Virologic Outcomes of Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) Through Week 48 in Children and Infants Aged ≥ 1 Month and Weighing ≥ 3 to < 25 kg

P239

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Conclusions

- In this Week 48 analysis of children and infants with HIV aged ≥ 1 month and weighing ≥ 3 to < 25 kg, bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) tablet for oral suspension (TOS) demonstrated a generally favorable efficacy and resistance profile
- Most participants achieved or maintained virologic suppression through Week 48
- Two participants developed treatment-emergent resistance through Week 48, both of whom had documented adherence challenges and drug concentrations below the expected range
- These results support continued evaluation of B/F/TAF TOS in young children and infants with HIV

Plain Language Summary

- B/F/TAF is a one-pill, once-daily treatment for human immunodeficiency virus (HIV) that combines three medicines: bictegravir (B), emtricitabine (F), and tenofovir alafenamide (TAF)
  - This treatment is approved for use in children and adolescents
- A new form of B/F/TAF is being developed as a tablet for oral suspension (TOS) that can be mixed with water
  - This way of giving the medicine may be easier for young children to take
- In this study, researchers wanted to find out how well B/F/TAF TOS worked to keep HIV under control in young children and infants aged 1 month and older who weighed between 3 and 25 kg
- After 48 weeks, B/F/TAF TOS worked well at keeping HIV under control
- Two children in the study developed genetic changes (mutations) in their HIV that could make the treatment less effective. Both children had reported difficulties taking treatment consistently and had lower-than-expected drug levels

Introduction

- B/F/TAF is an antiretroviral therapy (ART) approved for adults and children with HIV-1 weighing ≥ 14 kg, as a one-pill, once-daily option that can be taken with or without food[1,2]
- However, treatment remains challenging in pediatric populations, particularly in infants where consistent administration may be affected by caregiver burden, disclosure considerations, and tolerability/acceptability issues[3]
  - Age-appropriate formulations are needed to address challenges with administering ART to young children[4]
- A B/F/TAF TOS is being evaluated as an age-appropriate, dispersible option in this population

Objective

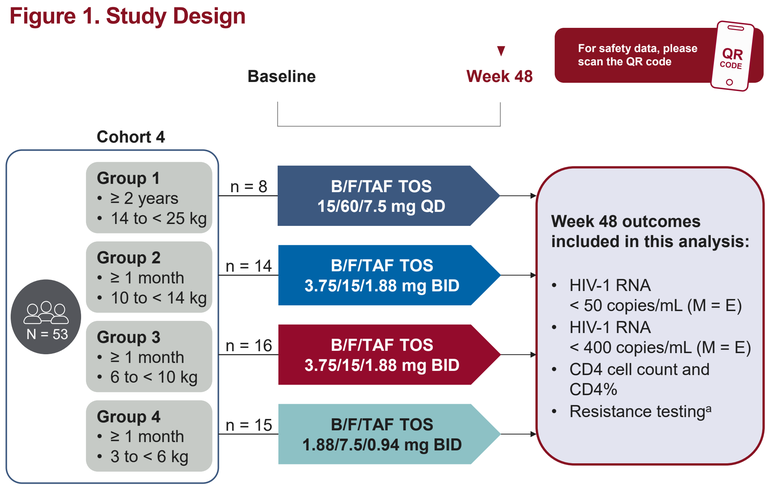
- To evaluate the virologic outcomes and resistance profile of B/F/TAF TOS in children and infants with HIV aged ≥ 1 month and weighing ≥ 3 to < 25 kg through Week 48

Methods

- GS-US-380-1474 (NCT02881320) is an ongoing Phase 2/3, open-label, multicenter, single-arm trial of B/F/TAF in children and adolescents with HIV
- This analysis focused on Cohort 4 participants who received B/F/TAF TOS (**Figure 1** and **Table 1**) at one of 11 centers across Uganda (n = 3), South Africa (n = 5), and the United States (n = 3)
- Cohort 4 key inclusion criteria:
  - Aged ≥ 1 month, weighing ≥ 3 to < 25 kg
  - Positive confirmatory HIV test result (nucleic acid–based testing) if aged < 18 months
  - Estimated glomerular filtration rate (eGFR) ≥ 90 mL/min/1.73 m^2[a]
  - HIV-1 RNA < 50 copies/mL on a stable ART[b] regimen for ≥ 6 months (Group 1), or treatment-naïve or on ART[b] for ≥ 1 month (Groups 2-4)
  - No evidence of active hepatitis B or C infection
- Cohort 4 key exclusion criterion:
  - CD4 count < 200 cells/μL if ≥ 2 years of age (Group 1), < 750 cells/μL if ≥ 1 to < 12 months of age, and < 500 cells/μL if ≥ 12 to < 24 months of age (Groups 2-4)

