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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AIDS 2026, the 26th International AIDS Conference; July 26–31, 2026; Rio de Janeiro, Brazil

Disclosures

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

Eva Natukunda reports research funding paid to their institution's Joint Clinical Research Centre by Gilead Sciences, Inc.

Samantha Fry reports grants/contracts from Gilead Sciences, Inc and Merck Sharp & Dohme Corp.

Pope Kosalaraksa reports research funding paid to their institution by Gilead Sciences, Inc.

Afaaf Liberty reports grants/contracts from GSK and Merck Sharp & Dohme Corp.

Carina A Rodriguez reports research funding paid to their institution by Gilead Sciences, Inc., GSK, and ViiV Healthcare.

Renate Strehlau reports research funding paid to their institution by Gilead Sciences, Inc.

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.

Aditya H Gaur reports research funding paid to their institution from Gilead Sciences, Inc., Merck, and ViiV Healthcare; and consulting fees for participating in an advisory board for ViiV Healthcare.

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

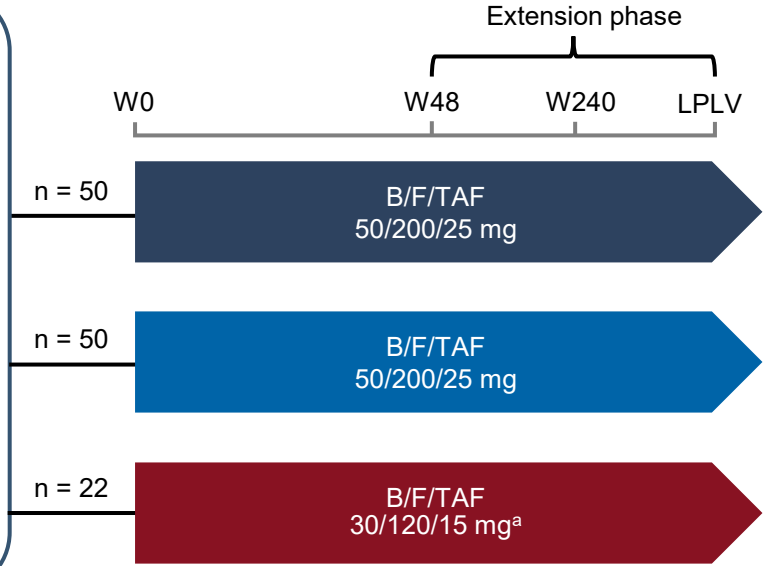
Key inclusion criteria:

- 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.

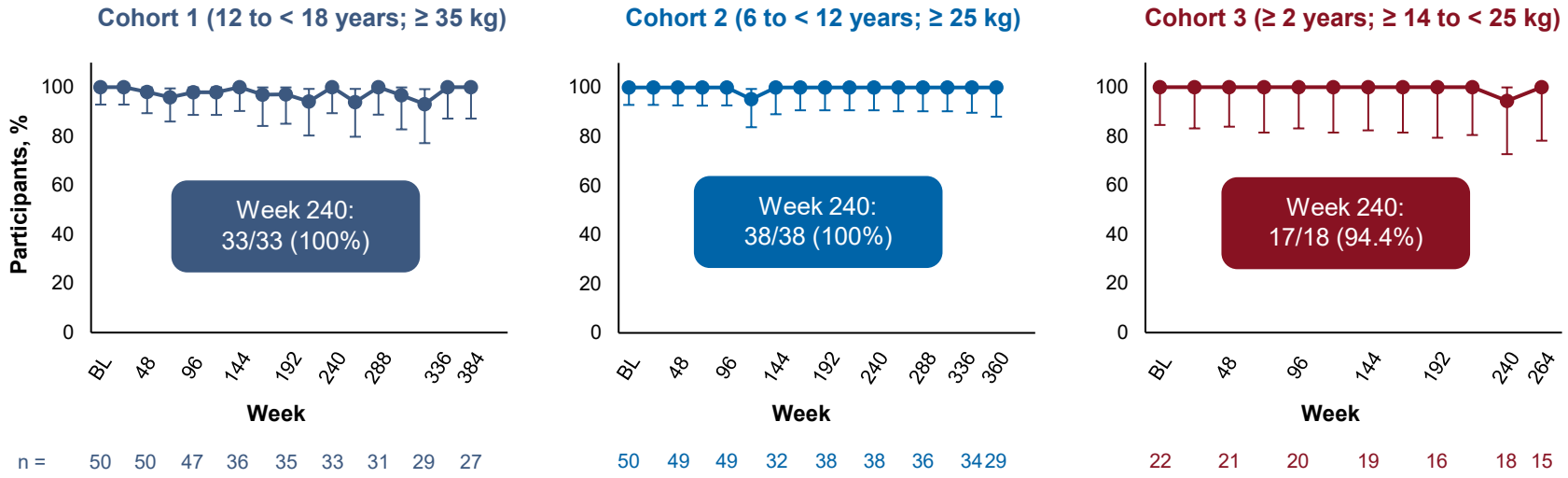
Baseline Demographics and Characteristics

