SUPPLEMENTARY TABLE 1: Characteristics by region at baseline in the CTART arm

|  | **Region** |  |
| --- | --- | --- |
| **Characteristic\*\*\*** |  | **Thailand/China(N=200)** | **Botswana(N=224)** | **Brazil/Haiti/Argentina/Peru(N=311)** | **US(N=67)** | **P-Value** |
| CD4 category  | 400 - <500 | 29 (15%) | 36 (16%) | 27 (9%) | 7 (10%) | <0.001\* |
|  | 500 - <750 | 115 (58%) | 113 (50%) | 129 (41%) | 29 (43%) |  |
|  | 750+ | 56 (28%) | 75 (33%) | 155 (50%) | 31 (46%) |  |
|  |
| Log10 RNA (copies/mL)  | Min-Max | 1.30-4.42 | 1.60-4.97 | 1.30-5.32 | 1.30-3.87 | <0.001\*\* |
|  | Median (Q1-Q3) | 1.60 (1.60-1.70) | 1.60 (1.60-1.64) | 1.70 (1.60-1.76) | 1.60 (1.30-1.76) |  |
|  |
| Age  | Min-Max | 17-47 | 18-42 | 16-41 | 18-41 | 0.79\*\* |
|  | Median (Q1-Q3) | 27 (23-31) | 27 (23-32) | 27 (22-32) | 27 (22-32) |  |
|  |
| Pre-entry ART duration (months) | Min-Max | 0.00-7.21 | 0.00-7.91 | 0.00-8.60 | 0.00-7.67 | <0.001\*\* |
|  | Median (Q1-Q3) | 4.19 (2.33-5.35) | 3.49 (2.09-4.65) | 4.19 (2.56-5.58) | 4.42 (2.79-5.81) |  |
|  |
| Last ART regimen before entry: ART/PI | No | 18 (9%) | 140 (63%) | 21 (7%) | 11 (16%) | <0.001\* |
|  | Yes | 182 (91%) | 84 (38%) | 290 (93%) | 56 (84%) |  |
|  |
| Baseline: Missed meds w/in last 4 weeks | No | 189 (95%) | 205 (92%) | 209 (69%) | 44 (67%) | <0.001\* |
|  | Yes | 11 (6%) | 18 (8%) | 94 (31%) | 22 (33%) |  |
|  | # missing | 0 | 1 | 8 | 1 |  |
|  |
| Baseline: General health | Excellent | 22 (11%) | 35 (16%) | 69 (22%) | 30 (45%) | <0.001\* |
|  | Very Good | 75 (38%) | 88 (39%) | 71 (23%) | 21 (31%) |  |
|  | Good | 87 (44%) | 82 (37%) | 134 (44%) | 13 (19%) |  |
|  | Fair/poor | 16 (8%) | 19 (8%) | 34 (11%) | 3 (4%) |  |
|  | # missing | 0 | 0 | 3 | 0 |  |
|  |
| \*Chi-Square Test\*\*Kruskal-Wallis Test |

*\*\*\* Baseline is study entry or the first visit within 28 days of entry*

SUPPLEMENTARY TABLE 2. Grade 3 or 4 signs & symptoms and chemistry abnormalities during the first 24 weeks on ART among women in the CTART arm

