

Efficacy and Safety of Single-Tablet BIC/LEN Compared With B/F/TAF in Maintaining Virologic Suppression Across Age, Sex, Race, and Geographic Region Subgroups in ARTISTRY-2

TUPEB103ARTISTRY-2

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Conclusions

- In this subanalysis of ARTISTRY-2, there were generally no differences in the efficacy or safety profile between a bictegravir/lenacapavir (BIC/LEN) single-tablet regimen (STR) and bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) across any of the subgroups analyzed
 - BIC/LEN maintained high rates of virologic suppression at Week 48 in all subgroups
 - Both BIC/LEN and B/F/TAF were well tolerated; discontinuations due to adverse events (AEs) were rare across treatment groups and subgroups
- These findings support the use of a BIC/LEN STR for expanding treatment options for people with HIV (PWH) with virologic suppression across different age groups, sex, race, and geographic regions

Plain Language Summary

- A new single tablet treatment for HIV, bictegravir and lenacapavir (BIC/LEN), is being studied in an ongoing trial called ARTISTRY-2
- ARTISTRY-2 previously showed that BIC/LEN was as good as the commonly used HIV treatment, bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF), at controlling the amount of HIV in participants' blood, and had a similar number of side effects, over 48 weeks
- In this analysis of ARTISTRY-2, researchers looked at whether BIC/LEN was as good as B/F/TAF in people who were:
 - Aged less than 55 years or 55 years and older
 - Male or female
 - White or non-White
 - From the US (including Puerto Rico) or outside the US
- In these groups, BIC/LEN was generally similar to B/F/TAF at controlling the amount of HIV in participants' blood, and had a similar number of side effects

Introduction

- STRs have transformed HIV treatment, improving adherence, clinical outcomes, and quality of life for PWH,^{1,2} and are guideline-recommended globally^{3,4}
- However, there is an ongoing unmet need for new and effective STR options for reasons including antiretroviral resistance, intolerance, contraindications, or drug-drug interactions⁵⁻⁷
- ARTISTRY-2 (NCT06333808) is an ongoing Phase 3 study evaluating the efficacy and safety of switching to a novel STR, BIC/LEN, compared with continuing standard-of-care treatment with a B/F/TAF STR in PWH with virologic suppression
 - BIC is a guideline-recommended integrase strand transfer inhibitor with a high barrier to resistance^{3,4,8,9}
 - LEN is a first-in-class capsid inhibitor with no documented *de novo* resistance in the absence of prior exposure¹⁰
- At Week 48, BIC/LEN was shown to be noninferior to B/F/TAF in maintaining high levels of virologic suppression, and was generally well tolerated^{11,12}

