Efficacy and Safety of B/F/TAF in Children and Infants Aged ≥ 1 Month, Weighing 3 to < 25 kg: Week 24

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Eva Natukunda[1], Peter Elyanu[2], Jeanne Coetzee[3], Samantha Fry[4], Elizabeth Helström[5], Umesh Lalloo[6], Afaaf Liberty[7], Kathleen A McGann[8], Carina A Rodriguez[9], Natella Rakhmanina[10], Athira Sudhakaran[11], Vinicius A Vieira[11], Kathryn Kersey[11], Flavia Matovu Kiweewa[12]

[1]Joint Clinical Research Centre, Kampala, Uganda; [2]Baylor College of Medicine Children's Foundation Uganda, Kampala, Uganda; [3]Wits Reproductive Health and HIV Institute, University of Witwatersrand, Johannesburg, South Africa; [4]FAMCRU, Stellenbosch University, Cape Town, South Africa; [5]Be Part Yoluntu Centre NPC, Paarl, South Africa; [6]Enhancing Care Foundation, Durban University of Technology, Durban, South Africa; [7]Perinatal HIV Research Unit, Chris Hani Baragwanath Hospital, Johannesburg, South Africa; [8]Duke University Medical Center, Durham, NC, USA; [9]Morsani College of Medicine, University of South Florida, Tampa, FL, USA; [10]Children's National Hospital, Washington, DC, USA; [11]Gilead Sciences, Inc., Foster City, CA, USA; [12]Makerere University–Johns Hopkins University Research Collaboration, Kampala, Uganda

Conclusions

- In this multicohort, single-group study, bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) showed favorable efficacy, safety, and acceptability in infants and children through 24 weeks of treatment
  - Virologic suppression (VS) was maintained and overall VS increased
  - B/F/TAF was well tolerated, with few drug-related adverse events (DRAEs; all Grade 1) and no serious DRAEs
  - There were no clinically significant changes in height or weight Z-scores, and estimated glomerular filtration rate (eGFR) remained within the expected physiological change for age
- Most caregivers perceived B/F/TAF tablet for oral suspension (TOS) as having neutral or favorable palatability, and all who responded were successfully able to give the entire dose to the child
- These data support continuing the evaluation of B/F/TAF as a potential treatment option in infants and younger children
  - Additional analyses will be conducted at Week 48 of treatment

Plain Language Summary

- Children with human immunodeficiency virus (HIV) need medicine to keep the virus under control
  - However, treatment options for young children are limited
  - Most HIV medicines come as tablets, which can be hard for children to swallow
- B/F/TAF is a once-daily HIV treatment pill that combines three medicines: bictegravir (B), emtricitabine (F), and tenofovir alafenamide (TAF)
  - It has been shown to work well in treating HIV in adults and older children, but this is the first time it has been looked at to see how well it works for infants and young children
- In this study, we wanted to find out how well B/F/TAF worked and if there were any side effects in children at least 1 month old who weighed at least 3 kg (6.6 lb) but less than 25 kg (55.1 lb)
  - During the study, children took B/F/TAF as a tablet that could be mixed in water and swallowed
  - Caregivers were also asked how easy it was for them to prepare the medicine and for the children to take it
  - After 24 weeks, B/F/TAF worked well at keeping HIV under control in children of different ages and weights
- There were few side effects, and most caregivers said that the medicine tasted "good" or "super good" to their children
- The study will continue to collect more results at 48 weeks of treatment

Introduction

- Guidelines recommend that antiretroviral therapy (ART) should be initiated in all infants and children diagnosed with HIV[1]; however, treatment options are limited and are often in formulations that the pediatric population finds difficult to tolerate, such as large pill size[2]
- B/F/TAF is a single-tablet regimen (STR) containing an unboosted integrase strand-transfer inhibitor, bictegravir (B), coformulated with the nucleoside/nucleotide reverse transcriptase inhibitors emtricitabine (F) and tenofovir alafenamide (TAF)
  - Studies have shown that TAF has an improved renal and bone safety profile compared with tenofovir disoproxil fumarate–based regimens[3]
- B/F/TAF is well tolerated with a high barrier to resistance,[4] and is approved for use in children with HIV-1 aged ≥ 2 years and/or weighing ≥ 14 kg[5,6]
  - Children weighing ≥ 25 kg: B/F/TAF 50/200/25 mg STR (full-strength tablet)
  - Children weighing 14 to < 25 kg[a]: B/F/TAF 30/120/15 mg STR (low-dose tablet)
- A newly formulated tablet for oral suspension (TOS), which is dispersed in water and administered as an oral suspension, may provide an alternative for children who are unable to swallow tablets

[a]The European Medicines Agency further specifies that children must be ≥ 2 years of age.

