Long-Term Efficacy and Safety of Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Children and Adolescents With HIV-1 Aged 2 to < 18 Years

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Disclosures

Kulkanya Chokephaibulkit, **Elizabeth Hellström**, and **Umesh Lalloo** have no conflicts of interest to report.

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Kathryn Kersey was an employee of Gilead Sciences, Inc., and remains a stockholder.

Athira Sudhakaran and **Vinicius Adriano Vieira** are employees of, and hold stock in, Gilead Sciences, Inc.

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Summary Slide

- **What is your main question?**
  We investigated whether B/F/TAF could maintain viral suppression and continue to be well tolerated in the long-term in children and adolescents

- **What did you find?**
  Our results demonstrated that B/F/TAF effectively maintained viral suppression and was well tolerated over 5 years, with no negative impact on growth observed

- **Why is it important?**
  Children and adolescents with HIV-1 have limited one-pill, once-a-day, fixed-dose combination options compared with adults. The data from this study support B/F/TAF as an efficacious and well-tolerated long-term treatment option for this population

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B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide.

Background

Children and adolescents with HIV-1 have limited one-pill, once-a-day, fixed-dose combination options compared with adults, thereby having increased dosing complexities and challenges with adherence[1]

B/F/TAF is approved for use in children aged ≥ 2 years with body weight ≥ 14 kg, as a one-pill, once-a-day option that can be taken with or without food[2,3]

We previously demonstrated that B/F/TAF was well tolerated and maintained virologic suppression in children and adolescents aged 2 to <18 years for up to 48 weeks of treatment[4,5]

We now assess long-term virologic suppression, safety, and growth outcomes through 240 weeks in children and adolescents receiving B/F/TAF

1. Prakoeswa FRS, et al. *AIDS Res Treat.* 2026;2026:1760508. **2.** Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) USPI, Gilead Sciences, Inc., July 2025. **3.** European Medicines Agency. https://www.ema.europa.eu/en/medicines/human/EPAR/biktarvy (accessed June 11, 2026). **4.** Gaur AH, et al. *Lancet Child Adolesc Health.* 2021;5:642-51. **5.** Rodriguez CA, et al. *Lancet HIV.* 2024;11:E300-8.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide.

Study Design

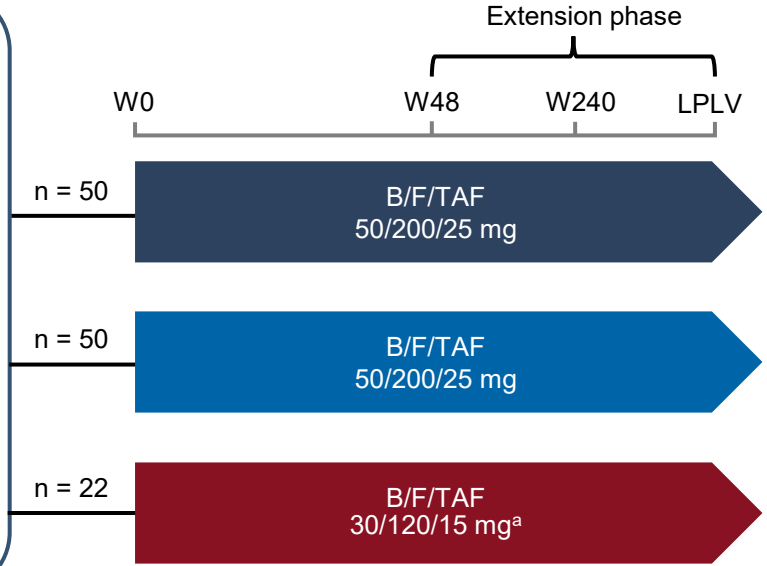
Key inclusion criteria:

- HIV-1 RNA < 50 c/mL on stable HIV treatment regimen for ≥ 6 months

Cohort 1
- 12 to < 18 years; ≥ 35 kg

Cohort 2
- 6 to < 12 years; ≥ 25 kg

Cohort 3[a]
- ≥ 2 years; ≥ 14 to < 25 kg



Outcomes through W240:
- HIV-1 RNA < 50 c/mL (M = E)
- CD4 cell count and CD4%
- Z-scores for weight, height, and BMI
- Safety through LPLV

Study GS-US-380-1474 (NCT02881320), carried out at 25 sites in the United States, South Africa, Thailand, and Uganda

NCT02881320. https://clinicaltrials.gov/study/NCT02881320 (accessed June 8, 2026).
[a]Upon attaining weight ≥ 25 kg, participants were permitted to switch to B/F/TAF 50/200/25 mg.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; **BMI**, body mass index; **c**, copies; **CD4**, cluster of differentiation 4; **LPLV**, last participant, last visit; **M = E**, missing = excluded; **W**, Week.