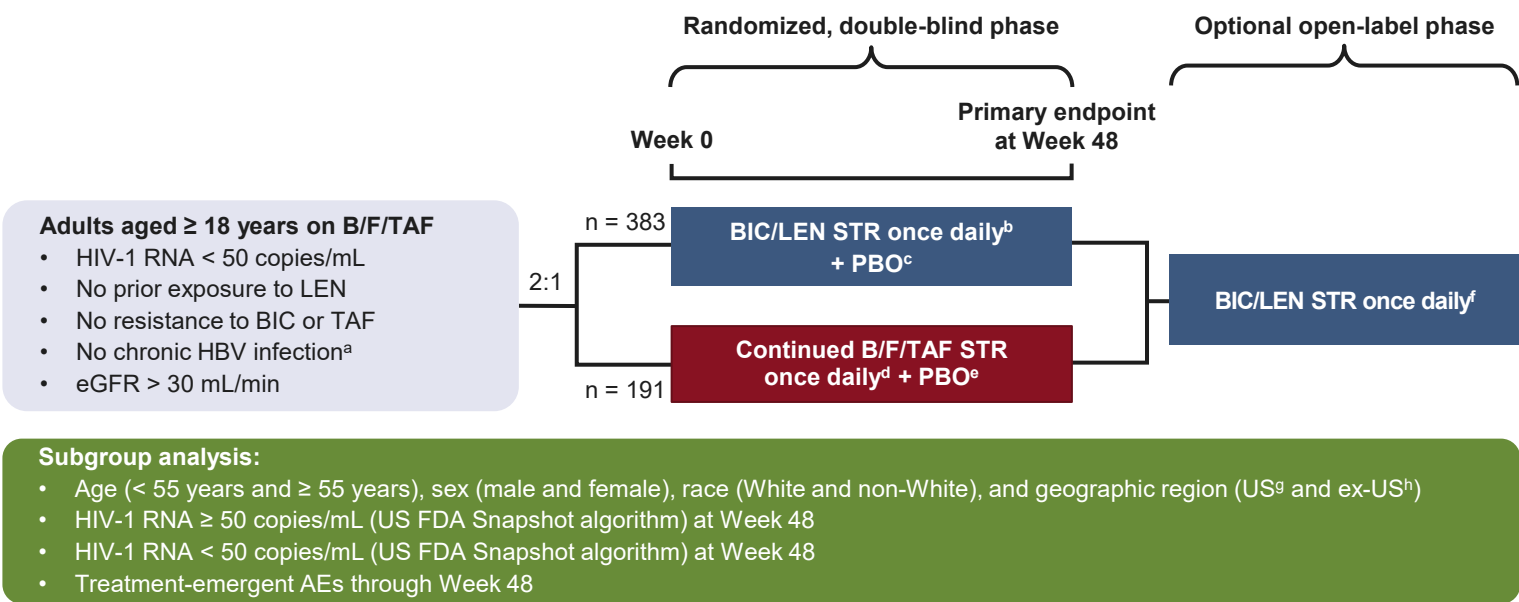
Objective

- To evaluate the efficacy and safety of switching from B/F/TAF to a BIC/LEN STR in PWH with virologic suppression in different demographic subgroups of ARTISTRY-2 participants

Methods

Phase 3 ARTISTRY-2 Study Design

- ARTISTRY-2 is a Phase 3, randomized, double-blind, active-controlled multicenter trial



^aDetermined by the following at the screening visit: either positive HBV surface antigen and negative HBV surface antibody regardless of HBV core antibody status, or positive HBV core antibody and negative HBV surface antibody regardless of HBV surface antigen status. ^bBIC/LEN 750 mg; participants received an oral loading dose of LEN 600 mg on Days 1 and 2 of treatment. ^cPlacebo-to-match B/F/TAF. ^dB/F/TAF 50/200/25 mg; participants received placebo-to-match LEN on Days 1 and 2 of treatment. ^ePlacebo-to-match BIC/LEN. ^fBIC/LEN 750 mg. ^gParticipants from US and Puerto Rico. ^hParticipants from all other countries excluding US and Puerto Rico. AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BIC, bictegravir; eGFR, estimated glomerular filtration rate; FDA, Food and Drug Administration; HBV, hepatitis B virus; LEN, lenacapavir; PBO, placebo; STR, single-tablet regimen; TAF, tenofovir alafenamide.

