

**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 5, 2018
Data through : May 5, 2018
Table 4 – Progression to Step 2 by Site**

	Overall	Baylor	Blantyre	Botha's Hill	DTTC-SU
Total Participants Enrolled ¹	139	0	0	0	0
Participants who have been enrolled for 6 weeks or received injection ²	101	0	0	0	0
Progressed to Step 2	96/101 (95.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	3/101 (3.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Did Not Progress to Step 2	2/101 (2.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product	1/101 (1.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Terminated from the study	1/101 (1.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/101 (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	9	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	23	0	33	0
Participants who have been enrolled for 6 weeks or received injection ²	0	13	0	30	0
Progressed to Step 2	0/0 (-%)	12/13 (92.3%)	0/0 (-%)	29/30 (96.7%)	0/0 (-%)
Progression Status Pending	0/0 (-%)	1/13 (7.7%)	0/0 (-%)	0/30 (0.0%)	0/0 (-%)
Did Not Progress to Step 2	0/0 (-%)	0/13 (0.0%)	0/0 (-%)	1/30 (3.3%)	0/0 (-%)
Permanently discontinued from the study product	0/0 (-%)	0/13 (0.0%)	0/0 (-%)	0/30 (0.0%)	0/0 (-%)
Terminated from the study	0/0 (-%)	0/13 (0.0%)	0/0 (-%)	1/30 (3.3%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (-%)	0/13 (0.0%)	0/0 (-%)	0/30 (0.0%)	0/0 (-%)

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	St.Mary's Clinic	Swaziland	UVRI-IAVI	Verulam	Ward 21
Total Participants Enrolled ¹	26	0	0	0	32
Participants who have been enrolled for 6 weeks or received injection ²	9	0	0	0	28
Progressed to Step 2	9/9 (100.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	27/28 (96.4%)
Progression Status Pending	0/9 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	1/28 (3.6%)
Did Not Progress to Step 2	0/9 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/28 (0.0%)
Permanently discontinued from the study product	0/9 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/28 (0.0%)
Terminated from the study	0/9 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/28 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/9 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/28 (0.0%)

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	Zengeza
Total Participants Enrolled ¹	16
Participants who have been enrolled for 6 weeks or received injection ²	14
Progressed to Step 2	13/14 (92.9%)
Progression Status Pending	1/14 (7.1%)
Did Not Progress to Step 2	0/14 (0.0%)
Permanently discontinued from the study product	0/14 (0.0%)
Terminated from the study	0/14 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/14 (0.0%)

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