CABOTEGRAVIR FOR HIV PrEP IN US BLACK MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN


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Disclosure: None
Background

• Black men who have sex with men (MSM) and transgender women (TGW) who have sex with men are disproportionately impacted by HIV in the US.¹

• HPTN 083 is an ongoing Phase 2b/3 randomized controlled trial of increased-risk, HIV-uninfected MSM + TGW at 43 sites in 7 countries²
  • HPTN 083 and HPTN 084 demonstrated that long-acting injectable Cabotegravir (CAB-LA) is superior to daily oral TDF/FTC for HIV PrEP across populations and regions²,³

• In the US, 49.7% of HPTN 083 enrollment is Black/African American and HIV prevention efficacy among Black MSM and TGW was a pre-specified sub-group analysis.

HPTN 083 Study Design

**STEP 1**
- **Group A**: Every day for 5 weeks
- **Group B**: Screening day and informed consent

**STEP 2**
- **Weeks 5 and 9**: TDF/FTC

**STEP 3**
- **Every day for 1 year**: TDF/FTC

- **Group A**: CAB
- **Group B**: CAB

**TDF/FTC pill**
- **Placebo for TDF/FTC pill**

**Cabotegravir (CAB) injection**
- **Placebo for cabotegravir (CAB) injection**

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAB</td>
<td>CAB</td>
</tr>
<tr>
<td>TDF/FTC</td>
<td>TDF/FTC</td>
</tr>
</tbody>
</table>
HIV Incidence: CAB vs TDF/FTC

Updated Primary Blinded Period

HIV Incidence Hazard Ratio (95% CI)
HIV Incidence Rate/100PY  
Favors CAB Favors TDF/FTC
0.75 Non-Inferiority Superiority
0.44 1.29
14 Infections
3204 PY 3187 PY
0.34 0.18 0.62
0 0.75 1 1.23 2
Nil margin

Landovitz CROI 2022 Abstract #96

Open to Enrollment 12-16-2016
4.4 Years
Primary Analysis 05-14-2020
Year 1 Unblinded Analysis 05-14-2021

CAB n=2241
TDF/FTC n=2247
Methods

• We will present HIV efficacy, adherence subset, and safety data among US Black MSM and TGW and Non-Black MSM and TGW.

• This pre-specified analysis is among US participants who self-identified as Black/African American or mixed race including Black.
  • This subgroup analysis includes visits in the blinded study period through May 14, 2020.
  • Overall efficacy and safety data from HPTN 083 have been previously presented for both the specified and post-hoc analysis.

• The modified intent to treat (MITT) analysis excludes inappropriately enrolled participants and those found to be HIV infected at enrollment.
### Baseline Demographics

<table>
<thead>
<tr>
<th>Category</th>
<th>Overall* N=1,698</th>
<th>US Black N=844 (49.7%)</th>
<th>US Non-Black N=852 (50.2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSM</td>
<td>1573 (92.6%)</td>
<td>775 (91.8%)</td>
<td>796 (93.4%)</td>
</tr>
<tr>
<td>TGW</td>
<td>125 (7.4%)</td>
<td>69 (8.2%)</td>
<td>56 (6.6%)</td>
</tr>
<tr>
<td>Age, median (IQR)</td>
<td>27 (24-34)</td>
<td>27 (23-32)</td>
<td>28 (24-36)</td>
</tr>
<tr>
<td>Latino or Hispanic</td>
<td>303 (17.8%)</td>
<td>79 (9.4%)</td>
<td>223 (26.2%)</td>
</tr>
<tr>
<td>College Education Or Higher</td>
<td>1280 (75.4%)</td>
<td>574 (68.0%)</td>
<td>704 (82.6%)</td>
</tr>
<tr>
<td>Single/Divorced/Widowed</td>
<td>1382 (81.4%)</td>
<td>708 (83.9%)</td>
<td>672 (78.9%)</td>
</tr>
</tbody>
</table>

*Includes data on two participants with missing race and ethnicity data
# Baseline HIV Risk Factors

<table>
<thead>
<tr>
<th>Behavioral*</th>
<th>Overall N=1,495</th>
<th>US Black N=771</th>
<th>US Non-Black N=722</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex Partners in past month, median (IQR)</td>
<td>2 (1-4)</td>
<td>2 (1-3)</td>
<td>2 (1-4)</td>
</tr>
<tr>
<td>Number of receptive anal acts, median (IQR)</td>
<td>1 (0-3)</td>
<td>1 (0-3)</td>
<td>1 (0-4)</td>
</tr>
<tr>
<td>Injected drugs in the past 6 months</td>
<td>18 (1.2%)</td>
<td>10 (1.3%)</td>
<td>8 (1.1%)</td>
</tr>
<tr>
<td>Any recreational drugs in the past 6 months</td>
<td>1,006 (67.3%)</td>
<td>481 (62.4%)</td>
<td>524 (72.6%)</td>
</tr>
<tr>
<td>AUDIT –C ≥ 4</td>
<td>617 (41.3%)</td>
<td>250 (32.4%)</td>
<td>366 (50.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevalent STIs</th>
<th>Overall N=1,698</th>
<th>US Black N=844</th>
<th>US Non-Black N=852</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Syphilis</td>
<td>50 (3.0%)</td>
<td>38 (4.0%)</td>
<td>16 (1.9%)</td>
</tr>
<tr>
<td>Rectal Gonorrhea</td>
<td>77 (4.6%)</td>
<td>48 (5.7%)</td>
<td>29 (3.4%)</td>
</tr>
<tr>
<td>Rectal Chlamydia</td>
<td>139 (8.2%)</td>
<td>74 (8.8%)</td>
<td>65 (7.7%)</td>
</tr>
<tr>
<td>Urine Gonorrhea</td>
<td>12 (0.7%)</td>
<td>9 (1.1%)</td>
<td>3 (0.4%)</td>
</tr>
<tr>
<td>Urine Chlamydia</td>
<td>33 (2.0%)</td>
<td>19 (2.3%)</td>
<td>14 (1.7%)</td>
</tr>
</tbody>
</table>

