Outcomes in Treatment-Experienced People With HIV and Detectable Viremia Switching to B/F/TAF in Routine Clinical Practice: 24-Month Results From the BICSTaR Study

TUPEB092

BICSTaR

Berend van Welzen[1], Sam McConkey[2], Marta Boffito[3], Alexander Wong[4], Giulia Marchetti[5], Alexy Inciarte[6], Daniel Elbirt[7], Christoph Stephan[8], Yeşim Taşova[9], Hung-Chin Tsai[10], Jun Yong Choi[11], Claudine Duvivier[12], Chiaw Yee Choy[13], David Thorpe[14], Andrea Marongiu[14], Tali Cassidy[14], Katsuji Teruya[15]

[1]University Medical Centre Utrecht, Utrecht, the Netherlands; [2]Beaumont Hospital, Dublin, Ireland; [3]Chelsea and Westminster Hospital, London, UK; [4]Regina General Hospital, Regina, SK, Canada; [5]University of Milan, ASST Santi Paolo e Carlo, Milan, Italy; [6]Hospital Clínic de Barcelona, Barcelona, Spain; [7]Kaplan Medical Center, Rehovot, Israel; [8]Universitätsklinikum Frankfurt, Frankfurt, Germany; [9]Cukurova University Hospital, Adana, Türkiye; [10]Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan; [11]Yonsei University Severance Hospital, Seoul, Republic of Korea; [12]AP-HP, Hôpital Necker-Enfants Malades, Necker-Pasteur Infectiology Center, Paris, France; [13]National Centre for Infectious Diseases, Singapore; [14]Gilead Sciences Ltd, Uxbridge, UK; [15]National Center for Global Health and Medicine, Tokyo, Japan

Conclusions

- In treatment-experienced people with HIV and uncontrolled viremia, switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) was associated with high rates of virologic suppression and was generally well tolerated
- An increase towards the population norm in 36-Item Short Form Health Survey (SF-36) Mental Component Summary scores indicated improvements in mental wellbeing after switching to B/F/TAF, and participants reported increased satisfaction with HIV treatment

Plain Language Summary

- B/F/TAF is a once-daily tablet used to treat human immunodeficiency virus (HIV). It combines three medicines: bictegravir (B), emtricitabine (F), and tenofovir alafenamide (TAF)
- The BICSTaR study looked at how well B/F/TAF worked and how safe it was for people with HIV in healthcare settings around the world
- In this part of the study, researchers focused on people who still had detectable HIV in their blood when they switched to B/F/TAF from other HIV medicines
- Researchers found that B/F/TAF was highly effective at reducing the amount of HIV in the blood, and most participants had undetectable HIV levels after 2 years of treatment
- People who switched to B/F/TAF had few side effects, which were mostly mild or moderate
- People reported that their mental wellbeing improved after switching to B/F/TAF
- Most people in the study said they were happier with their HIV treatment after switching to B/F/TAF

Introduction

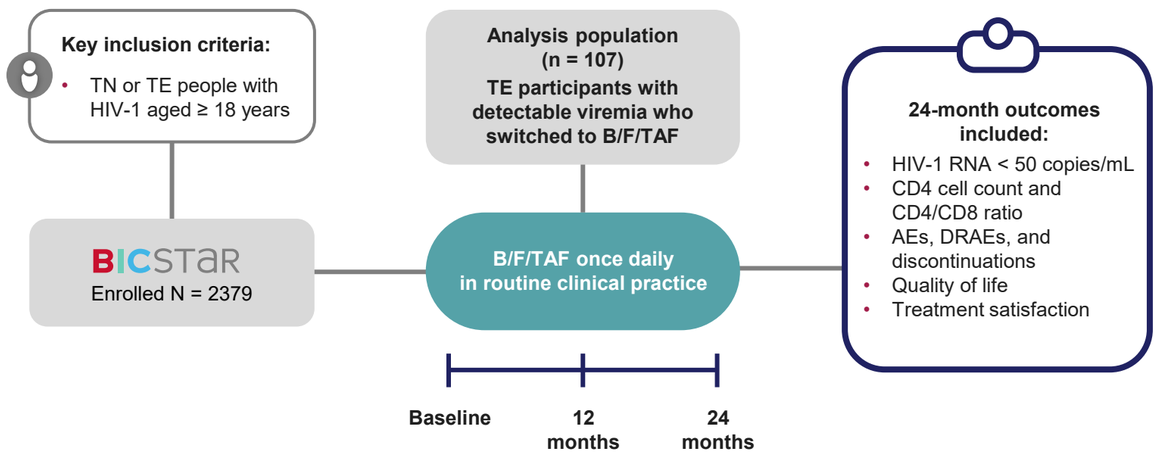
- B/F/TAF is a single tablet regimen recommended in international clinical guidelines for people with HIV[1-3]
- Since marketing approval, cumulative exposure to B/F/TAF is estimated to be 5,807,885 person-years[4]
- BICtegravir Single Tablet Regimen (BICSTaR) was a prospective, observational, 24-month cohort study evaluating the safety and effectiveness of B/F/TAF in people with HIV receiving real-world clinical care[5]
  - The study enrolled 2379 treatment-naïve and treatment-experienced people with HIV-1 from routine clinical practice across 14 countries[5]
  - The pooled analysis showed that B/F/TAF was highly effective and well tolerated through 24 months among a broad range of people with HIV-1[5]
- Multiple studies have demonstrated that B/F/TAF is effective at maintaining virologic suppression in treatment-experienced individuals who are virologically suppressed at the time of switching to B/F/TAF, but data are limited in those with active viremia at the time of switching[6-8]
- Here, we present data on the effectiveness, safety profile, and patient-reported outcomes through 24 months for people with HIV-1 who had detectable viremia at the time of switching to B/F/TAF

