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 − June 16, 2018
Data through : June 16, 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]	141	0	0	0	0
Progressed to Step 2	134/141 (95.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Progression Status Pending	5/141 (3.5%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Did Not Progress to Step 2	2/141 (1.4%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product	1/141 (0.7%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Terminated from the study	1/141 (0.7%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product first and then terminated from the study	0/141 (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 (16JUN2018,5:32)

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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	11	0	0	0
Progressed to Step 2	0/0 (−%)	10/11 (90.9%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Progression Status Pending	0/0 (−%)	0/11 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Did Not Progress to Step 2	0/0 (−%)	1/11 (9.1%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product	0/0 (−%)	1/11 (9.1%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Terminated from the study	0/0 (−%)	0/11 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (−%)	0/11 (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	23	0	33	0
Progressed to Step 2	0/0 (−%)	21/23 (91.3%)	0/0 (−%)	32/33 (97.0%)	0/0 (−%)
Progression Status Pending	0/0 (−%)	2/23 (8.7%)	0/0 (−%)	0/33 (0.0%)	0/0 (−%)
Did Not Progress to Step 2	0/0 (−%)	0/23 (0.0%)	0/0 (−%)	1/33 (3.0%)	0/0 (−%)
Permanently discontinued from the study product	0/0 (−%)	0/23 (0.0%)	0/0 (−%)	0/33 (0.0%)	0/0 (−%)
Terminated from the study	0/0 (−%)	0/23 (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 (−%)	0/23 (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	32
Participants who have been enrolled for 6 weeks or received injection[2]	26	0	0	0	32
Progressed to Step 2	26/26 (100.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	30/32 (93.8%)
Progression Status Pending	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	2/32 (6.3%)
Did Not Progress to Step 2	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)
Permanently discontinued from the study product	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)
Terminated from the study	0/26 (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	0/26 (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]	16
Progressed to Step 2	15/16 (93.8%)
Progression Status Pending	1/16 (6.3%)
Did Not Progress to Step 2	0/16 (0.0%)
Permanently discontinued from the study product	0/16 (0.0%)
Terminated from the study	0/16 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/16 (0.0%)

[1] Inappropriately enrolled participants are excluded.
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