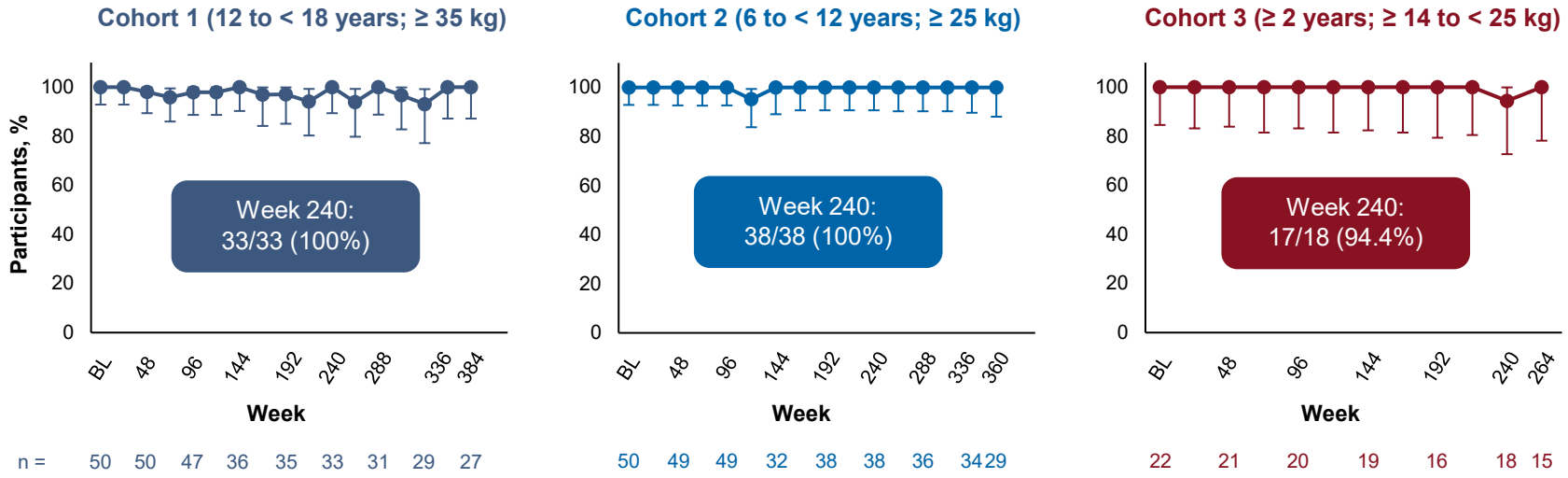
Baseline Demographics and Characteristics

	Cohort 1 12 to < 18 years; ≥ 35 kg n = 50	Cohort 2 6 to < 12 years; ≥ 25 kg n = 50	Cohort 3 ≥ 2 years; ≥ 14 to < 25 kg n = 22
Age, years, median (range)	15 (12-17)	10 (6-11)	6 (3-9)
Female sex at birth, n (%)	32 (64.0)	27 (54.0)	11 (50.0)
Black race, n (%)[a]	32 (65.3)	36 (72.0)	16 (72.7)
Weight, kg, median (range)	44.8 (35.4-122.8)	29.0 (25.0-69.1)	18.7 (14.1-24.1)
Weight Z-score, median (Q1, Q3)[b]	-0.54 (-1.55, 0.39)	-0.35 (-1.30, 0.45)	-0.35 (-1.47, 0.10)
Height Z-score, median (Q1, Q3)	-0.87 (-1.62, -0.41)	-0.67 (-1.27, 0.01)	-0.53 (-1.74, 0.00)
BMI Z-score, median (Q1, Q3)	-0.10 (-0.89, 0.79)	0.08 (-0.98, 0.81)	-0.11 (-1.48, 0.60)
CD4 count, cells/μL, median (Q1, Q3)	750 (586, 926)	898 (707, 1121)	962 (748, 1419)
CD4%, median (Q1, Q3)	32.9 (28.5, 38.2)	36.5 (31.9, 41.1)	32.0 (29.3, 37.2)

[a]Local regulators did not allow the collection of race information for one participant in Cohort 1; percentages were calculated using total number of participants as the denominator.
[b]Z-scores were generated using 2000 US Centers for Disease Control and Prevention Growth Charts.
BMI, body mass index; **CD4**, cluster of differentiation 4; **Q**, quartile.