Objective

- To describe the effectiveness, safety profile, and patient-reported outcomes through 24 months in treatment-experienced people with HIV-1 with detectable viremia who switched to B/F/TAF during routine clinical care in the BICSTaR study

Methods

Study Design



Outcomes in this analysis[a]:

- Effectiveness assessments: proportion of participants with HIV-1 RNA < 50 copies/mL (M = E), CD4 cell count, and CD4/CD8 ratio
- Safety profile assessments: AEs, DRAEs, B/F/TAF discontinuations
- Quality of life (SF-36 scores)
- Treatment satisfaction (HIVTSQ status and change[b] scores)

[a]Outcomes were evaluated at 24 months, except where indicated. [b]HIVTSQ status: Measures a participant's satisfaction with their current treatment. Scores range from 0 (very dissatisfied) to 60 (very satisfied). HIVTSQ change: Assesses change in treatment satisfaction between a participant's previous and current treatment (evaluated after 12 months in this study to minimize recall bias). Scores range from -30 (deterioration) to +30 (improvement).
AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BICSTaR, BICtegravir Single Tablet Regimen; CD, cluster of differentiation; DRAE, drug-related adverse event; HIVTSQ, HIV Treatment Satisfaction Questionnaire; M = E, missing = excluded; SF-36, 36-Item Short Form Health Survey; TE, treatment-experienced; TN, treatment-naïve.

Results

Baseline Demographics

	TE People With HIV-1 and Viremia at Baseline n = 107
Age at B/F/TAF initiation, years, median (Q1, Q3)	46 (34, 52)
≥ 50 years, n (%)	38 (36)
≥ 65 years, n (%)	3 (3)
Sex assigned at birth, n (%)	
Male	85 (79)
Female	22 (21)
Race/ethnicity, n (%)	
White	66 (62)
Black	25 (23)
Asian	10 (9)
Other[a]	6 (6)

[a]Includes American Indian or Alaska Native (n = 1), Hispanic/Latine (n = 1), First Nations Indigenous (n = 1), North African (n = 1), Afro and White (n = 1), and Argentina (n = 1).
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; Q, quartile; TE, treatment-experienced.

