Five-Year Extended Follow-Up of the Observational BICStaR Cohort: Final Analysis in People With HIV Receiving Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Routine Clinical Practice

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BICStaR

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Conclusions

- Extended follow-up through 5 years in the observational BICSTaR (BICtegravir Single Tablet Regimen) cohort (Canada, France, Germany) demonstrated that:
  - Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) maintained high levels of effectiveness and immunologic recovery through 5 years in treatment-naïve (TN) and treatment-experienced (TE) people with HIV in routine clinical care
  - The safety profile of B/F/TAF was consistent with previous clinical trials[1] and real-world analyses,[2-5] with few participants experiencing drug-related adverse events (DRAEs) that required discontinuation of treatment
  - Participants experienced improvements in quality of life (QoL) outcomes, supporting B/F/TAF as a durable long-term therapy\

Plain Language Summary

- B/F/TAF is a tablet taken once a day to treat human immunodeficiency virus (HIV). It combines three medications: bictegravir (B), emtricitabine (F), and tenofovir alafenamide (TAF)
- In this study, researchers wanted to find out how well B/F/TAF worked and how safe it was for people with HIV. The study included people in Canada, France, and Germany who were taking it as part of their usual treatment
- After 5 years, researchers found that B/F/TAF was very effective at stopping HIV from showing in the blood. This was seen in people who were taking it as their first HIV medication, as well as in those who switched to it after using other HIV treatments
- Researchers also found that people taking B/F/TAF experienced few side effects, and most of these occurred in the first 6 months of treatment
- People taking B/F/TAF reported that their mental health had improved
- Additionally, people said that their satisfaction with HIV treatment increased during the study

Introduction

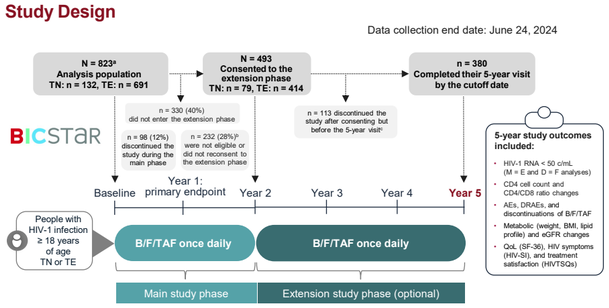
- B/F/TAF is a single tablet regimen recommended for the treatment of HIV-1 in people with HIV[6-8]
- As of February 6, 2025, approximately 6107 participants have been enrolled in studies involving B/F/TAF, of whom around 4701 have received B/F/TAF[9]
  - Since first marketing approval, cumulative exposure to B/F/TAF is estimated to be 4,525,987 patient-years[9]
- BICSTaR is a multicountry, prospective, observational, 2-year cohort study evaluating the effectiveness and safety of B/F/TAF in TN and TE people with HIV-1 in routine clinical practice[2]
- The study enrolled 2379 participants from five observational cohorts across 14 countries
- The pooled analysis of the five cohorts demonstrated that B/F/TAF was highly effective and well tolerated through 2 years across a broad range of people with HIV[3]
- The study was extended for a further 3 years in Canada, France, and Germany, allowing for a total of 5 years of follow-up
  - B/F/TAF continued to be effective and well tolerated at the 3- and 4-year follow-ups (2 years of main study plus 1 and 2 years of an extension phase, respectively)[4,5]

Objectives

- To assess the effectiveness, safety, quality of life (QoL), and HIV treatment satisfaction in the extension cohort of participants who received B/F/TAF in routine clinical practice over 5 years of follow-up (2 years of main study plus 3 years of an extension phase)

