

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 – June 2, 2018
Data through : June 2, 2018
Table 4 – Progression to Step 2 by Site

	Overall	Baylor	Blantyre	Botha's Hill	DTTC-SU
Total Participants Enrolled ¹	151	0	0	0	0
Participants who have been enrolled for 6 weeks or received injection ²	127	0	0	0	0
Progressed to Step 2	120/127 (94.5%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	5/127 (3.9%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Did Not Progress to Step 2	2/127 (1.6%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product	1/127 (0.8%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Terminated from the study	1/127 (0.8%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/127 (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	12	0	0	0
Participants who have been enrolled for 6 weeks or received injection ²	0	8	0	0	0
Progressed to Step 2	0/0 (-%)	7/8 (87.5%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	0/0 (-%)	0/8 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Did Not Progress to Step 2	0/0 (-%)	1/8 (12.5%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product	0/0 (-%)	1/8 (12.5%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Terminated from the study	0/0 (-%)	0/8 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (-%)	0/8 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)

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	MU-JHU	Parirenyatwa	Seke South	Soweto	Spilhaus
Total Participants Enrolled ¹	0	25	0	33	0
Participants who have been enrolled for 6 weeks or received injection ²	0	19	0	33	0
Progressed to Step 2	0/0 (–%)	16/19 (84.2%)	0/0 (–%)	32/33 (97.0%)	0/0 (–%)
Progression Status Pending	0/0 (–%)	3/19 (15.8%)	0/0 (–%)	0/33 (0.0%)	0/0 (–%)
Did Not Progress to Step 2	0/0 (–%)	0/19 (0.0%)	0/0 (–%)	1/33 (3.0%)	0/0 (–%)
Permanently discontinued from the study product	0/0 (–%)	0/19 (0.0%)	0/0 (–%)	0/33 (0.0%)	0/0 (–%)
Terminated from the study	0/0 (–%)	0/19 (0.0%)	0/0 (–%)	1/33 (3.0%)	0/0 (–%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (–%)	0/19 (0.0%)	0/0 (–%)	0/33 (0.0%)	0/0 (–%)

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	St.Mary's Clinic	Swaziland	UVRI-IAVI	Verulam	Ward 21
Total Participants Enrolled ¹	29	0	0	0	32
Participants who have been enrolled for 6 weeks or received injection ²	22	0	0	0	30
Progressed to Step 2	22/22 (100.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	29/30 (96.7%)
Progression Status Pending	0/22 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	1/30 (3.3%)
Did Not Progress to Step 2	0/22 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/30 (0.0%)
Permanently discontinued from the study product	0/22 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/30 (0.0%)
Terminated from the study	0/22 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/30 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/22 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/30 (0.0%)

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	Zengeza
Total Participants Enrolled ¹	20
Participants who have been enrolled for 6 weeks or received injection ²	15
Progressed to Step 2	14/15 (93.3%)
Progression Status Pending	1/15 (6.7%)
Did Not Progress to Step 2	0/15 (0.0%)
Permanently discontinued from the study product	0/15 (0.0%)
Terminated from the study	0/15 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/15 (0.0%)

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