[a]Calculated using the Schwartz formula. For children aged < 1 year: eGFR ≥ minimum normal range values for age using the Schwartz formula; for > 4 weeks to ≤ 95 days: eGFR ≥ 30 mL/min/1.73 m^2; for ≥ 96 days to ≤ 6 months: eGFR ≥ 39 mL/min/1.73 m^2; for > 6 to < 12 months: eGFR ≥ 49 mL/min/1.73 m^2. [b]Two nucleoside/nucleotide reverse transcriptase inhibitors in combination with a third agent. CD4, cluster of differentiation.

Figure 1. Study Design



[a]HIV-1 genotypic and phenotypic analyses were performed in participants who had HIV-1 RNA ≥ 50 copies/mL at Week 48 and ≥ 200 copies/mL at confirmed virologic failure or last visit. B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BID, twice daily; CD4, cluster of differentiation 4; M = E, missing = excluded; QD, once daily; TOS, tablet for oral suspension.

Results

Table 1. Baseline Demographics and Clinical Characteristics

	Group 1 ≥ 2 years; 14 to < 25 kg n = 8	Group 2 ≥ 1 month; 10 to < 14 kg n = 14	Group 3 ≥ 1 month; 6 to < 10 kg n = 16	Group 4 ≥ 1 month; 3 to < 6 kg n = 15	Overall N = 53
Age, months, median (range)	48 (24-84)	24 (20-48)	8 (2-19)	4 (2-16)	15 (2-84)
Female sex assigned at birth, n (%)	3 (38)	8 (57)	11 (69)	9 (60)	31 (59)
Black race, n (%)	7 (88)	14 (100)	14 (88)	15 (100)	50 (94)
Not Hispanic or Latine, n (%)	8 (100)	14 (100)	15 (94)	15 (100)	52 (98)
Weight, kg, median (range)	15.9 (14.1, 18.8)	11.3 (10.0, 13.8)	8.0 (6.0, 9.6)	5.4 (4.6, 5.9)	8.5 (4.6, 18.8)
Weight Z-score, median (range)	-0.7 (-2.0, 0.8)	-1.5 (-2.9, 1.5)	-0.8 (-2.9, 1.4)	-2.0 (-5.1, 0.2)	-1.2 (-5.1, 1.5)
Height/length Z-score, median (range)	-0.37 (-1.62, 1.23)	-2.00 (-5.49, 0.11)	-0.88 (-3.94, 0.84)	-2.20 (-6.31, -0.30)	-1.58 (-6.31, 1.23)
Treatment-naïve before entering the study					
Yes	0	0	0	2 (13)	2 (4)
No	8 (100)	14 (100)	16 (100)	13 (87)	51 (96)

Results (cont.)

Table 1. Baseline Demographics and Clinical Characteristics (cont.)

	Group 1 ≥ 2 years; 14 to < 25 kg n = 8	Group 2 ≥ 1 month; 10 to < 14 kg n = 14	Group 3 ≥ 1 month; 6 to < 10 kg n = 16	Group 4 ≥ 1 month; 3 to < 6 kg n = 15	Overall N = 53
HIV-1 RNA < 400 copies/mL, n (%)	8 (100)	13 (100)[a]	14 (88)	7 (47)	42 (81)[a]
HIV-1 RNA < 50 copies/mL, n (%)	8 (100)	6 (46)[a]	9 (56)	1 (7)	24 (46)[a]
CD4 count, cells/μL, median (Q1, Q3)	932 (604, 1254)	1573 (1126, 1987)	2310 (1742, 2595)	1903 (1425, 3371)	1791 (1291, 2317)
CD4%, median (Q1, Q3)	38.3 (31.7, 42.9)	33.6 (31.6, 35.7)	34.9 (27.6, 39.3)	33.8 (22.5, 34.9)	33.8 (29.3, 38.1)
Genotypic resistance data available, n (%)	0	0	4 (25)	12 (80)	16 (30)
Participants with primary resistance mutations, n (%)					
NNRTI resistance	NA	NA	3 (19)	7 (47)	10 (19)
NRTI resistance	NA	NA	1 (6)	2 (13)	3 (6)
INSTI resistance	NA	NA	0	0	0
PI resistance	NA	NA	0	0	0