Methods

Study Design



The analysis population includes participants who had a visit at 60 months and those who discontinued the study having initiated treatment ≥ 54 months (lower bound of the 60-month visit window) before the end of data collection. [a]823 participants enrolled in the main phase of the study in Canada, France, and Germany. [b]69 participants (8%) discontinued B/F/TAF but were still in the analysis population study at 24 months and 163 (20%) were eligible for the extension phase but did not reconsent (reasons not recorded). [c]Due to study drug discontinuation (n = 43), loss to follow-up (n = 41), participant's decision (n = 16), death (n = 7), and investigator's discretion (n = 1); 5 participants had no reason for discontinuation recorded.
AE, adverse event; BMI, body mass index; c, copies; CD, cluster of differentiation; D = F, discontinuation = failure; eGFR, estimated glomerular filtration rate [by Chronic Kidney Disease Epidemiology Collaboration 2021 formula]; HIV-SI, HIV Symptom Index; HIVTSQs, HIV Treatment Satisfaction Questionnaire: status version; M = E, missing = excluded; SF-36, 36-Item Short Form Health Survey.

Results

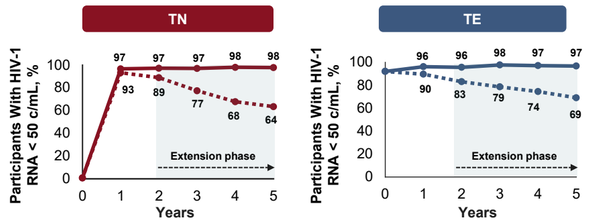
Baseline Demographic and Clinical Characteristics at Entry to the Main Study

	TN (n = 132)	TE (n = 691)
Age, years, median (Q1, Q3)	39.0 (30.0, 50.5)	49.0 (39.0, 56.0)
≥ 50 years, n (%)	35 (26.5)	336 (48.6)
≥ 65 years, n (%)	7 (5.3)	55 (8.0)
Sex at birth, n (%)		
Male	119 (90.2)	598 (86.5)
Female	13 (9.8)	93 (13.5)
Race, n (%)		
White	108 (81.8)	564 (81.6)
Black	14 (10.6)	71 (10.3)
Weight, kg, median (Q1, Q3)	70.0 (63.3, 81.2) [n = 120]	77.0 (67.0, 87.0) [n = 615]
BMI, kg/m², median (Q1, Q3)	23.0 (21.2, 25.7) [n = 118]	24.7 (22.3, 28.0) [n = 613]
Concomitant medication, n (%)	61 (48.4)	437 (64.7)
HIV-1 RNA, $\log_{10}$ c/mL, median (Q1, Q3)	4.83 (4.02, 5.31) [n = 130]	1.28 (1.28, 1.28) [n = 622]
HIV-1 viral load < 50 c/mL, n (%)	1 (0.8) [n = 130]	572 (92.0) [n = 622]
HIV-1 viral load > 100,000 c/mL, n (%)	51 (39.2) [n = 130]	4 (0.6) [n = 622]
Era of HIV diagnosis[a]		
1980 to 1995	1 (0.8)	92 (13.3)
1996 to 2014	11 (8.3)	443 (64.2)
2015 onwards	120 (90.9)	155 (22.5)
Any comorbidity at baseline, n (%)[b]	84 (63.6)	581 (84.1)
Neuropsychiatric disorder	27 (20.5)	247 (35.7)
Hyperlipidemia	10 (7.6)	157 (22.7)
Hypertension	14 (10.6)	149 (21.6)
Late diagnosis, n (%)		
CD4 count < 350 cells/μL and/or ≥ 1 AIDS-defining event	56 (44.1)	N/A
CD4 count < 200 cells/μL and/ or ≥ 1 AIDS-defining event	34 (26.8)	N/A
≥ 1 primary resistance mutation, n (%)	12 (9.1)	85 (12.3)
Most common primary resistance mutations relevant to B/F/TAF, n (%)		
NRTI overall / K65R / T69ins / M184V/I	4 (3.0) / 1 (0.8) / 0 / 0	50 (7.2) / 1 (0.1) / 1 (0.1) / 32 (4.6)
INSTI overall / T97A	0 / 0	1 (0.1) / 1 (0.1)
eGFR, n (%)		
< 60 mL/min/1.73 m²	4 (3.1) [n = 127]	31 (5.1) [n = 610]
≥ 60 mL/min/1.73 m²	123 (96.9) [n = 127]	579 (94.9) [n = 610]

Baseline demographic and clinical characteristics are shown for the total analysis population. [a]Data on era of HIV diagnosis were missing for one TE participant. [b]Any comorbidity at baseline and history of comorbidity. Data on comorbidities were missing for one TN participant.
INSTI, integrase strand transfer inhibitor; N/A, not applicable; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; Q, quartile.

