and received oral CAB (n=1) or alternative PrEP (n=5)
- Most participants in the study (94%, n=131/139) did not find attending Q2M clinical visits difficult (responded "very easy," "easy," or "neither easy or difficult")

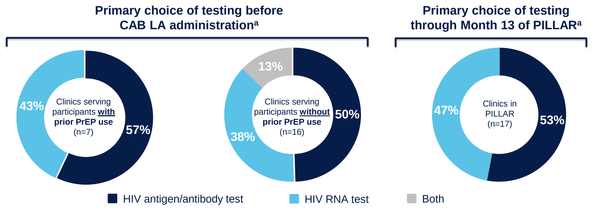
Figure 3. Persistence and HIV Acquisition Through Month 12

[a]Includes all participants up to their last visit on study.

HIV Testing

- Study sites utilized either HIV antigen/antibody or HIV RNA testing as their primary testing method during PILLAR (Figure 4)
- Per the label, individuals receiving CAB LA are recommended to be tested with both HIV antigen/antibody and HIV RNA testing
- In the real world, 53% of the study sites used HIV antigen/antibody testing and 47% used HIV RNA testing as their primary testing method during PILLAR; no study site used both types of tests for the majority of participants

Figure 4. Primary HIV Testing Methods During PILLAR



[a]Primary method of testing is the test that clinics reported using for the majority of participants.

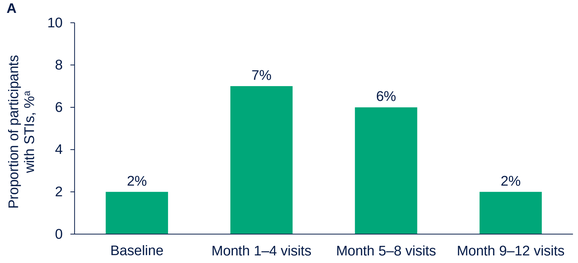
Adherence to the Injection Window

- Injection windows (±7 days) were recommended to be calculated from Day 1 of the study; using this method, proportions of injections administered within the window decreased over time (93% at Month 2 [dose 2]; 85% at Month 12 [dose 7])
- In PILLAR, clinics adjusted the target date over time based on the previous injection visit to maintain the Q2M window

Sexually Transmitted Infection Acquisitions

- A total of 27 (13%; n=26 men who have sex with men, n=1 transgender man) participants were identified as acquiring a sexually transmitted infection (STI) through last on-study visit (gonorrhea, n=14; chlamydia, n=12; syphilis, n=7; Figure 5)
- Q2M clinic visits with CAB LA facilitated the early detection of STIs, with ~20% (n=9/44) of participants in qualitative interviews reporting that more frequent STI checks were a benefit of increased clinic visits

Figure 5. (A) STI Acquisitions Through Month 12 and (B) Participant Quotation on Frequency of STI Testing



B

…When I'm single and not in a monogamous relationship, I do like to get tested more frequently. It just gives me peace of mind and keeps other people healthy... stuff gets passed around so easily so quickly, that I prefer a regular check up..
Man who has sex with men, 32

[a]Percentages represent the proportion of participants with any STI at each visit; the same participant may have had an STI identified at more than 1 visit.

Safety and Tolerability

- CAB LA was well tolerated, with few (5%, n=11) discontinuations due to adverse events (AEs; Table)
  - Other reasons for discontinuation were not related to CAB LA (n=44); relocation (n=9), insurance (n=7), lost to follow-up (n=7), and sexual lifestyle change (n=7) were the most common

Table. Safety Summary Through Month 12

Parameter, n (%)	CAB LA (N=201)
Participants with ≥1 AE related to CAB PrEP resulting in discontinuation[a]	11 (5)
AEs related to CAB PrEP reported by ≥1% of participants	
Injection site pain	6 (3)
Fatigue	2 (1)
Serious AEs	1 (<1)[b]

[a]Of the 11 AEs leading to discontinuation, 6 were due to injection site pain. [b]Clavicle fracture, rib fracture, and pneumothorax (n=1); unrelated to CAB LA.

Conclusions

- PILLAR enrolled a diverse, gender-aligned population in EHE territories that reflects US national HIV demographics and exceeds its target enrollment of 50% Black or Hispanic participants and 2% to 4% transgender men
  - PILLAR reached 22% of participants who had not recently received oral PrEP, demonstrating CAB LA's potential to expand PrEP adoption across varied populations
- Zero cases of HIV acquisition were found through Month 12, supporting the robust and sustained effectiveness of CAB LA in the real world
  - 100% effectiveness was observed through 12 months, irrespective of the testing method(s) used
- Persistence with CAB LA (Month 6: 85% and Month 12: 73%) was higher than previously reported with oral PrEP (Month 12: 56%),[13] with few discontinuations due to AEs
- More frequent clinic visits with CAB LA facilitate increased interactions with healthcare providers and earlier detection and treatment of STIs
- PILLAR reinforces safety and effectiveness of CAB LA across diverse populations and clinical settings, underscoring the importance of real-world PrEP studies to build on robust clinical trial data

Presenting author: Sonia Patel; sonia.8.patel@viivhealthcare.com