

**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 11, 2018**  
**Data through : August 11, 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>   | 172             | 0             | 0               | 0                   | 0              |
| Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>       | 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 (–%)       |

<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                  | 12              | 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                 | 42            | 0               |
| Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>       | 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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|  | <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              | 44             |
| Participants who have been enrolled for 6 weeks or received injection <sup>2</sup>       | 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%)    |

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|  | <b>Zengeza</b> |
|--|----------------|
| Total Participants Enrolled <sup>1</sup>   | 20             |
| 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.