For additional details on baseline demographics in participants who did and did not enter the extension phase, please scan the QR code

Virologic Effectiveness Through 5 Years (M = E and D = F analyses)



Number of participants with available data						
M = E	130	116	107	67	54	48
D = F	130	120	117	84	78	74

Number of participants with available data						
M = E	622	570	523	383	359	316
D = F	622	611	602	476	469	443

The lower rate of effectiveness over time in the D=F analysis was driven by increasing drop-outs due to AEs/participant/physician choice, etc., rather than by lack of effectiveness.

- High rates of virologic suppression were maintained through 5 years of follow-up in both TN and TE participants who continued to take B/F/TAF
- No treatment-emergent resistance to the components of B/F/TAF was reported through 5 years

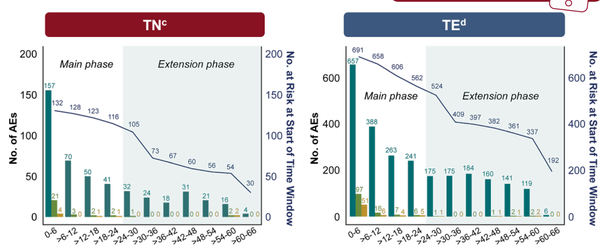
Please scan the QR code for reasons participants discontinued B/F/TAF

Changes in Immunologic, Metabolic, and Renal Parameters at 5 Years

	TN Participants (n = 132)			TE Participants (n = 691)		
	n[a]	At Baseline	Change at 5 Years[b]	n[a]	At Baseline	Change at 5 Years[b]
Immunologic parameters, median (Q1, Q3)						
CD4 count, cells/μL	42	436.5 (248.0, 598.0)	+363.5 (261.0, 550.0)[c]	236	672.0 (465.5, 912.0)	+91.0 (-67.0, 221.0)[c]
CD4/CD8 ratio	42	0.4 (0.3, 0.6)	+0.5 (0.3, 0.8)[c]	206	0.9 (0.6, 1.3)	+0.1 (0.0, 0.3)[c]
Metabolic parameters, median (Q1, Q3)						
Weight, kg	36	71.9 (66.0, 81.7)	+4.0 (0.0, 11.5)[c]	240	77.5 (68.0, 87.0)	+2.0 (-1.5, 5.0)[c]
BMI, kg/m²	36	23.3 (21.7, 26.8)	+1.4 (0.0, 3.6)[c]	240	25.1 (22.4, 28.1)	+0.6 (-0.5, 1.6)[c]
Lipid profile, median (Q1, Q3)						
Total cholesterol, mmol/L	27	4.9 (4.4, 5.5)	+0.5 (-0.4, 1.1)	186	4.7 (4.0, 5.5)	0.0 (-0.5, 0.7)
HDL cholesterol, mmol/L	25	1.2 (1.0, 1.5)	0.0 (-0.3, 0.3)	161	1.2 (1.0, 1.5)	0.0 (-0.1, 0.2)
LDL cholesterol, mmol/L	24	2.9 (2.3, 3.8)	+0.4 (-0.2, 1.1)[c]	161	2.8 (2.2, 3.6)	0.0 (-0.5, 0.6)
Triglycerides, mmol/L	26	1.5 (0.9, 1.6)	0.0 (-0.6, 0.3)	180	1.5 (1.1, 2.3)	-0.2 (-0.7, 0.3)[c]
Total:HDL cholesterol ratio	25	4.6 (3.6, 4.9)	-0.1 (-0.8, 0.7)	161	4.0 (3.1, 4.9)	0.0 (-0.6, 0.5)
Renal parameters, median (Q1, Q3)						
eGFR, mL/min/1.73 m²	46	104.6 (89.2, 114.5)	-11.8 (-21.2, 5.1)	274	88.7 (76.4, 102.5)	-4.7 (-12.0, 3.4)
30–59 mL/min/1.73 m² at baseline	0	N/A	N/A	16	54.5 (50.7, 57.9)	-0.7 (-5.3, 19.6)
60–89 mL/min/1.73 m² at baseline	13	81.8 (73.0, 86.0)	-3.3 (-9.3, 1.3)	127	78.4 (72.0, 85.0)	-2.2 (-9.3, 6.6)
≥ 90 mL/min/1.73 m² at baseline	33	111.4 (102.7, 120.1)	-13.0 (-23.5, 8.7)[c]	131	103.1 (97.5, 110.8)	-7.5 (-17.0, -1.6)[c]