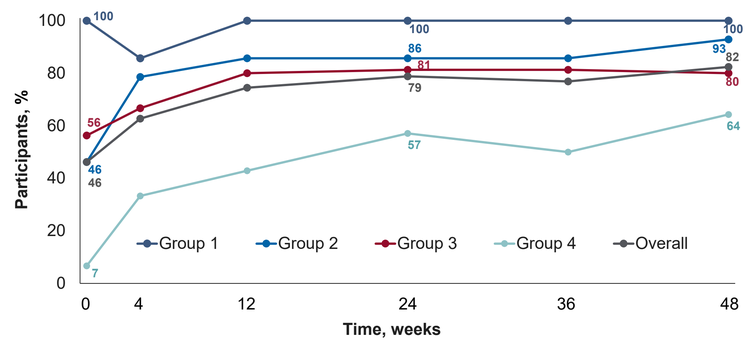
[a]Missing data: n = 1. CD4, cluster of differentiation 4; INSTI, integrase strand-transfer inhibitor; NA, not available; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PI, protease inhibitor; Q, quartile.

- All participants acquired HIV by vertical transmission and were asymptomatic at baseline

Virologic Outcomes Through Week 48

- Most participants achieved or maintained virologic suppression through Week 48, with only two participants reporting HIV-1 RNA ≥ 400 copies/mL (missing = excluded) at Week 48 (**Figure 2** and **Figure 3**)

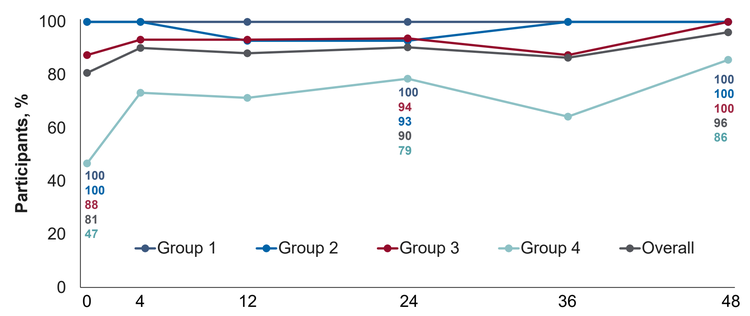
Figure 2. Participants With HIV-1 RNA < 50 copies/mL (M = E)



Group 1, n[a] = 8	7	8	8	8	8
Group 2, n[a] =13	14	14	14	14	14
Group 3, n[a] =16	15	15	16	16	15
Group 4, n[a] =15	15	14	14	14	14
Overall, n[a] = 52	51	51	52	52	51

[a]Number of participants with available data at each timepoint. M = E, missing = excluded.

Figure 3. Participants With HIV-1 RNA < 400 copies/mL (M = E)



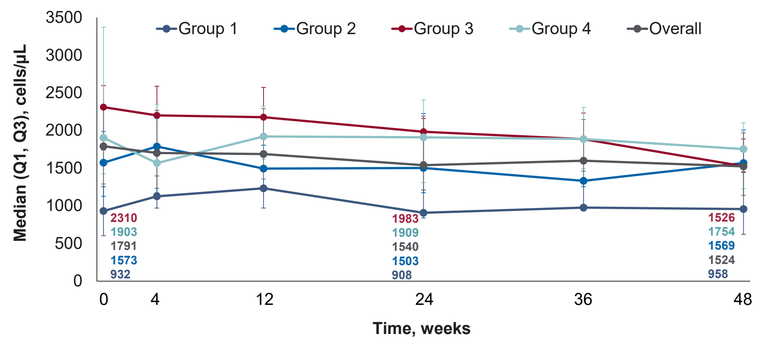
Group 1, n[a] = 8	7	8	8	8	8
Group 2, n[a] =13	14	14	14	14	14
Group 3, n[a] =16	15	15	16	16	15
Group 4, n[a] =15	15	14	14	14	14
Overall, n[a] = 52	51	51	52	52	51

[a]Number of participants with available data at each timepoint. M = E, missing = excluded.