Results

Baseline Demographic and Disease Characteristics

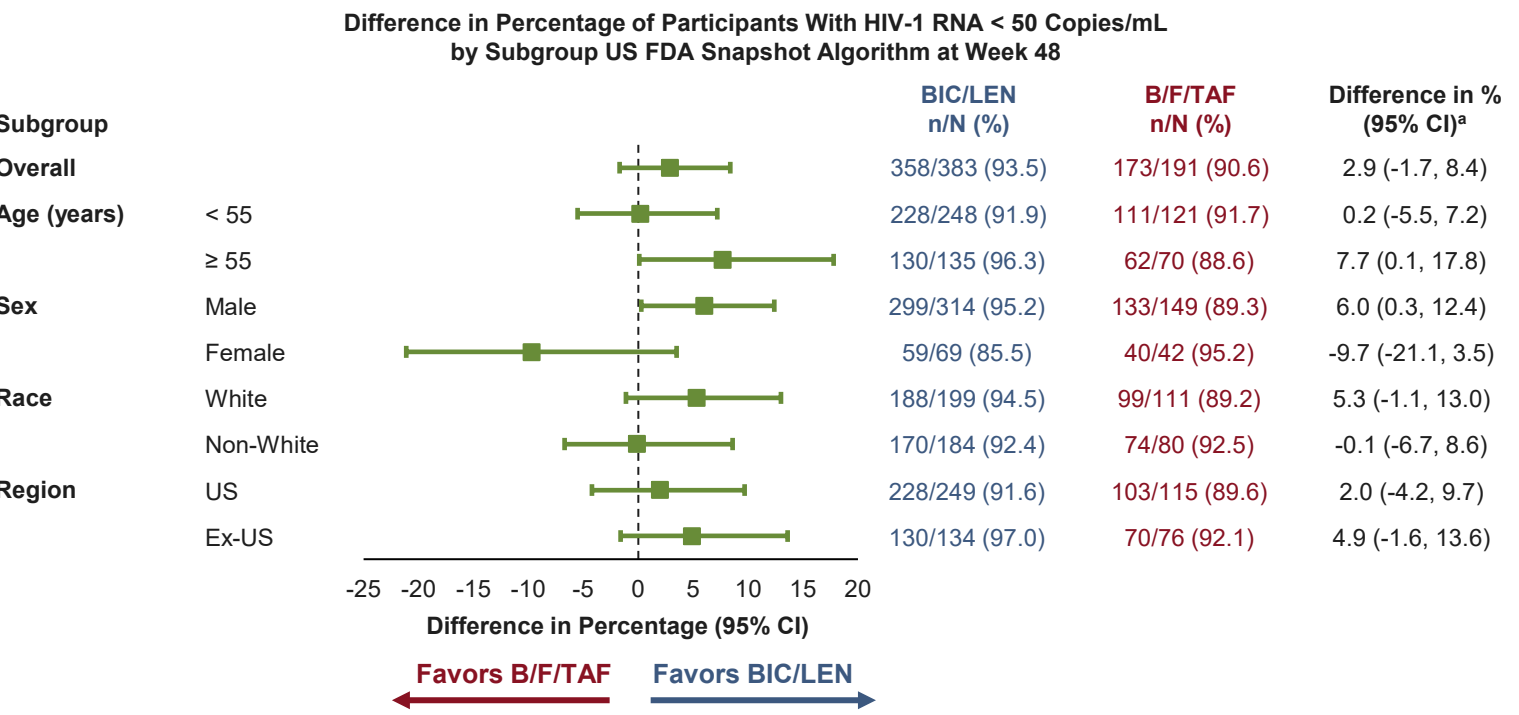
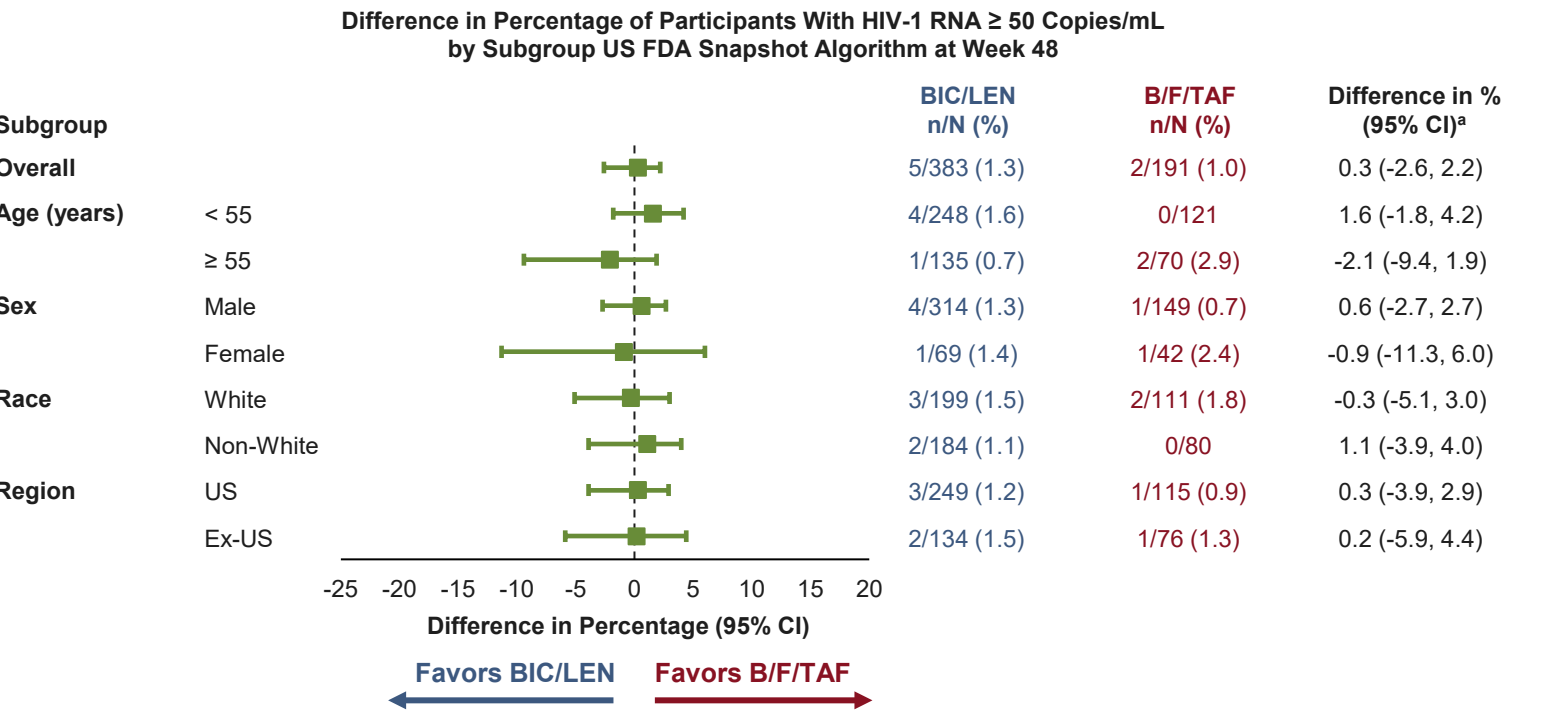
- Baseline demographic and disease characteristics were generally similar between treatment groups and subgroups

