

**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 21, 2018
Data through : April 21, 2018
Table 4 – Progression to Step 2 by Site**

	Overall	Baylor	Blantyre	Botha's Hill	DTTC-SU
Total Participants Enrolled ¹	119	0	0	0	0
Participants who have been enrolled for 6 weeks or received injection ²	78	0	0	0	0
Progressed to Step 2	73/78 (93.6%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	3/78 (3.8%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Did Not Progress to Step 2	2/78 (2.6%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product	1/78 (1.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Terminated from the study	1/78 (1.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/78 (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	8	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 (-%)	4/5 (80.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	0/0 (-%)	0/5 (0.0%)	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	16	0	32	0
Participants who have been enrolled for 6 weeks or received injection ²	0	7	0	26	0
Progressed to Step 2	0/0 (–%)	7/7 (100.0%)	0/0 (–%)	25/26 (96.2%)	0/0 (–%)
Progression Status Pending	0/0 (–%)	0/7 (0.0%)	0/0 (–%)	0/26 (0.0%)	0/0 (–%)
Did Not Progress to Step 2	0/0 (–%)	0/7 (0.0%)	0/0 (–%)	1/26 (3.8%)	0/0 (–%)
Permanently discontinued from the study product	0/0 (–%)	0/7 (0.0%)	0/0 (–%)	0/26 (0.0%)	0/0 (–%)
Terminated from the study	0/0 (–%)	0/7 (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 (–%)	0/7 (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	18	0	0	0	30
Participants who have been enrolled for 6 weeks or received injection ²	5	0	0	0	24
Progressed to Step 2	4/5 (80.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	23/24 (95.8%)
Progression Status Pending	1/5 (20.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	1/24 (4.2%)
Did Not Progress to Step 2	0/5 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/24 (0.0%)
Permanently discontinued from the study product	0/5 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/24 (0.0%)
Terminated from the study	0/5 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/24 (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 (-%)	0/24 (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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