Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) for the treatment of people living with HIV: 12-month effectiveness, persistence, and safety in a multi-country cohort study

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Introduction

B/F/TAF is a guidelines-recommended single-tablet regimen for the treatment of HIV-1 infection and is widely used in clinical practice

BICSTaR is a large, ongoing, multi-country, prospective, observational study that plans to enroll over 2,000 ARV treatment-naïve (TN) and treatment-experienced (TE) people living with HIV across Europe, Canada, Israel, Japan, Taiwan, South Korea, and Singapore

Here we report pooled **12-month effectiveness and safety data** for 1,135 people living with HIV receiving B/F/TAF in routine clinical care across Europe (France, Germany, Ireland, Italy, Netherlands, Spain, UK), Canada, and Israel

Study design

BICSTaR

Cut-off date for analysis: 22 Feb 2021

N=1,135

HIV-1 infection
TN or TE
≥18 years of age

Baseline — 12 months: primary endpoint — 24 months

B/F/TAF once daily

Analysis of people living with HIV starting B/F/TAF between Jun 2018 and Sep 2020

12-month study outcomes included:
- HIV-1 RNA <50 cp/mL (M=E analysis)
- Treatment persistence (% of participants still on B/F/TAF)
- Resistance status
- DRAEs, renal function, lipid levels, weight, and BMI changes

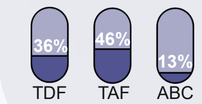
Participants: baseline characteristics

TN N=180		TE N=955
	Overall 78% White; 84% male	
38 (30, 48)	*Age, years	49 (39, 56)
70 (63, 81)	*Weight, kg	76 (67, 87)
23 (21, 26)	*BMI, kg/m^2	25 (22, 28)
47%	Any comorbidity	72%
16%	Neuropsychiatric	26%
6%	Hyperlipidaemia	22%
7%	Hypertension	19%
2%	Osteopathic	13%
1%	HIV-1 RNA <50 cp/mL	92%
400 (184, 553)	*CD4 count, cells/μL	652 (424, 850)
0.36 (0.19, 0.60)	*CD4/CD8 ratio	0.85 (0.58, 1.20)
7%	≥1 primary resistance mutation	13%

*Median (Q1, Q3)

TE

Prior ART regimens, %



Conclusions

- **B/F/TAF demonstrated effectiveness and persistence at 12 months in a large, real-world cohort of people living with HIV**
  - **Results were consistent across key populations (females, older individuals, and individuals presenting late for HIV care)**
  - **No emergence of resistance to the components of B/F/TAF**
  - **No new or unexpected safety findings**
- **These real-world data continue to support the use of B/F/TAF in clinical practice**

Results

Effectiveness

HIV-1 RNA <50 cp/mL at 12 months (M=E analysis)

of all TN participants

of all TE participants

Subgroups: HIV-1 RNA <50 cp/mL at 12 months

Female — **TN 100%** (18/18) **TE 97%** (125/129)

≥50 years — **TN 94%** (32/34) **TE 96%** (370/387)

≥65 years — **TN 100%** (6/6) **TE 93%** (63/68)

LP-AD — **TN 93%** (39/42)
Late presenters with advanced disease (CD4 count <200 cells/μL and/or ≥1 AIDS-defining event)

Persistence

Participants still on B/F/TAF at 12 months

of all TN participants

of all TE participants

103 (9%) participants discontinued B/F/TAF (9 TN/94 TE) (including 66 due to AEs, 5 due to lack of efficacy, and 6 deaths)*

*In nine participants, the AE leading to B/F/TAF discontinuation was not considered drug-related

Safety

13 %* with DRAEs

2 † serious DRAEs

6 %‡ discontinued B/F/TAF due to DRAEs

No discontinuations due to renal, hepatic, or bone AEs

6 § deaths (unrelated to B/F/TAF)

Most common DRAEs (in ≥1% overall)

Weight increase	Nausea	Depression	Headache	Fatigue	Diarrhoea	Sleep disorder
3%	1%	1%	1%	1%	1%	1%