	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

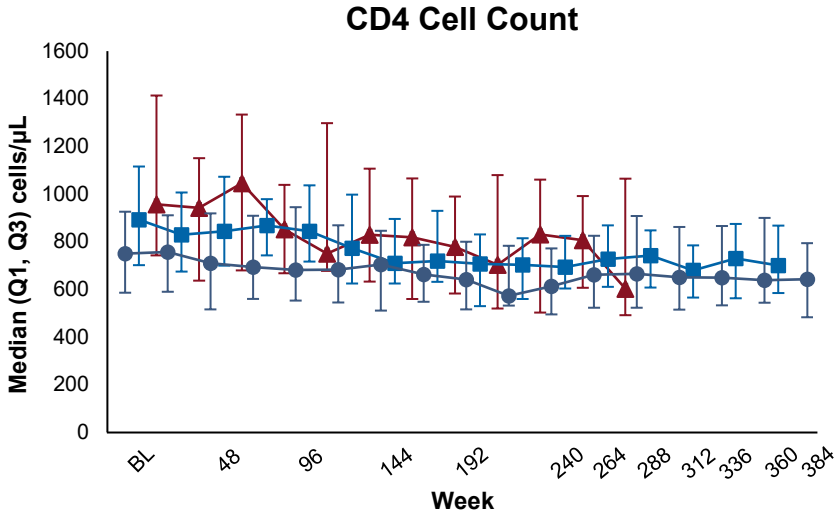
Participants With HIV-1 RNA < 50 c/mL (M = E)

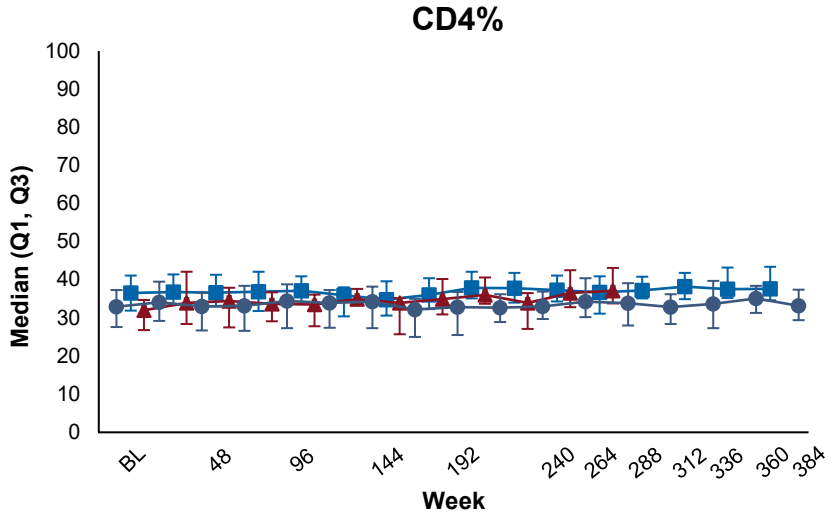


Virologic suppression was maintained at close to 100% through 5 years of treatment