[a]Participants with data at baseline and 5 years. [b]Absolute change from baseline to 5 years. [c]$P < 0.05$ by sign or Wilcoxon signed-rank tests or by Student's *t*-test. HDL, high-density lipoprotein; LDL, low-density lipoprotein.

AEs, DRAEs, and DRAEs Leading to B/F/TAF Discontinuation Through 5 Years

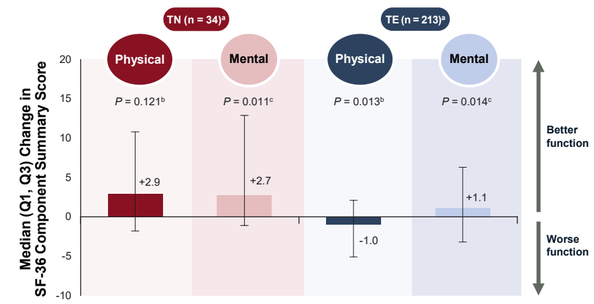


For additional details on AEs, DRAEs, and DRAEs leading to B/F/TAF discontinuation, please scan the QR code

Some AEs were reported after 60 months (5 years). [a]DRAEs occurring in ≥ 1% of participants overall were: weight increase (TN: n = 12 [9.1%]; TE: n = 25 [3.6%]), depression (TN: n = 1 [0.8%]; TE: n = 10 [1.4%]), fatigue (TN: n = 2 [1.5%]; TE: n = 8 [1.2%]), nausea (TN: n = 2 [1.5%]; TE: n = 8 [1.2%]). One TE participant experienced a serious DRAE (depression). [b]DRAEs leading to discontinuation occurring in ≥ 1% of participants overall were: weight increase (TN: n = 5 [3.8%]; TE: n = 17 [2.5%]). [c]There were an additional 210 AEs and 11 DRAEs reported that did not have a start date (4 of these DRAEs led to discontinuation of B/F/TAF). [d]There were an additional 27 AEs and 2 DRAEs reported that did not have a start date.

- The majority of DRAEs and DRAEs leading to discontinuation of B/F/TAF occurred during the first 6 months of the main study phase
- DRAEs leading to discontinuation of B/F/TAF occurred in 7 (5%) TN and 56 (8%) TE participants overall
  - There were no renal or hepatic DRAEs resulting in discontinuation of B/F/TAF
  - One TE participant experienced a serious DRAE (depression) leading to discontinuation of B/F/TAF

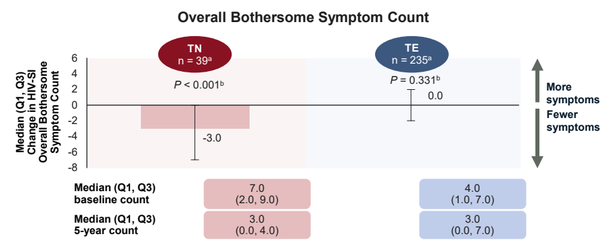
Change From Baseline in QoL (SF-36) Physical and Mental Health Component Summary Scores at 5 Years