Objective

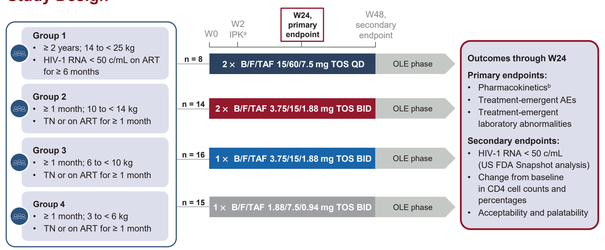
- To assess the efficacy and safety of B/F/TAF (administered based on weight band), and acceptability/palatability of TOS formulations, through Week 24 in infants and children with HIV aged ≥ 1 month, weighing 3 to < 25 kg, who are treatment naïve or on ART

Methods

- This is an ongoing Phase 2/3, open-label, multicenter, multicohort, single-group study to evaluate the pharmacokinetics, safety, and efficacy of B/F/TAF in children and adolescents with HIV (GS-US-380-1474; NCT02881320)
- Data from Cohort 4 were analyzed, comprising four groups of participants stratified by age and weight band
- Cohort 4 key inclusion criteria:
  - Cluster of differentiation 4 (CD4) count: Group 1, ≥ 200 cells/mm^3; Groups 2-4, ≥ 750 cells/mm^3 for ≥ 1 to < 12 months of age, and ≥ 500 cells/mm^3 for ≥ 12 to < 24 months of age
  - eGFR ≥ 90 mL/min/1.73 m^2 for children ≥ 1 year of age[a]
  - No evidence of active hepatitis B or C infection

[a]Or adequate renal function (eGFR ≥ minimum values for normal adjusted eGFR for children < 1 year of age using the Schwartz formula).

Study Design



[a]For Groups 2-4 only. [b]Not presented.
AE, adverse event; ART, antiretroviral therapy; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BID, twice daily; c, copies; CD4, cluster of differentiation 4; eGFR, estimated glomerular filtration rate; FDA, Food and Drug Administration; IPK, intensive pharmacokinetics; OLE, open-label extension; QD, once daily; TN, treatment-naïve; TOS, tablet for oral suspension; W, Week.

Results

Baseline Characteristics

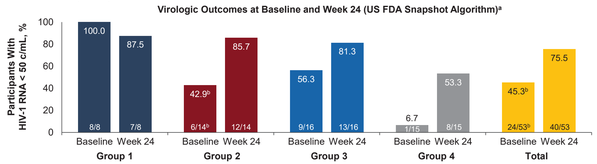
	Group 1 ≥ 2 Years; 14 to < 25 kg n = 8	Group 2 ≥ 1 Month; 10 to < 14 kg n = 14	Group 3 ≥ 1 Month; 6 to < 10 kg n = 16	Group 4 ≥ 1 Month; 3 to < 6 kg n = 15	Total[a] N = 53
Age, median (range)	4 (2-7) years	2 (1-4) years	8 (2-19) months	4 (2-16) months	15 (2-84) months
Weight, kg, median (range)	15.9 (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)
Assigned female at birth, n (%)	3 (37.5)	8 (57.1)	11 (68.8)	9 (60.0)	31 (58.5)
Black race, n (%)	7 (87.5)	14 (100.0)	14 (87.5)	15 (100.0)	50 (94.3)
HIV-1 RNA < 50 c/mL, n (%)	8 (100.0)	6 (42.9)	9 (56.3)	1 (6.7)	24 (45.3)
HIV-1 RNA $\log_{10}$ c/mL, median (range)	1.3 (1.3-1.4)	1.7 (1.3-2.5)	1.6 (1.3-4.8)	2.6 (1.3-6.9)	1.7 (1.3-6.9)
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)
eGFR, mL/min/1.73 m^2, median (Q1, Q3)	173 (150, 179)	151 (136, 158)	127 (110, 166)	109 (97, 111)	136 (110, 157)

Participants' country of origin: Group 1, Uganda, n = 2; South Africa, n = 5; USA, n = 1; Group 2, Uganda, n = 12; South Africa, n = 2; Group 3, Uganda, n = 10; South Africa, n = 4; USA, n = 2; Group 4, Uganda, n = 14; South Africa, n = 1. [a]All participants acquired HIV via vertical transmission, and all had asymptomatic disease.
c, copies; CD4, cluster of differentiation 4; eGFR, estimated glomerular filtration rate; Q, quartile.

- Median (quartile [Q]1, Q3) exposure to B/F/TAF was 97.4 (71.5, 108.8) weeks, 107.0 (82.1, 114.1) weeks, 70.5 (62.4, 97.3) weeks, and 48.1 (31.1, 63.1) weeks for Groups 1-4, respectively

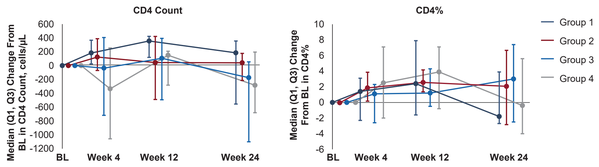
Virologic Outcomes (HIV-1 RNA < 50 c/mL) at Baseline and Week 24

- At Week 24, overall VS rate for the cohort was 75.5% (40/53) by US FDA Snapshot algorithm
  - In the missing = excluded analysis (participants with non-missing HIV-1 RNA value at each visit), the VS rate was 100.0% (8/8), 85.7% (12/14), 81.3% (13/16), and 57.1% (8/14) for Groups 1-4, respectively, and 78.8% (41/52) overall



[a]Baseline values are not included in the US FDA Snapshot algorithm. [b]Data were missing for one participant from Group 2 who was included in the denominator for the percentage.
c, copies; FDA, Food and Drug Administration; M = E, missing = excluded.