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

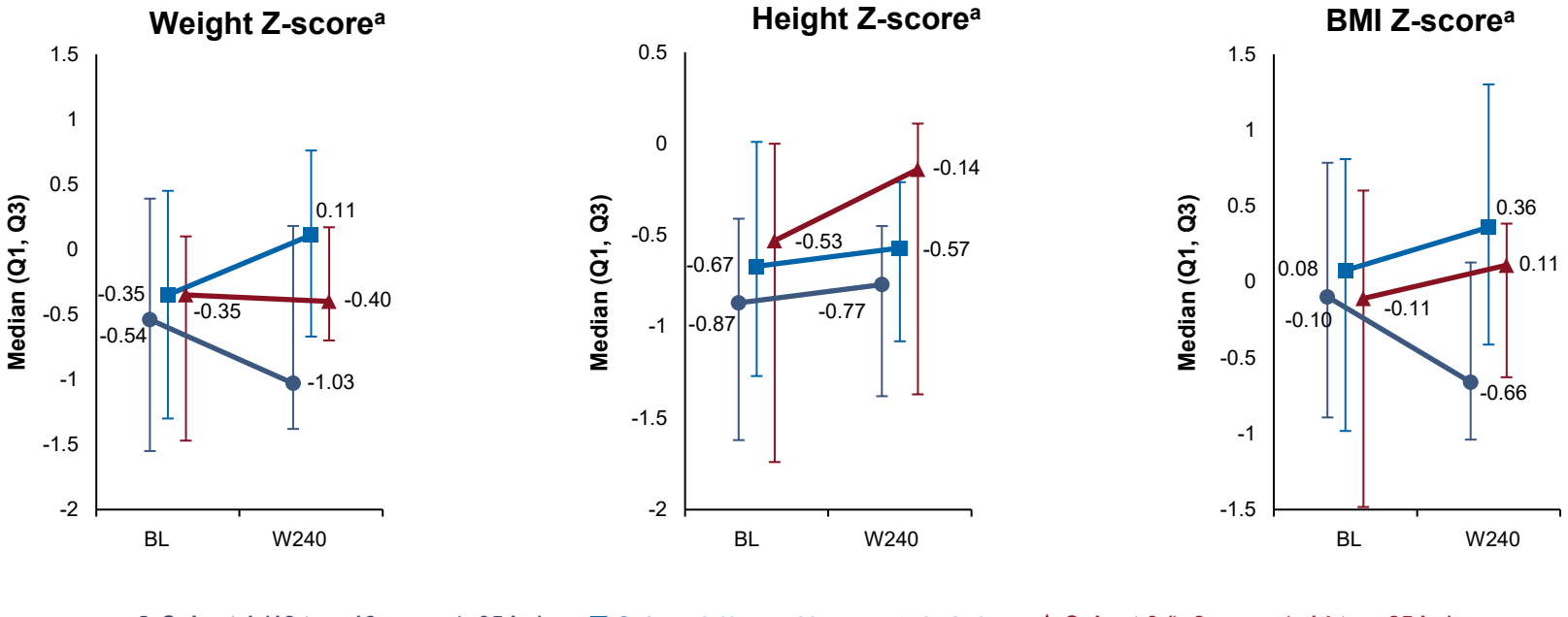
- Median exposure to B/F/TAF was 392 weeks in Cohort 1, 371 weeks in Cohort 2, and 279 weeks in Cohort 3

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.

Acknowledgments

- We extend our thanks to the participants, their families, and all participating investigators
- This study was funded by Gilead Sciences, Inc.
- All authors contributed to and approved the presentation
- Medical writing support was provided by Sil Pregnolato, PhD (Aspire Scientific Ltd, UK), and was funded by Gilead Sciences, Inc.

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