	Age < 55 Years		Age ≥ 55 Years		Male		Female		White		Non-White		US		Ex-US	
	BIC/LEN n = 248	B/F/TAF n = 121	BIC/LEN n = 135	B/F/TAF n = 70	BIC/LEN n = 314	B/F/TAF n = 149	BIC/LEN n = 69	B/F/TAF n = 42	BIC/LEN n = 199	B/F/TAF n = 111	BIC/LEN n = 184	B/F/TAF n = 80	BIC/LEN n = 249	B/F/TAF n = 115	BIC/LEN n = 134	B/F/TAF n = 76
Age, years, median (range)	41 (23-54)	45 (26-54)	62 (55-77)	62 (55-77)	46 (23-77)	51 (26-77)	53 (34-76)	56 (38-73)	52 (23-74)	52 (26-74)	45 (24-77)	50 (26-76)	50 (23-77)	52 (26-76)	46 (25-74)	51 (28-77)
Assigned female at birth, n (%)	39 (15.7)	20 (16.5)	30 (22.2)	22 (31.4)	0	0	69 (100.0)	42 (100.0)	22 (11.1)	18 (16.2)	47 (25.5)	24 (30.0)	52 (20.9)	31 (27.0)	17 (12.7)	11 (14.5)
Race, n (%)																
White	113 (45.6)	64 (52.9)	86 (63.7)	47 (67.1)	177 (56.4)	93 (62.4)	22 (31.9)	18 (42.9)	199 (100.0)	111 (100.0)	0	0	134 (53.8)	69 (60.0)	65 (48.5)	42 (55.3)
Black	67 (27.0)	27 (22.3)	46 (34.1)	17 (24.3)	69 (22.0)	24 (16.1)	44 (63.8)	20 (47.6)	0	0	113 (61.4)	44 (55.0)	102 (41.0)	41 (35.7)	11 (8.2)	3 (3.9)
Asian	51 (20.6)	23 (19.0)	0	3 (4.3)	50 (15.9)	24 (16.1)	1 (1.4)	2 (4.8)	0	0	51 (27.7)	26 (32.5)	2 (0.8)	0	49 (36.6)	26 (34.2)
Other ^a	17 (6.9)	7 (5.8)	3 (2.2)	3 (4.3)	18 (5.7)	8 (5.4)	2 (2.9)	2 (4.8)	0	0	20 (10.9)	10 (12.5)	11 (4.4)	5 (4.3)	9 (6.7)	5 (6.6)
Hispanic or Latine, ^b n (%)	74 (29.8)	35 (28.9)	32 (23.7)	14 (20.0)	89 (28.3)	39 (26.2)	17 (24.6)	10 (23.8)	74 (37.2)	42 (37.8)	32 (17.4)	7 (8.8)	78 (31.3)	34 (29.6)	28 (20.9)	15 (19.7)
CD4 count, cells/ μ L, median (Q1, Q3)	738 (572, 936)	681 (532, 867)	651 (500, 898)	641 (506, 873)	693 (530, 898)	653 (496, 837)	806 (619, 974)	740 (585, 1097)	712 (541, 915)	639 (496, 835)	701 (554, 913)	695 (546, 946)	713 (565, 907)	711 (540, 930)	691 (507, 942)	603 (512, 833)
Selected comorbidities, ^{c,d} n (%)																
Dyslipidemia	71 (28.6)	38 (31.4)	87 (64.4)	41 (58.6)	132 (42.0)	60 (40.3)	26 (37.7)	19 (45.2)	99 (49.7)	48 (43.2)	59 (32.1)	31 (38.8)	123 (49.4)	60 (52.2)	35 (26.1)	19 (25.0)
Hypertension	55 (22.2)	27 (22.3)	86 (63.7)	36 (51.4)	105 (33.4)	42 (28.2)	36 (52.2)	21 (50.0)	75 (37.7)	32 (28.8)	66 (35.9)	31 (38.8)	111 (44.6)	55 (47.8)	30 (22.4)	8 (10.5)
Hyperglycemia/diabetes mellitus	23 (9.3)	15 (12.4)	45 (33.3)	16 (22.9)	43 (13.7)	17 (11.4)	25 (36.2)	14 (33.3)	32 (16.1)	9 (8.1)	36 (19.6)	22 (27.5)	61 (24.5)	28 (24.3)	7 (5.2)	3 (3.9)
Chronic kidney disease	4 (1.6)	7 (5.8)	16 (11.9)	5 (7.1)	15 (4.8)	7 (4.7)	5 (7.2)	5 (11.9)	11 (5.5)	3 (2.7)	9 (4.9)	9 (11.3)	16 (6.4)	10 (8.7)	4 (3.0)	2 (2.6)
Number of selected comorbidities, n (%)																
1	56 (22.6)	33 (27.3)	38 (28.1)	24 (34.3)	83 (26.4)	46 (30.9)	11 (15.9)	11 (26.2)	55 (27.6)	37 (33.3)	39 (21.2)	20 (25.0)	59 (23.7)	35 (30.4)	35 (26.1)	22 (28.9)
≥ 2	45 (18.1)	23 (19.0)	76 (56.3)	29 (41.4)	88 (28.0)	34 (22.8)	33 (47.8)	18 (42.9)	68 (34.2)	25 (22.5)	53 (28.8)	27 (33.8)	102 (41.0)	47 (40.9)	19 (14.2)	5 (6.6)