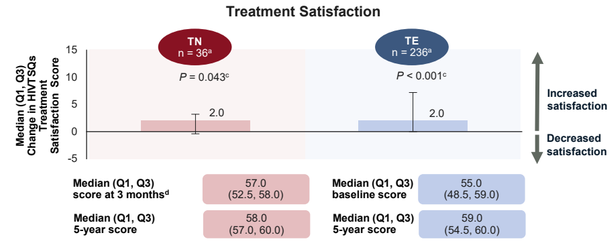
	TN (n = 34)[a] Physical	TN (n = 34)[a] Mental	TE (n = 213)[a] Physical	TE (n = 213)[a] Mental
Median (Q1, Q3) baseline score	52.7 (45.6, 59.6)	47.5 (35.9, 53.4)	56.2 (50.1, 59.5)	48.4 (38.8, 56.2)
Median (Q1, Q3) 5-year score	58.0 (51.5, 60.8)	52.3 (45.8, 55.5)	55.5 (47.7, 59.0)	51.8 (41.9, 56.2)

Median scores > 50 indicate better-than-average function. [a]Participants with SF-36 scores available at baseline and 5 years. [b]Sign test. [c]Wilcoxon signed-ranked test.

Change From Baseline in Overall Bothersome Symptom Count (HIV-SI) and Treatment Satisfaction (HIVTSQs) at 5 Years



	TN n = 39[a]	TE n = 235[a]
Median (Q1, Q3) baseline count	7.0 (2.0, 9.0)	4.0 (1.0, 7.0)
Median (Q1, Q3) 5-year count	3.0 (0.0, 4.0)	3.0 (0.0, 7.0)



	TN n = 36[a]	TE n = 236[a]
Median (Q1, Q3) score at 3 months[d]	57.0 (52.5, 58.0)	Median (Q1, Q3) baseline score: 55.0 (48.5, 59.0)
Median (Q1, Q3) 5-year score	58.0 (57.0, 60.0)	Median (Q1, Q3) 5-year score: 59.0 (54.5, 60.0)

Overall bothersome symptom count can range from 0 to 20, with higher values indicating more bothersome symptoms. Treatment satisfaction scores range from 0 to 60, with higher scores indicating higher treatment satisfaction. [a]Participants with scores available at baseline and 5 years. [b]Wilcoxon signed-ranked test. [c]Sign test. [d]For TN participants, HIVTSQs was first completed at 3 months.

QoL Outcomes

- In TN participants:
  - Improvements in mental and physical health scores, with a reduction in bothersome symptoms count and high treatment satisfaction scores
- In TE participants:
  - Small changes in mental and physical health scores, and increases in treatment satisfaction scores

References: **1.** Curteis T, et al. *J Comp Eff Res*. 2025;14:e240231. **2.** Esser S, et al. *HIV Med*. 2024;25:440-53. **3.** Trottier B, et al. *HIV Res Clin Pract*. 2025;26:2456890. **4.** Sabranski M, et al. Poster eP.A.081 presented at: EACS; Oct. 18-21, 2023; Warsaw, Poland. **5.** Wong A, et al. Poster P063 presented at: HIV Glasgow; Nov. 10-13, 2024; Glasgow, UK. **6.** European AIDS Clinical Society. https://eacs.sanfordguide.com/eacs-part1/art/eacs-initial-regimens-arv-naive-adults (accessed June 24, 2025). **7.** Gandhi RT, et al. *JAMA*. 2023;329:63-84. **8.** US Department of Health and Human Services. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf (accessed June 26, 2025). **9.** Gilead Sciences, Inc. Data on file.

Acknowledgments: These studies were sponsored by Gilead Sciences, Inc. We thank all study participants and all participating study investigators and staff. We thank Rebecca Harrison, MSc, of IQVIA (London, UK) and Tali Cassidy, PhD, of Gilead Sciences Europe Ltd. (Uxbridge, UK) for epidemiological and statistical support. Medical writing support was provided by Flint Stevenson-Jones, PhD (Aspire Scientific Ltd, UK), and was funded by Gilead Sciences, Inc.
Disclosures: **JdW** reports consulting fees from and participation on advisory boards for Gilead Sciences, Inc., Merck, and ViiV Healthcare; and payment or honoraria for lectures, presentations for speakers' bureaus, manuscript writing, or educational events, and support for attending meetings and/or travel, from Gilead Sciences, Inc. and ViiV Healthcare.
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