Virologic Outcomes

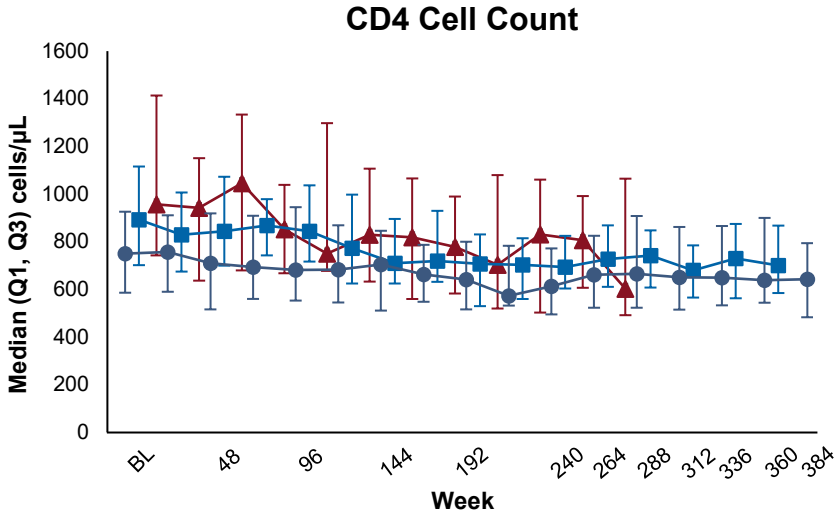
Participants With HIV-1 RNA < 50 c/mL (M = E)

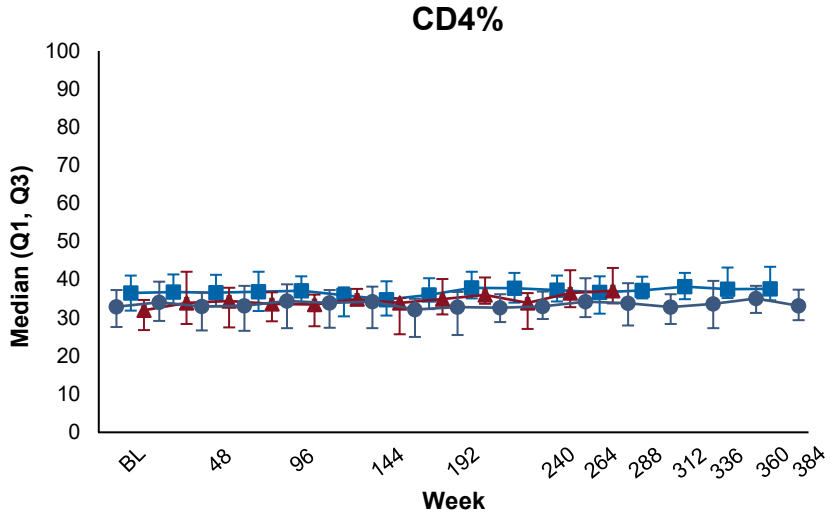


Virologic suppression was maintained at close to 100% through 5 years of treatment

Data are shown as n/N (%). Representative timepoints are shown for visualization purposes and up to the last timepoint where ≥ 50% of participants in each cohort had available data.
BL, baseline; **c**, copies; **M = E**, missing = excluded.

Immunologic Outcomes





Cohort 1	n =	50	50	47	29	32	32	32	31	29	28	26	26
Cohort 2	n =	50	49	48	25	36	38	35	36	36	34	29	
Cohort 3	n =	22	21	17	18	16	17	15					

Cohort 1	n =	50	50	47	29	32	32	32	31	29	28	26	26
Cohort 2	n =	50	49	48	25	36	38	35	36	36	34	29	
Cohort 3	n =	22	21	17	18	16	17	15					

● Cohort 1 (12 to < 18 years; ≥ 35 kg) ■ Cohort 2 (6 to < 12 years; ≥ 25 kg) ▲ Cohort 3 (≥ 2 years; ≥ 14 to < 25 kg)

Absolute CD4 cell count and CD4% remained stable and within expected physiological variation in all cohorts through 5 years of treatment

Representative timepoints are shown for visualization purposes and up to the last timepoint where ≥ 50% of participants in each cohort had available data.
BL, baseline; **CD4**, cluster of differentiation 4; **Q**, quartile.