^aCategory includes American Indian or Alaska Native, Native Hawaiian, Pacific Islander, and other. ^bLocal regulators did not allow the collection of ethnicity information for one participant in the B/F/TAF group who was aged < 55 years, male, non-White, and from the US. ^cCategories are not mutually exclusive. ^dGrouped terms on standardized MedDRA query narrow search. B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BIC, bictegravir; CD4, cluster of differentiation 4; LEN, lenacapavir; MedDRA, Medical Dictionary for Regulatory Activities; Q, quartile.

Virologic Outcomes at Week 48 (US FDA Snapshot Algorithm)

- Overall, at Week 48, BIC/LEN maintained high rates of virologic suppression after switching from B/F/TAF
 - The proportions of participants with HIV-1 RNA $\geq$ 50 copies/mL and < 50 copies/mL were generally comparable in those receiving BIC/LEN and those continuing B/F/TAF across subgroups



Virologic data were not available for 36 participants (BIC/LEN, n = 20; B/F/TAF, n = 16). The Week 48 window was between Days 295 and 378 (inclusively). ^aDifferences in percentages of participants between treatment groups (BIC/LEN minus B/F/TAF) and 95% CIs were calculated based on an unconditional exact method using two inverted one-sided tests. On-treatment values included all available data for ongoing participants or up to the last dose date + 1 day for participants who discontinued study drug prematurely. B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BIC/LEN, bictegravir/lenacapavir; CI, confidence interval; FDA, Food and Drug Administration.