Clinical Characteristics

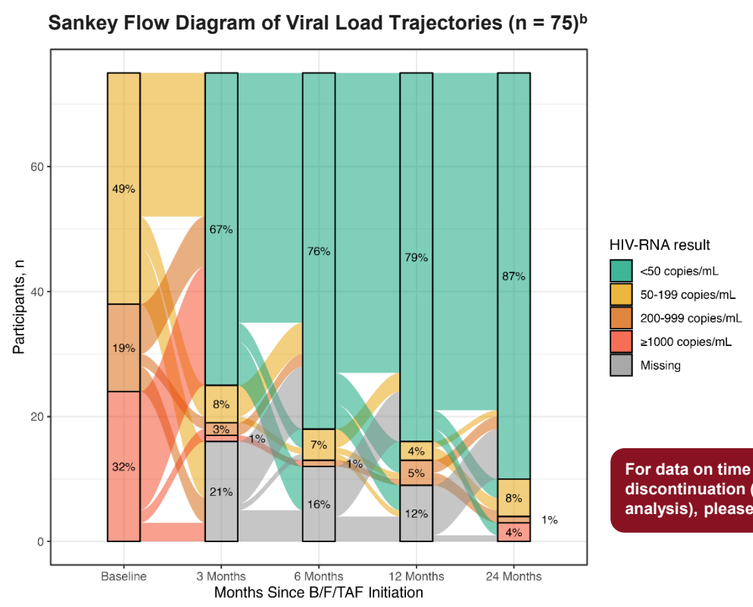
	TE People With HIV-1 and Viremia at Baseline n = 107
HIV-1 RNA at baseline, log_{10} copies/mL, median (Q1, Q3)	2.34 (1.89, 3.65)
HIV-1 RNA viral load, n (%)	
≥ 50 to < 200 copies/mL	50 (47)
≥ 200 to < 1000 copies/mL	21 (20)
≥ 1000 to < 100,000 copies/mL	26 (24)
≥ 100,000 copies/mL	10 (9)
CD4 count at baseline, cells/µL, median (Q1, Q3)	504 (248, 727)
Reason for switching to B/F/TAF, n (%)[a]	
Simplification of ART	46 (43)
Participant's preference	15 (14)
Side effects of current ART	20 (19)
Other	36 (34)
Number of comorbidities ongoing at B/F/TAF initiation, n (%)	
1	27 (25)
2	21 (20)
≥ 3	26 (24)
Any concomitant medication at B/F/TAF initiation, n (%)	64 (62)
Number of previous ART regimens, n (%)[b]	
1	39 (38)
2	23 (22)
≥ 3	41 (40)
History of virologic failure on any ART regimen, n (%)[c]	
No	64 (60)
Yes	27 (25)
At least one primary resistance mutation at baseline, n (%)[d]	
No	40 (38)
Yes	11 (10)

[a]Multiple reasons for switching to B/F/TAF are possible. [b]Data were missing for four participants. [c]Data were missing for one participant and unknown for 15 (14%). [d]Data were missing for one participant and unavailable for 55 (52%).
ART, antiretroviral therapy; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CD, cluster of differentiation; Q, quartile; TE, treatment-experienced.

Virologic Effectiveness Through 24 Months

- The majority of participants transitioned from having uncontrolled viremia at baseline to an undetectable viral load at 24 months
- In the missing = excluded analysis, at 24 months, 87% (65/75) of participants with available data had undetectable viremia[a]
- Among the 10 participants with detectable viremia at 24 months, the median (quartile [Q]1, Q3) HIV-1 viral load was 1.93 (1.79, 3.37) log_{10} copies/mL

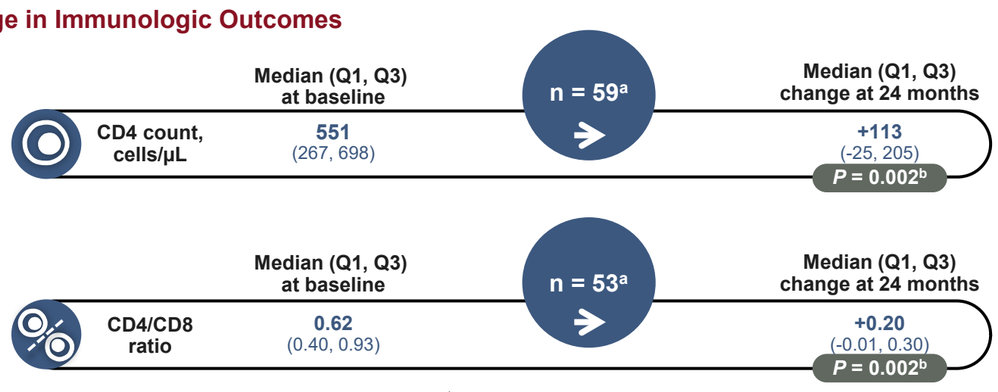
Sankey Flow Diagram of Viral Load Trajectories (n = 75)[b]



For data on time to B/F/TAF discontinuation (Kaplan-Meier analysis), please scan the QR code

[a]Missing = excluded: participants who discontinued the study and/or B/F/TAF before the 24-month window (18-30 months) and those without viral load data in the 24-month window were excluded (no imputation). [b]The Sankey diagram provides a visualization of the evolution of the population viral load over 24 months. Data shown are for participants with viral load data available at baseline and 24 months. Thicker links represent a larger transition of participants over time. For participants who discontinued B/F/TAF during study follow-up and remained in the study, results collected after discontinuation of B/F/TAF were not considered for analysis.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide.