*Behavioral data includes data from 1,495 completed baseline CASI
HIV Incidence and Efficacy

HIV Incidence, US Black MSM and TGW

- TDF/FTC: 2.11
- CAB-LA: 0.58

HR: 0.28 (0.096-0.834)

15 Infections

HIV Incidence, US Non-Black MSM and TGW

- TDF/FTC: 0.63
- CAB-LA: 0.00

HR: 0.86 (0.004-2.060)

5 Infections

0 Infections
TDF/FTC and CAB-LA Adherence

TDF/FTC Adherence as Measured by Dried Blood Spot (DBS)

- Overall: 60%, US Black: 70%, US Non-Black: 40%

On-Time CAB-LA Injection Coverage

- Overall: 89.7%
- US Black: 83.1%
- US Non-Black: 90.2%
Injection Site Reactions

<table>
<thead>
<tr>
<th>Participants with at least one injection (n)</th>
<th>Overall</th>
<th>US Black</th>
<th>US Non-Black</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of injections given</td>
<td>18,475</td>
<td>8,530</td>
<td>9,930</td>
</tr>
<tr>
<td>Injection Site Reactions (ISR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>927 (60.9%)</td>
<td>411 (56.0%)</td>
<td>515 (65.4%)</td>
</tr>
<tr>
<td>Grade 2 or above</td>
<td>334 (21.9%)</td>
<td>135 (18.4%)</td>
<td>198 (25.1%)</td>
</tr>
<tr>
<td>Grade 3 or above</td>
<td>34 (2.2%)</td>
<td>12 (1.6%)</td>
<td>22 (2.8%)</td>
</tr>
</tbody>
</table>

Overall, the most common ISR was injection site pain (17.3%) and tenderness (11.5%).
Conclusions

• In HPTN 083, HIV incidence was higher among US Black MSM and TGW than US Non-Black MSM and TGW.

• Protective efficacy of CAB-LA vs. TDF/FTC remained high among US Black MSM and TGW.

• TDF/FTC adherence consistent with $\geq 4$ dose/week was lower among Black MSM and TGW than non-Black MSM and TGW. CAB-LA adherence was high among both groups.

• CAB-LA is a powerful HIV prevention tool to increase access to PrEP and address continued racial disparities in HIV incidence in the US.
Acknowledgments

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HIV Prevention Trials Network (HPTN)

• Laboratory Center (Johns Hopkins University)
• Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchinson Cancer Research Center
• Leadership and Operations Center, FHI 360
• HPTN Leadership

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• Usha Sharma

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- Todd Brown, Johns Hopkins University
- Meredith Clement (Clinical Management Committee)
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- Eric Daar (Clinical Safety Committee)
- Carlos del Rio, Emory University
- María del Rosario, HPTN 083 Community Representative
- Joseph Eron, University of North Carolina at Chapel Hill
- Sheldon Fields, HPTN Black Caucus
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- Lei Weng
- Chuwen Li
- Richard Berman

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Our Community Educators & Recruiters and CAB Members
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- Barranco CRS (Javier Antonio Valencia Huamani)
- Bridge HIV CRS (Albert Liu)
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- New Orleans Adolescent Trials Unit CRS (Sue Ellen Abdalian)
- New York Blood Center CRS (Hong Van Tieu)

- Ohio State University CRS (Jose Bazan)
- Penn Prevention CRS (Ian Frank)
- Ponce de Leon Center CRS (Carlos del Rio)
- San Miguel CRS (Pedro Gonzales)
- Silom Community Clinic CRS (Chaiwat Ungsedhapand)
- St. Jude Children's Research Hospital CRS (Aditya Gaur)
- Thai Red Cross AIDS Research Centre (TRC-ARC) CRS (Nittaya Phanuphak)
- UCLA Care Center CRS (Raphael Landovitz)
- UCLA Vine Street Clinic CRS (Jesse Clark)
- UIC Project WISH CRS (Richard Novak)
- Via Libre CRS (Robinson Cabello)
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- Weill Cornell Chelsea CRS (Roy (Trip) Gulick)
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- Richard Haubrich
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- Cal Cohen
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- David Piontkowsky
and

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