Safety Outcomes Through Week 48

- The incidence of drug-related AEs was low in the BIC/LEN and B/F/TAF groups, and was generally similar across subgroups
 - Most drug-related AEs were Grade 1/2 and no serious drug-related AEs were reported
- Study drug discontinuations due to AEs were rare

	Age < 55 Years		Age ≥ 55 Years		Male		Female		White		Non-White		US		Ex-US	
	BIC/LEN n = 248	B/F/TAF n = 121	BIC/LEN n = 135	B/F/TAF n = 70	BIC/LEN n = 314	B/F/TAF n = 149	BIC/LEN n = 69	B/F/TAF n = 42	BIC/LEN n = 199	B/F/TAF n = 111	BIC/LEN n = 184	B/F/TAF n = 80	BIC/LEN n = 249	B/F/TAF n = 115	BIC/LEN n = 134	B/F/TAF n = 76
≥ 1 AE ^a	188 (75.8)	92 (76.0)	100 (74.1)	49 (70.0)	233 (74.2)	112 (75.2)	55 (79.7)	29 (69.0)	144 (72.4)	82 (73.9)	144 (78.3)	59 (73.8)	179 (71.9)	83 (72.2)	109 (81.3)	58 (76.3)
≥ 1 Grade 3/4 AE	24 (9.7)	12 (9.9)	14 (10.4)	3 (4.3)	27 (8.6)	13 (8.7)	11 (15.9)	2 (4.8)	18 (9.0)	7 (6.3)	20 (10.9)	8 (10.0)	31 (12.4)	14 (12.2)	7 (5.2)	1 (1.3)
≥ 1 serious AE	16 (6.5)	8 (6.6)	11 (8.1)	5 (7.1)	17 (5.4)	11 (7.4)	10 (14.5)	2 (4.8)	12 (6.0)	8 (7.2)	15 (8.2)	5 (6.3)	24 (9.6)	12 (10.4)	3 (2.2)	1 (1.3)
≥ 1 drug-related AE	27 (10.9)	15 (12.4)	13 (9.6)	8 (11.4)	36 (11.5)	19 (12.8)	4 (5.8)	4 (9.5)	20 (10.1)	13 (11.7)	20 (10.9)	10 (12.5)	21 (8.4)	13 (11.3)	19 (14.2)	10 (13.2)
≥ 1 Grade 3/4 drug-related AE ^b	1 (0.4)	0	0	0	1 (0.3)	0	0	0	1 (0.5)	0	0	0	1 (0.4)	0	0	0
≥ 1 serious drug-related AE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
≥ 1 AE leading to study treatment discontinuation ^c	4 (1.6)	2 (1.7)	2 (1.5)	1 (1.4)	3 (1.0)	3 (2.0)	3 (4.3)	0	1 (0.5)	2 (1.8)	5 (2.7)	1 (1.3)	5 (2.0)	2 (1.7)	1 (0.7)	1 (1.3)
Death ^d	0	0	0	1 (1.4)	0	1 (0.7)	0	0	0	0	0	1 (1.3)	0	1 (0.9)	0	0

^aAEs with $\geq$ 5% frequency in the BIC/LEN or B/F/TAF groups, overall: nasopharyngitis (BIC/LEN n = 30 [7.8%], B/F/TAF n = 13 [6.8%]), diarrhea (BIC/LEN n = 31 [8.1%], B/F/TAF n = 9 [4.7%]), upper respiratory tract infection (BIC/LEN n = 29 [7.6%], B/F/TAF n = 9 [4.7%]), nausea (BIC/LEN n = 20 [5.2%], B/F/TAF n = 11 [5.8%]), headache (BIC/LEN n = 22 [5.7%]), B/F/TAF n = 6 [3.1%]), and COVID-19 (BIC/LEN n = 5 [1.3%], B/F/TAF n = 10 [5.2%]). ^bOne Grade 3 AE of rhabdomyolysis was reported (BIC/LEN, age < 55 years, male, White, US). ^cBIC/LEN: anxiety (n = 1; age < 55 years, male, White, US), colon cancer (n = 1; age $\geq$ 55 years, male, non-White, US), decreased libido (n = 1; age < 55 years, male, non-White, US), and encephalopathy and intracranial mass (n = 1; age $\geq$ 55 years, female, non-White, US), all deemed unrelated to study treatment; alopecia and fatigue (n = 1; age < 55 years, female, non-White, US), all deemed related to study treatment. B/F/TAF: abdominal discomfort (n = 1; age $\geq$ 55 years, male, White, US) and road traffic accident (n = 1; age < 55 years, male, White, US), both deemed unrelated to study treatment; dry mouth (n = 1; age < 55 years, male, non-White, ex-US), deemed related to study treatment. ^dOne death due to coronary artery disease (B/F/TAF; age $\geq$ 55 years, male, non-White, US), deemed unrelated to study treatment. AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BIC/LEN, bictegravir/lenacapavir.

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