|  | **Viremia** |
| --- | --- |
|  | **No(N=627)** | **Yes(N=175)** |
|  | **Grade** |  | **Grade** |  |
| **Toxicities\*** | **3** | **4** | **Total** | **(%)** | **(95% CI)^** | **3** | **4** | **Total**  | **(%)** | **(95% CI)^** |
| ***Signs and Symptoms*** |  |  |
| Any event | 15 | 0 | 15 | (2%) | (1%, 4%) | 8 | 1 | 9 | (5%) | (2%, 10%) |
| Any General Body | 9 | 0 | 9 | (1%) | (<1%, 3%) | 5 | 0 | 5 | (3%) | (<1%, 7%) |
| Any Respiratory | 0 | 0 | 0 | (0%) | (0%, <1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Hematology | 1 | 0 | 1 | (<1%) | (<1%, <1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Liver/Hepatic | 1 | 0 | 1 | (<1%) | (<1%, <1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Gastro-Intestinal | 0 | 0 | 0 | (0%) | (0%, <1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Reproductive | 2 | 0 | 2 | (<1%) | (<1%, 1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Skin | 1 | 0 | 1 | (<1%) | (<1%, <1%) | 1 | 1 | 2 | (1%) | (<1%, 4%) |
| Any Neurological | 2 | 0 | 2 | (<1%) | (<1%, 1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Other | 1 | 0 | 1 | (<1%) | (<1%, <1%) | 3 | 0 | 3 | (2%) | (<1%, 5%) |
| Any Multiple attribution | 2 | 0 | 2 | (<1%) | (<1%, 1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| ***Chemistry Events*** |
| Any event | 39 | 5 | 44 | (7%) | (5%, 9%) | 5 | 2 | 7 | (4%) | (2%, 8%) |
| Any Liver/Hepatic | 4 | 1 | 5 | (<1%) | (<1%, 2%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Renal | 0 | 0 | 0 | (0%) | (0%, <1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |
| Any Chemistry, General | 6 | 3 | 9 | (1%) | (<1%, 3%) | 1 | 2 | 3 | (2%) | (<1%, 5%) |
| Any Metabolic | 29 | 1 | 30 | (5%) | (3%, 7%) | 4 | 0 | 4 | (2%) | (<1%, 6%) |
| Any Endocrine, Metabolic | 1 | 0 | 1 | (<1%) | (<1%, <1%) | 0 | 0 | 0 | (0%) | (0%, 2%) |

*\*In the above table each participant is counted once for the specific safety event, once for the safety category total, and once for the overall total. For any given participant, the highest grade for each safety event is counted. At-risk period: first 24 weeks after ART initiation.*

*^Clopper-Pearson (exact) method used for confidence intervals*

SUPPLEMENTARY TABLE 3. Grade 3 or 4 signs & symptoms and chemistry abnormalities during the first 24 weeks on ART among women in the DCART arm who reinitiated treatment

|  | **Viremia** |
| --- | --- |
|  | **No(N=106)** | **Yes(N=31)** |
|  | **Grade** |  | **Grade** |  |
| **Toxicities\*** | **3** | **4** | **Total** | **(%)** | **(95% CI)^** | **3** | **4** | **Total** | **(%)** | **(95% CI)^** |
| ***Signs & Symptoms*** |  |  |  |  |  |  |  |  |  |  |
| Any event | 4 | 1 | 5 | (5%) | (2%, 11%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any General Body | 2 | 0 | 2 | (2%) | (<1%, 7%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Respiratory | 0 | 1 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Hematology | 0 | 0 | 0 | (0%) | (0%, 3%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Liver/Hepatic | 0 | 0 | 0 | (0%) | (0%, 3%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Gastro-Intestinal | 1 | 0 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Reproductive | 1 | 0 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Skin | 0 | 0 | 0 | (0%) | (0%, 3%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Neurological | 0 | 1 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Other | 1 | 0 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Multiple attribution | 0 | 0 | 0 | (0%) | (0%, 3%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| ***Chemistry Events*** |  |  |  |  |  |  |  |  |  |  |
| Any event | 2 | 1 | 3 | (3%) | (<1%, 8%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Liver/Hepatic | 0 | 0 | 0 | (0%) | (0%, 3%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Renal | 0 | 1 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Chemistry, General | 1 | 0 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Metabolic | 1 | 0 | 1 | (<1%) | (<1%, 5%) | 0 | 0 | 0 | (0%) | (0%, 11%) |
| Any Endocrine, Metabolic | 0 | 0 | 0 | (0%) | (0%, 3%) | 0 | 0 | 0 | (0%) | (0%, 11%) |

*\*In the above table each participant is counted once for the specific safety event, once for the safety category total, and once for the overall total. For any given participant, the highest grade for each safety event is counted. At-risk period: first 24 weeks after starting ART.*

*^Clopper-Pearson (exact) method used for confidence intervals*

SUPPLEMENTARY FIGURE 1: Estimated probability of viral re-suppression after first confirmed viremia among women in the CTART arm

