

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 – September 1, 2018
Data through : September 1, 2018
Table 4 – Progression to Step 2 by Site

	Overall	Baylor	Blantyre	Botha's Hill	DTTC-SU
Total Participants Enrolled ¹	181	0	0	0	0
Participants who have been enrolled for 6 weeks or received injection ²	160	0	0	0	0
Progressed to Step 2	153/160 (95.6%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Progression Status Pending	4/160 (2.5%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Did Not Progress to Step 2	3/160 (1.9%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Permanently discontinued from the study product	2/160 (1.3%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Terminated from the study	1/160 (0.6%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Permanently discontinued from the study product first and then terminated from the study	0/160 (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	12	0	0	0
Progressed to Step 2	0/0 (–%)	10/12 (83.3%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Progression Status Pending	0/0 (–%)	0/12 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Did Not Progress to Step 2	0/0 (–%)	2/12 (16.7%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Permanently discontinued from the study product	0/0 (–%)	2/12 (16.7%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Terminated from the study	0/0 (–%)	0/12 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (–%)	0/12 (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	47	0
Participants who have been enrolled for 6 weeks or received injection ²	0	25	0	37	0
Progressed to Step 2	0/0 (–%)	23/25 (92.0%)	0/0 (–%)	36/37 (97.3%)	0/0 (–%)
Progression Status Pending	0/0 (–%)	2/25 (8.0%)	0/0 (–%)	0/37 (0.0%)	0/0 (–%)
Did Not Progress to Step 2	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	1/37 (2.7%)	0/0 (–%)
Permanently discontinued from the study product	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	0/37 (0.0%)	0/0 (–%)
Terminated from the study	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	1/37 (2.7%)	0/0 (–%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	0/37 (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	48
Participants who have been enrolled for 6 weeks or received injection ²	29	0	0	0	37
Progressed to Step 2	29/29 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	36/37 (97.3%)
Progression Status Pending	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	1/37 (2.7%)
Did Not Progress to Step 2	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/37 (0.0%)
Permanently discontinued from the study product	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/37 (0.0%)
Terminated from the study	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/37 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/37 (0.0%)

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	Zengeza
Total Participants Enrolled ¹	20
Participants who have been enrolled for 6 weeks or received injection ²	20
Progressed to Step 2	19/20 (95.0%)
Progression Status Pending	1/20 (5.0%)
Did Not Progress to Step 2	0/20 (0.0%)
Permanently discontinued from the study product	0/20 (0.0%)
Terminated from the study	0/20 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/20 (0.0%)

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