Immunologic Outcomes Through Week 24



BL, baseline; CD4, cluster of differentiation 4; Q, quartile.

- Median change in CD4 count and percentage was within the expected range of physiological fluctuation for this age group

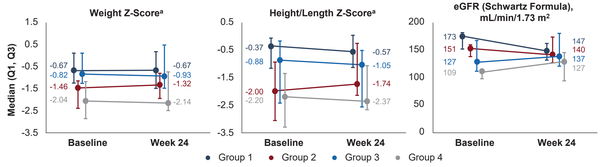
Safety Outcomes

	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	Total N = 53
Any TEAE	8 (100.0)	13 (92.9)	15 (93.8)	15 (100.0)	51 (96.2)
TE DRAEs	2 (25.0)[a]	0	2 (12.5)[b]	4 (26.7)[c]	8 (15.1)
Grade 3/4 TE DRAEs	0	0	0	0	0
Serious TE DRAEs	0	0	0	0	0
TEAEs leading to discontinuation of study drug	1 (12.5)[d]	0	0	0	1 (1.9)
Deaths	0	0	0	1 (6.7)[e]	1 (1.9)
Grade 3/4 TE laboratory abnormalities affecting ≥ 3 participants					
Amylase increased	1 (12.5)	1 (7.1)	5 (31.3)	3 (20.0)	10 (18.9)
Neutrophils decreased	1 (12.5)	0	1 (6.3)	2 (13.3)	4 (7.5)
Alkaline phosphatase increased	0	1 (7.1)	0	2 (13.3)	3 (5.7)
Hypomagnesemia	0	0	3 (18.8)	0	3 (5.7)

Data are n (%) of participants. AEs were coded according to MedDRA, Version 28.0. TEAEs began on or after the study drug start date up to 30 days after the date of the last dose of study drug. [a]Vomiting, n = 1; alanine aminotransferase increased and amylase increased, n = 1. [b]Vomiting, n = 1 and pruritus, n = 1. [c]Vomiting, n = 4. [d]Pulmonary tuberculosis, not related to study drug. [e]Pneumonia, not related to study drug.
AE, adverse event; DRAE, drug-related adverse event; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.

- Adverse events considered drug-related by the investigator occurred in 15% (8/53) of participants; all were Grade 1 in severity
- Grade 3/4 laboratory abnormalities occurred in 32% (17/53) of participants
  - Increases in amylase occurred without reported increases in lipase or pancreatitis; amylase levels typically returned to baseline on follow up without study drug interruption

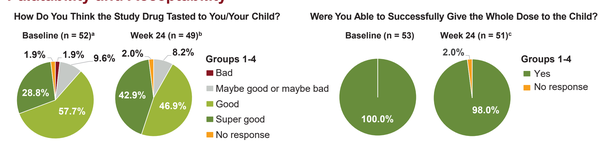
Weight, Height/Length, and Renal Parameters at Baseline and Week 24



[a]Z-scores were generated using 2000 US Centers for Disease Control and Prevention Growth Charts for participants ≥ 24 months old[1]; World Health Organization growth charts were used for participants < 24 months old.[2] eGFR, estimated glomerular filtration rate; Q, quartile.

- Changes in weight, height, or eGFR from baseline to Week 24 were not clinically significant
  - Changes in eGFR were within the expected physiological variation for this age group

Palatability and Acceptability



Data were missing for [a]n = 1; [b]n = 4; [c]n=2.

- Most caregivers perceived B/F/TAF as having neutral or favorable palatability and acceptability

References: **1.** Department of Health and Human Services. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-arv/guidelines-pediatric-arv.pdf (accessed Nov. 12, 2025). **2.** Lee C, et al. *J Pediatr Pharmacol Ther.* 2021;26:783-94. **3.** Tao X, et al. *Int J Infect Dis.* 2020;93:108-17. **4.** Sax PE, et al. *EClinicalMedicine.* 2023;59:101991. **5.** Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) USPI, Gilead Sciences, Inc., July 2025. **6.** European Medicines Agency. https://www.ema.europa.eu/en/medicines/human/EPAR/biktarvy (accessed Nov. 12, 2025). **7.** Kuczmarski RJ, et al. *Vital Health Stat.* 2002;11:1-190. **8.** World Health Organization. https://www.who.int/tools/child-growth-standards/standards (accessed Nov. 28, 2025).

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Correspondence: Eva Natukunda, enatukunda@jcrc.org.ug.