

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 – May 26, 2018
Data through : May 26, 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	116	0	0	0	0
Progressed to Step 2	110/116 (94.8%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	4/116 (3.4%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Did Not Progress to Step 2	2/116 (1.7%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product	1/116 (0.9%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Terminated from the study	1/116 (0.9%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/116 (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	7	0	0	0
Progressed to Step 2	0/0 (-%)	6/7 (85.7%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	0/0 (-%)	0/7 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Did Not Progress to Step 2	0/0 (-%)	1/7 (14.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product	0/0 (-%)	1/7 (14.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Terminated from the study	0/0 (-%)	0/7 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (-%)	0/7 (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	15	0	32	0
Progressed to Step 2	0/0 (-%)	13/15 (86.7%)	0/0 (-%)	31/32 (96.9%)	0/0 (-%)
Progression Status Pending	0/0 (-%)	2/15 (13.3%)	0/0 (-%)	0/32 (0.0%)	0/0 (-%)
Did Not Progress to Step 2	0/0 (-%)	0/15 (0.0%)	0/0 (-%)	1/32 (3.1%)	0/0 (-%)
Permanently discontinued from the study product	0/0 (-%)	0/15 (0.0%)	0/0 (-%)	0/32 (0.0%)	0/0 (-%)
Terminated from the study	0/0 (-%)	0/15 (0.0%)	0/0 (-%)	1/32 (3.1%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (-%)	0/15 (0.0%)	0/0 (-%)	0/32 (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	17	0	0	0	30
Progressed to Step 2	17/17 (100.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	29/30 (96.7%)
Progression Status Pending	0/17 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	1/30 (3.3%)
Did Not Progress to Step 2	0/17 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/30 (0.0%)
Permanently discontinued from the study product	0/17 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/30 (0.0%)
Terminated from the study	0/17 (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	0/17 (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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