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 19, 2018
Data through : May 19, 2018
Table 4 − Progression to Step 2 by Site

	Overall	Baylor	Blantyre	Botha's Hill	DTTC−SU
Total Participants Enrolled[1]	149	0	0	0	0
Participants who have been enrolled for 6 weeks or received injection[2]	111	0	0	0	0
Progressed to Step 2	104/111 (93.7%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Progression Status Pending	5/111 (4.5%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Did Not Progress to Step 2	2/111 (1.8%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product	1/111 (0.9%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Terminated from the study	1/111 (0.9%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/0 (−%)
Permanently discontinued from the study product first and then terminated from the study	0/111 (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 (19MAY2018,5:31)

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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	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	25	0	33	0
Participants who have been enrolled for 6 weeks or received injection[2]	0	14	0	32	0
Progressed to Step 2	0/0 (−%)	12/14 (85.7%)	0/0 (−%)	31/32 (96.9%)	0/0 (−%)
Progression Status Pending	0/0 (−%)	2/14 (14.3%)	0/0 (−%)	0/32 (0.0%)	0/0 (−%)
Did Not Progress to Step 2	0/0 (−%)	0/14 (0.0%)	0/0 (−%)	1/32 (3.1%)	0/0 (−%)
Permanently discontinued from the study product	0/0 (−%)	0/14 (0.0%)	0/0 (−%)	0/32 (0.0%)	0/0 (−%)
Terminated from the study	0/0 (−%)	0/14 (0.0%)	0/0 (−%)	1/32 (3.1%)	0/0 (−%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (−%)	0/14 (0.0%)	0/0 (−%)	0/32 (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]	14	0	0	0	29
Progressed to Step 2	14/14 (100.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	27/29 (93.1%)
Progression Status Pending	0/14 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	2/29 (6.9%)
Did Not Progress to Step 2	0/14 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/29 (0.0%)
Permanently discontinued from the study product	0/14 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/29 (0.0%)
Terminated from the study	0/14 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/29 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/14 (0.0%)	0/0 (−%)	0/0 (−%)	0/0 (−%)	0/29 (0.0%)

[1] Inappropriately enrolled participants are excluded.
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	Zengeza
Total Participants Enrolled[1]	18
Participants who have been enrolled for 6 weeks or received injection[2]	15
Progressed to Step 2	14/15 (93.3%)
Progression Status Pending	1/15 (6.7%)
Did Not Progress to Step 2	0/15 (0.0%)
Permanently discontinued from the study product	0/15 (0.0%)
Terminated from the study	0/15 (0.0%)
Permanently discontinued from the study product first and then terminated from the study	0/15 (0.0%)

[1] Inappropriately enrolled participants are excluded.
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