Change in Immunologic Outcomes



[a]Partcipants with viremia at baseline and data available at baseline and 24 months. [b]Sign test.
CD, cluster of differentiation; Q, quartile.

Safety Outcomes

- Overall, 11% (12/107) of participants reported ≥ 1 drug-related adverse event (DRAE) within 24 months of B/F/TAF initiation
- DRAEs led to B/F/TAF discontinuation in 6/107 (6%) participants; five had moderate DRAEs and one had a mild DRAE
- No serious DRAEs were reported

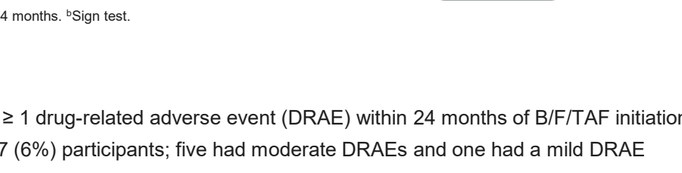
Participants, n (%)	TE People With HIV-1 and Viremia at Baseline n = 107
≥ 1 AE	69 (64)
≥ 1 DRAE	12 (11)
Mild	7 (7)
Moderate	6 (6)
Severe	1 (1)
Discontinued B/F/TAF due to DRAEs[a]	6 (6)
Discontinued B/F/TAF due to a "lack of efficacy"[b]	5 (5)
Death	2 (2)[c]

Data are shown for participants with AEs occurring within 24 months of B/F/TAF initiation. [a]The only DRAE occurring in ≥ 1% of participants that led to discontinuation was depression (n = 2; 2%). [b]Among participants who discontinued B/F/TAF, last on-treatment HIV-1 viral load values were 180 copies/mL (Day 165), 55 copies/mL (Day 203), 57 copies/mL (Day 267), 131 copies/mL (Day 272), and 105 copies/mL (Day 309). All switched to another ART regimen. [c]Pulmonary insufficiency following trauma (n = 1); unknown (n = 1).
AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DRAE, drug-related adverse event; TE, treatment-experienced.

Quality-of-Life Outcomes

- An increase in median SF-36 Mental Component Summary score was observed at 24 months following the switch to B/F/TAF ($P = 0.006$[a])
- Median SF-36 Physical Component Summary scores remained stable

Change From Baseline to Month 24 in SF-36 Scores



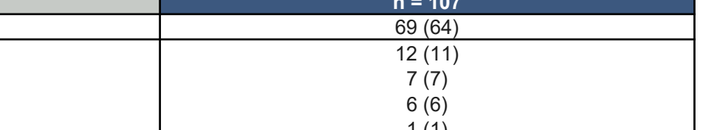
	MCS (n = 53)	PCS (n = 53)
Median (Q1, Q3) score at baseline[b]	48.9 (37.9, 55.4)	55.8 (45.2, 59.5)

[a]Wilcoxon signed-rank test. [b]For participants with data available at baseline and 24 months.
MCS, Mental Component Summary; PCS, Physical Component Summary; Q, quartile; SF-36, 36-Item Short Form Health Survey.

HIV Treatment Satisfaction

- Median HIV Treatment Satisfaction Questionnaire (HIVTSQ) status[a] score was high at baseline and increased at 24 months
- Median (Q1, Q3) HIVTSQ change[b] score at 12 months was +26.0 (21.0, 29.0) ($P < 0.001$[c]), indicating an improvement in treatment satisfaction following a switch to B/F/TAF compared with the prior antiretroviral regimen

HIVTSQ Status Scores



[a]HIVTSQ status scores range from 0 to 60, with 60 representing highest treatment satisfaction. [b]HIVTSQ change scores range from -30 to +30: the higher the score, the greater the improvement in satisfaction with treatment compared with the previous regimen. [c]Sign test.
HIVTSQ, HIV Treatment Satisfaction Questionnaire; Q, quartile.

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Correspondence: David Thorpe, david.thorpe@gilead.com.