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 9, 2018
Data through : June 9, 2018
Table 4 − Progression to Step 2 by Site

	Overall	Baylor	Blantyre	Botha's Hill	DTTC−SU	Emavundleni	Gaborone
Total Participants Enrolled[1]	151	0	0	0	0	0	12
Participants who have been enrolled for 6 weeks or received injection[2]	136	0	0	0	0	0	9
Progressed to Step 2	129/136 (94.9%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	8/9 (88.9%)
Progression Status Pending	5/136 (3.7%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/9 (0.0%)
Did Not Progress to Step 2	2/136 (1.5%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	1/9 (11.1%)
Permanently discontinued from the study product	1/136 (0.7%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	1/9 (11.1%)
Terminated from the study	1/136 (0.7%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/9 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/136 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/9 (0.0%)

	Isipingo	Kisumu	Lilongwe	MU−JHU	Parirenyatwa	Seke South	Soweto
Total Participants Enrolled[1]	0	0	0	0	25	0	33
Participants who have been enrolled for 6 weeks or received injection[2]	0	0	0	0	20	0	33
Progressed to Step 2	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	18/20 (90.0%)	0/0 (−%)	32/33 (97.0%)
Progression Status Pending	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	2/20 (10.0%)	0/0 (−%)	0/33 (0.0%)
Did Not Progress to Step 2	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/20 (0.0%)	0/0 (−%)	1/33 (3.0%)
Permanently discontinued from the study product	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/20 (0.0%)	0/0 (−%)	0/33 (0.0%)
Terminated from the study	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/20 (0.0%)	0/0 (−%)	1/33 (3.0%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/20 (0.0%)	0/0 (−%)	0/33 (0.0%)

	Spilhaus	St.Mary's Clinic	Swaziland	UVRI−IAVI	Verulam	Ward 21	Zengeza
Total Participants Enrolled[1]	0	29	0	0	0	32	20
Participants who have been enrolled for 6 weeks or received injection[2]	0	26	0	0	0	32	16
Progressed to Step 2	0/0 (−%)	26/26 (100.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	30/32 (93.8%)	15/16 (93.8%)
Progression Status Pending	0/0 (−%)	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	2/32 (6.3%)	1/16 (6.3%)
Did Not Progress to Step 2	0/0 (−%)	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)	0/16 (0.0%)
Permanently discontinued from the study product	0/0 (−%)	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)	0/16 (0.0%)
Terminated from the study	0/0 (−%)	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)	0/16 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (−%)	0/26 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/32 (0.0%)	0/16 (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 (09JUN2018,5:32)