

**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 – September 15, 2018  
Data through : September 15, 2018  
Table 4 – Progression to Step 2 by Site**

	<b>Overall</b>	<b>Baylor</b>	<b>Blantyre</b>	<b>Botha's Hill</b>	<b>DTTC-SU</b>
Total Participants Enrolled <sup>1</sup>	190	0	0	0	0
Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>	173	0	0	0	0
Progressed to Step 2	165/173 (95.4%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Progression Status Pending	5/173 (2.9%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Did Not Progress to Step 2	3/173 (1.7%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product	2/173 (1.2%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Terminated from the study	1/173 (0.6%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Permanently discontinued from the study product first and then terminated from the study	0/173 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

<sup>2</sup> Participants who did not progress to Step 2 due to HIV infection are not included.

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	<b>Emavundleni</b>	<b>Gaborone</b>	<b>Isipingo</b>	<b>Kisumu</b>	<b>Lilongwe</b>
Total Participants Enrolled <sup>1</sup>	0	13	0	0	0
Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>	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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	<b>MU-JHU</b>	<b>Parirenyatwa</b>	<b>Seke South</b>	<b>Soweto</b>	<b>Spilhaus</b>
Total Participants Enrolled <sup>1</sup>	0	25	0	51	0
Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>	0	25	0	43	0
Progressed to Step 2	0/0 (–%)	23/25 (92.0%)	0/0 (–%)	42/43 (97.7%)	0/0 (–%)
Progression Status Pending	0/0 (–%)	2/25 (8.0%)	0/0 (–%)	0/43 (0.0%)	0/0 (–%)
Did Not Progress to Step 2	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	1/43 (2.3%)	0/0 (–%)
Permanently discontinued from the study product	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	0/43 (0.0%)	0/0 (–%)
Terminated from the study	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	1/43 (2.3%)	0/0 (–%)
Permanently discontinued from the study product first and then terminated from the study	0/0 (–%)	0/25 (0.0%)	0/0 (–%)	0/43 (0.0%)	0/0 (–%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

<sup>2</sup> Participants who did not progress to Step 2 due to HIV infection are not included.

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	<b>St.Mary's Clinic</b>	<b>Swaziland</b>	<b>UVRI-IAVI</b>	<b>Verulam</b>	<b>Ward 21</b>
Total Participants Enrolled <sup>1</sup>	29	0	0	0	51
Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>	29	0	0	0	44
Progressed to Step 2	29/29 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	42/44 (95.5%)
Progression Status Pending	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	2/44 (4.5%)
Did Not Progress to Step 2	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/44 (0.0%)
Permanently discontinued from the study product	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/44 (0.0%)
Terminated from the study	0/29 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/44 (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 (–%)	0/44 (0.0%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

<sup>2</sup> Participants who did not progress to Step 2 due to HIV infection are not included.

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	<b>Zengeza</b>
Total Participants Enrolled <sup>1</sup>	21
Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>	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%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

<sup>2</sup> Participants who did not progress to Step 2 due to HIV infection are not included.