Safety Through Week 240

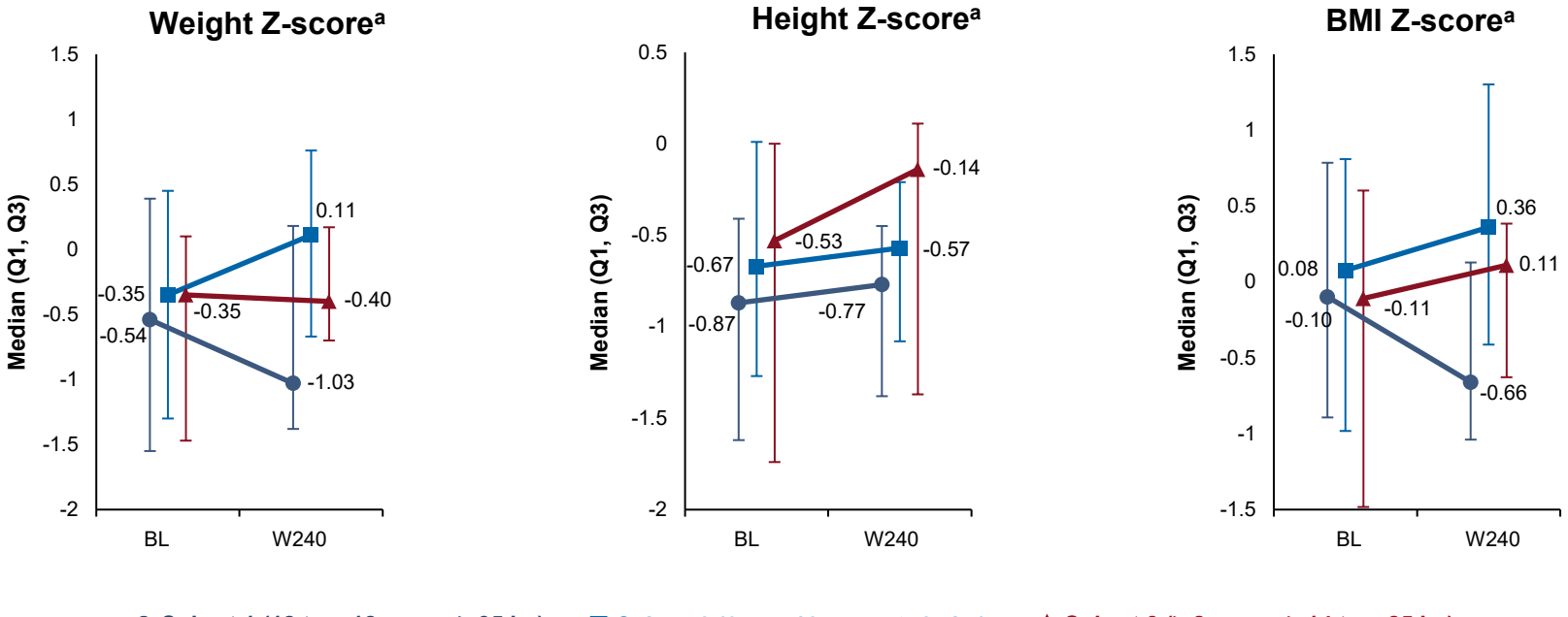
- Median exposure to B/F/TAF was 392 weeks in Cohort 1, 371 weeks in Cohort 2, and 279 weeks in Cohort 3

Participants, n (%)	Cohort 1 12 to < 18 years; ≥ 35 kg n = 50	Cohort 2 6 to < 12 years; ≥ 25 kg n = 50	Cohort 3 ≥ 2 years; ≥ 14 to < 25 kg n = 22
AE[a]	45 (90)	47 (94)	21 (95)
≥ Grade 3	11 (22)	6 (12)	3 (14)
Serious	8 (16)	5 (10)	0
Drug-related AE	5 (10)	10 (20)	3 (14)
≥ Grade 3[b]	1 (2)	0	0
Serious[b]	1 (2)	0	0
AE leading to treatment discontinuation[c]	1 (2)	2 (4)	0

B/F/TAF was well tolerated and no new safety concerns emerged

[a]AEs were coded according to Medical Dictionary for Regulatory Activities, Version 28.0. [b]Grade 3 upper abdominal pain, nausea, and vomiting on Day 1957; study drug was resumed 5 days later.
[c]Two participants in Cohorts 1 and 2 had pulmonary tuberculosis and one participant in Cohort 2 experienced drug-related insomnia and worsening anxiety.
AE, adverse event; **B/F/TAF**, bictegravir/emtricitabine/tenofovir alafenamide.

Growth Parameters



Growth parameters were consistent with expected age-related changes

[a]Z-scores were generated using the 2000 US Centers for Disease Control and Prevention Growth Charts.
BL, baseline; **BMI**, body mass index; **Q**, quartile; **W**, Week.

Conclusions

- After up to 5 years of treatment, B/F/TAF continued to show favorable long-term efficacy and safety in children and adolescents with HIV-1 aged 2 years of age and older who weighed at least 14 kg
  - B/F/TAF was given as a one-pill, once-a-day, fixed-dose combination
  - B/F/TAF maintained high levels of virologic suppression
  - B/F/TAF remained well tolerated, with low rates of discontinuations due to AEs and no new safety concerns
  - No negative impact on growth was observed

These data are consistent with B/F/TAF being an effective and well-tolerated long-term treatment option for children and adolescents with HIV-1

AE, adverse event; **B/F/TAF**, bictegravir/emtricitabine/tenofovir alafenamide.

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