*TN: 12% (21/180), TE: 13% (127/955); †Both in the TE group (depression); ‡TN: 4% (7/180), TE: 6% (55/955); §All in the TE group; causes: sudden death, sepsis, brain metastasis, lung cancer, heart failure, and unknown

Weight, lipid levels, and eGFR

Median (Q1, Q3)	TN (N=90)* Baseline	12 months	Median change†,‡	TE (N=532)* Baseline	12 months	Median change†,‡
Weight, kg	70.0 (62.5, 80.4)	75.9 (68.0, 84.0)	+3.4 (p<0.001)	75.9 (67.0, 87.0)	77.0 (68.0, 87.8)	+1.0 (p<0.001)
BMI, kg/m^2	22.4 (20.4, 25.7)	24.5 (21.9, 28.0)	+1.1 (p<0.001)	25.1 (22.5, 28.1)	25.5 (22.9, 28.5)	+0.3 (p<0.001)

Median (Q1, Q3)	TN (N=180) Baseline (n=127)	12 months (n=118)	Median change†,‡ (n=88)	TE (N=955) Baseline (n=652)	12 months (n=613)	Median change†,‡ (n=482)
TC, mmol/L	4.30 (3.50, 5.02)	4.74 (4.10, 5.39)	+0.24 (p=0.009)	4.73 (4.08, 5.48)	4.82 (4.09, 5.41)	-0.08 (p<0.019)
LDL, mmol/L	2.70 (n=117) (2.04, 3.20)	2.94 (n=108) (2.30, 3.59)	+0.15 (n=76) (NS)	2.92 (n=562) (2.28, 3.52)	2.95 (n=553) (2.37, 3.57)	-0.05 (n=406) (NS)
HDL, mmol/L	1.02 (n=119) (0.88, 1.30)	1.24 (n=113) (1.02, 1.42)	+0.09 (n=80) (p=0.010)	1.19 (n=574) (0.99, 1.46)	1.19 (n=563) (1.01, 1.43)	0.00 (n=418) (NS)
Triglycerides, mmol/L	1.22 (n=128) (0.84, 1.70)	1.38 (n=111) (0.89, 2.31)	+0.08 (n=87) (NS)	1.40 (n=645) (0.98, 2.10)	1.36 (n=606) (0.96, 2.08)	-0.05 (n=472) (NS)
TC/HDL ratio	4.11 (n=119) (3.26, 5.0)	3.87 (n=113) (3.20, 4.71)	-0.12 (n=80) (NS)	3.93 (n=574) (3.14, 4.71)	3.92 (n=563) (3.19, 4.73)	-0.02 (n=418) (NS)

	TN (N=180) Baseline (n=156)	12 months (n=92)	Median change†,‡ (n=80)	TE (N=955) Baseline (n=751)	12 months (n=548)	Median change†,‡ (n=470)
eGFR§, mL/min	114.22 (90.51, 133.08)	100.66 (86.08, 119.43)	-10.36 (p<0.001)	98.07 (80.53, 116.85)	97.33 (80.62, 117.66)	-3.10 (p<0.001)

*Population with weight and BMI data available at both baseline and 12 months; †Calculated as changes from baseline to 12 months for each individual participant; ‡p-values calculated using the Sign test for the absolute change from baseline within TN or TE groups; §eGFR was calculated using the Cockcroft-Gault formula.

Abbreviations
ABC, abacavir; AE, adverse event; ARV, antiretroviral; ART, antiretroviral treatment; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BMI, body mass index; CD, cluster of differentiation; CI, confidence interval; cp, copies; DRAE, drug-related adverse event; eGFR, estimated glomerular filtration rate; HDL, high-density lipoprotein; INSTI, integrase strand transfer inhibitor; LDL, low-density lipoprotein; LP-AD, late presenters with advanced disease; M=E, missing=excluded; NNRTI, non-nucleoside reverse transcriptase inhibitor; NS, not significant; PI, protease inhibitor; Q, quartile; TC, total cholesterol; TDF, tenofovir disoproxil fumarate; TE, treatment-experienced; TN, treatment-naive

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