

**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for
Pre-Exposure Prophylaxis in HIV-Uninfected Women
Report – April 14, 2018
Visit Cutoff Date: April 13, 2018
Table 4 – Progression to Step 2 by Site**

| | Overall | Baylor | Blantyre | Botha's Hill | DTTC-SU |
|--|----------------|---------------|-----------------|---------------------|----------------|
| Total Participants Enrolled ¹ | 112 | 0 | 0 | 0 | 0 |
| Participants who have been enrolled for 6 weeks or received injection ² | 73 | 0 | 0 | 0 | 0 |
| Progressed to Step 2 | 67/73 (91.8%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Progression Status Pending | 4/73 (5.5%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Did Not Progress to Step 2 | 2/73 (2.7%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Permanently discontinued from the study product | 1/73 (1.4%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Terminated from the study | 1/73 (1.4%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Permanently discontinued from the study product first and then terminated from the study | 0/73 (0.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |

¹ Inappropriately enrolled participants are excluded.

² Participants who did not progress to Step 2 due to HIV infection are not included.

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| | Emavundleni | Gaborone | Isipingo | Kisumu | Lilongwe |
|--|--------------------|-----------------|-----------------|---------------|-----------------|
| Total Participants Enrolled ¹ | 0 | 7 | 0 | 0 | 0 |
| Participants who have been enrolled for 6 weeks or received injection ² | 0 | 5 | 0 | 0 | 0 |
| Progressed to Step 2 | 0/0 (-%) | 3/5 (60.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Progression Status Pending | 0/0 (-%) | 1/5 (20.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Did Not Progress to Step 2 | 0/0 (-%) | 1/5 (20.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Permanently discontinued from the study product | 0/0 (-%) | 1/5 (20.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Terminated from the study | 0/0 (-%) | 0/5 (0.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |
| Permanently discontinued from the study product first and then terminated from the study | 0/0 (-%) | 0/5 (0.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) |

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| | MU-JHU | Parirenyatwa | Seke South | Soweto | Spilhaus |
|--|---------------|---------------------|-------------------|---------------|-----------------|
| Total Participants Enrolled ¹ | 0 | 15 | 0 | 32 | 0 |
| Participants who have been enrolled for 6 weeks or received injection ² | 0 | 5 | 0 | 26 | 0 |
| Progressed to Step 2 | 0/0 (–%) | 5/5 (100.0%) | 0/0 (–%) | 25/26 (96.2%) | 0/0 (–%) |
| Progression Status Pending | 0/0 (–%) | 0/5 (0.0%) | 0/0 (–%) | 0/26 (0.0%) | 0/0 (–%) |
| Did Not Progress to Step 2 | 0/0 (–%) | 0/5 (0.0%) | 0/0 (–%) | 1/26 (3.8%) | 0/0 (–%) |
| Permanently discontinued from the study product | 0/0 (–%) | 0/5 (0.0%) | 0/0 (–%) | 0/26 (0.0%) | 0/0 (–%) |
| Terminated from the study | 0/0 (–%) | 0/5 (0.0%) | 0/0 (–%) | 1/26 (3.8%) | 0/0 (–%) |
| Permanently discontinued from the study product first and then terminated from the study | 0/0 (–%) | 0/5 (0.0%) | 0/0 (–%) | 0/26 (0.0%) | 0/0 (–%) |

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| | St.Mary's Clinic | Swaziland | UVRI-IAVI | Verulam | Ward 21 |
|--|-------------------------|------------------|------------------|----------------|----------------|
| Total Participants Enrolled ¹ | 14 | 0 | 0 | 0 | 29 |
| Participants who have been enrolled for 6 weeks or received injection ² | 5 | 0 | 0 | 0 | 21 |
| Progressed to Step 2 | 4/5 (80.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 20/21 (95.2%) |
| Progression Status Pending | 1/5 (20.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 1/21 (4.8%) |
| Did Not Progress to Step 2 | 0/5 (0.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/21 (0.0%) |
| Permanently discontinued from the study product | 0/5 (0.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/21 (0.0%) |
| Terminated from the study | 0/5 (0.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/21 (0.0%) |
| Permanently discontinued from the study product first and then terminated from the study | 0/5 (0.0%) | 0/0 (-%) | 0/0 (-%) | 0/0 (-%) | 0/21 (0.0%) |

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| | Zengeza |
|--|----------------|
| Total Participants Enrolled ¹ | 15 |
| Participants who have been enrolled for 6 weeks or received injection ² | 11 |
| Progressed to Step 2 | 10/11 (90.9%) |
| Progression Status Pending | 1/11 (9.1%) |
| Did Not Progress to Step 2 | 0/11 (0.0%) |
| Permanently discontinued from the study product | 0/11 (0.0%) |
| Terminated from the study | 0/11 (0.0%) |
| Permanently discontinued from the study product first and then terminated from the study | 0/11 (0.0%) |

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