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 − August 25, 2018
Data through : August 25, 2018
Table 4 − Progression to Step 2 by Site

	Overall	Baylor	Blantyre	Botha's Hill	DTTC−SU
Total Participants Enrolled[1]	177	0	0	0	0
Participants who have been enrolled for 6 weeks or received injection[2]	151	0	0	0	0
Progressed to Step 2	144/151 (95.4%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Progression Status Pending	4/151 (2.6%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Did Not Progress to Step 2	3/151 (2.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product	2/151 (1.3%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Terminated from the study	1/151 (0.7%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product first and then terminated from the study	0/151 (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.

Source: SCHARP (zwang) − /trials/hptn/p084/analysis/atlas/code/open/t_prog2step2.sas, SAS Version 9.4 (25AUG2018,5:32)

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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	44	0
Participants who have been enrolled for 6 weeks or received injection[2]	0	25	0	33	0
Progressed to Step 2	0/0 (−%)	23/25 (92.0%)	0/0 (−%)	32/33 (97.0%)	0/0 (−%)
Progression Status Pending	0/0 (−%)	2/25 (8.0%)	0/0 (−%)	0/33 (0.0%)	0/0 (−%)
Did Not Progress to Step 2	0/0 (−%)	0/25 (0.0%)	0/0 (−%)	1/33 (3.0%)	0/0 (−%)
Permanently discontinued from the study product	0/0 (−%)	0/25 (0.0%)	0/0 (−%)	0/33 (0.0%)	0/0 (−%)
Terminated from the study	0/0 (−%)	0/25 (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 (−%)	0/25 (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	47
Participants who have been enrolled for 6 weeks or received injection[2]	29	0	0	0	32
Progressed to Step 2	29/29 (100.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	31/32 (96.9%)
Progression Status Pending	0/29 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	1/32 (3.1%)
Did Not Progress to Step 2	0/29 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)
Permanently discontinued from the study product	0/29 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)
Terminated from the study	0/29 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (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 (−%)	0/32 (0.0%)

[1] Inappropriately enrolled participants are excluded.
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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%)

[1] Inappropriately enrolled participants are excluded.
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