Immunologic Outcomes Through Week 48

- CD4 cell count and CD4% remained stable within the physiological variation for this age group (**Figure 4** and **Figure 5**)

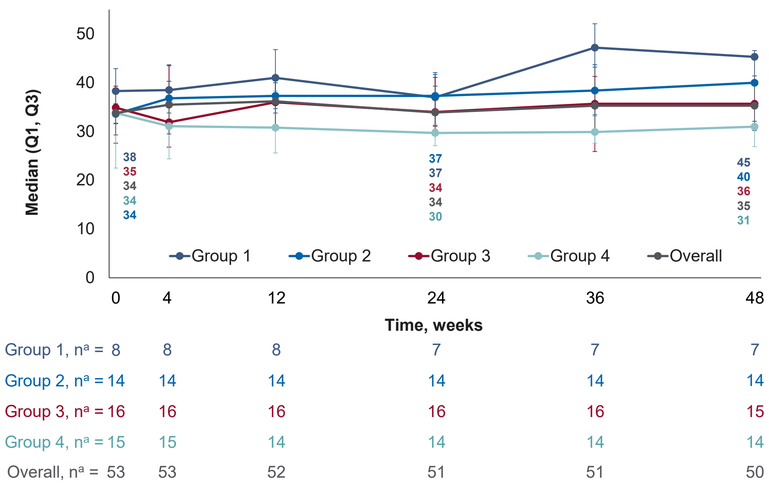
Figure 4. CD4 Cell Count



Group 1, n[a] = 8	8	8	7	7	7
Group 2, n[a] = 14	14	14	14	14	14
Group 3, n[a] = 16	16	16	16	16	15
Group 4, n[a] = 15	15	14	14	14	14
Overall, n[a] = 53	53	52	51	51	50

[a]Number of participants with available data at each timepoint. CD4, cluster of differentiation 4; Q, quartile.

Figure 5. CD4%



Group 1, n[a] = 8	8	8	7	7	7
Group 2, n[a] = 14	14	14	14	14	14
Group 3, n[a] = 16	16	16	16	16	15
Group 4, n[a] = 15	15	14	14	14	14
Overall, n[a] = 53	53	52	51	51	50

[a]Number of participants with available data at each timepoint. CD4, cluster of differentiation 4; Q, quartile.

Table 2. Resistance Analysis Population by Week 48

n (%)	Group 1 ≥ 2 years; 14 to < 25 kg n = 8	Group 2 ≥ 1 month; 10 to < 14 kg n = 14	Group 3 ≥ 1 month; 6 to < 10 kg n = 16	Group 4 ≥ 1 month; 3 to < 6 kg n = 15	Overall N = 53
Final resistance analysis population[a]	0	0	1 (6)	4 (27)	5 (9)
With data	0	0	1 (6)	3 (20)	4 (8)
Developed resistance to study drugs	0	0	0	2 (13)	2 (4)
M184V/I (NRTI resistance)	0	0	0	1 (7)	1 (2)
R263K (INSTI resistance)	0	0	0	1 (7)	1 (2)

- Among the five participants who met criteria for resistance analyses,[a] resistance data were available for four; two participants developed treatment-emergent resistance through Week 48, both in Group 4 (**Table 2**)

[a]HIV-1 genotypic and phenotypic analyses were performed in participants who had HIV-1 RNA ≥ 50 copies/mL at Week 48 and ≥ 200 copies/mL at confirmed virologic failure or last visit. INSTI, integrase strand-transfer inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor.

Table 3. Analysis of Participants who Developed Treatment-Emergent Resistance Through Week 48 (n = 2)[a]

	Participant #1	Participant #2
Resistance mutation	M184M/V/I emerged at Week 24; M184V persisted at Week 48	R263R/K emerged at Week 36; not detected at Week 48
Adherence	Adequate pill count; investigator reported challenging social circumstances and difficulty swallowing doses	Adequate pill count; investigator reported frequent missed evening dose
PK findings	Drug concentrations below expected range from Week 12 through Week 48	Drug concentrations below expected range at Week 36

- In both participants, treatment-emergent resistance mutations were associated with documented adherence challenges and drug concentrations below the expected range (**Table 3**)
- Both participants discontinued B/F/TAF at Week 48

[a]HIV-1 genotypic and phenotypic analyses were performed in participants who had HIV-1 RNA ≥ 50 copies/mL at Week 48 and ≥ 200 copies/mL at confirmed virologic failure or last visit. PK, pharmacokinetics.

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