

Metabolic and Safety Outcomes With BIC/LEN Single-Tablet Regimen in People With HIV and Comorbidities in ARTISTRY-2

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Conclusions

- In this subanalysis of ARTISTRY-2, metabolic outcomes, including fasting lipid parameters, glucose levels, and body weight, remained stable at Week 48 in people with HIV who switched to bicitegravir/lenacapavir (BIC/LEN) or remained on bicitegravir/emtricitabine/tenofovir alafenamide (B/F/TAF), regardless of baseline comorbidities
- The proportions of participants using lipid-lowering, antihypertensive, antidiabetic and glucagon-like peptide 1 (GLP-1) medications during the study were similar in the BIC/LEN and B/F/TAF groups
- BIC/LEN was well tolerated through 48 weeks of treatment in people with HIV and select comorbidities of dyslipidemia, hypertension, hyperglycemia/diabetes mellitus, and chronic kidney disease
- Rates of adverse events (AEs) were generally similar with BIC/LEN and B/F/TAF within each select baseline comorbidity group, with very few discontinuations due to AEs
- These data support BIC/LEN single-tablet regimen (STR) as a new option for virologically suppressed people with HIV, including those with comorbidities

Plain Language Summary

- People with human immunodeficiency virus (HIV) are more likely to get other health conditions as they get older than people in the general population
 - These health conditions can include high levels of cholesterol or other fats in the blood, high blood pressure, diabetes, and kidney disease
- In the ARTISTRY-2 study, switching to a new single-tablet HIV treatment, bicitegravir and lenacapavir (BIC/LEN), was as effective and well tolerated as continuing with the commonly used HIV medicine bicitegravir/emtricitabine/tenofovir alafenamide (B/F/TAF)
- In this analysis of ARTISTRY-2, researchers wanted to find out whether switching to BIC/LEN affected levels of cholesterol and other fats in the blood, blood sugar levels, or body weight compared with continuing B/F/TAF
- Researchers also looked at side effects in people with HIV who had concerns about their cholesterol, blood pressure, blood sugar, or kidney health
- There were no meaningful changes in blood levels of cholesterol and other fats, blood sugar levels, or body weight in people who switched to BIC/LEN or those who continued taking B/F/TAF
- Across all health conditions studied, people generally had a similar number of side effects whether they took BIC/LEN or B/F/TAF

Introduction

- Comorbidities are more common among people with HIV than in the general population, with prevalence increasing as individuals age¹
- BIC/LEN is a novel once-daily STR that combines BIC,^{2,4} a guideline-recommended integrase strand-transfer inhibitor, and LEN, a first-in-class capsid inhibitor with no documented *de novo* resistance in the absence of prior exposure⁵
- In two Phase 3 trials, switching to BIC/LEN STR was noninferior in maintaining virologic suppression compared with:
 - Continuing complex HIV treatment regimens (ARTISTRY-1; NCT05502341),⁶ or
 - Standard-of-care B/F/TAF (ARTISTRY-2; NCT06333808)⁷
- In both trials,^{6,7} BIC/LEN was well tolerated through Week 48
- In ARTISTRY-1, fasting lipid levels improved after switching from a complex regimen to BIC/LEN⁶

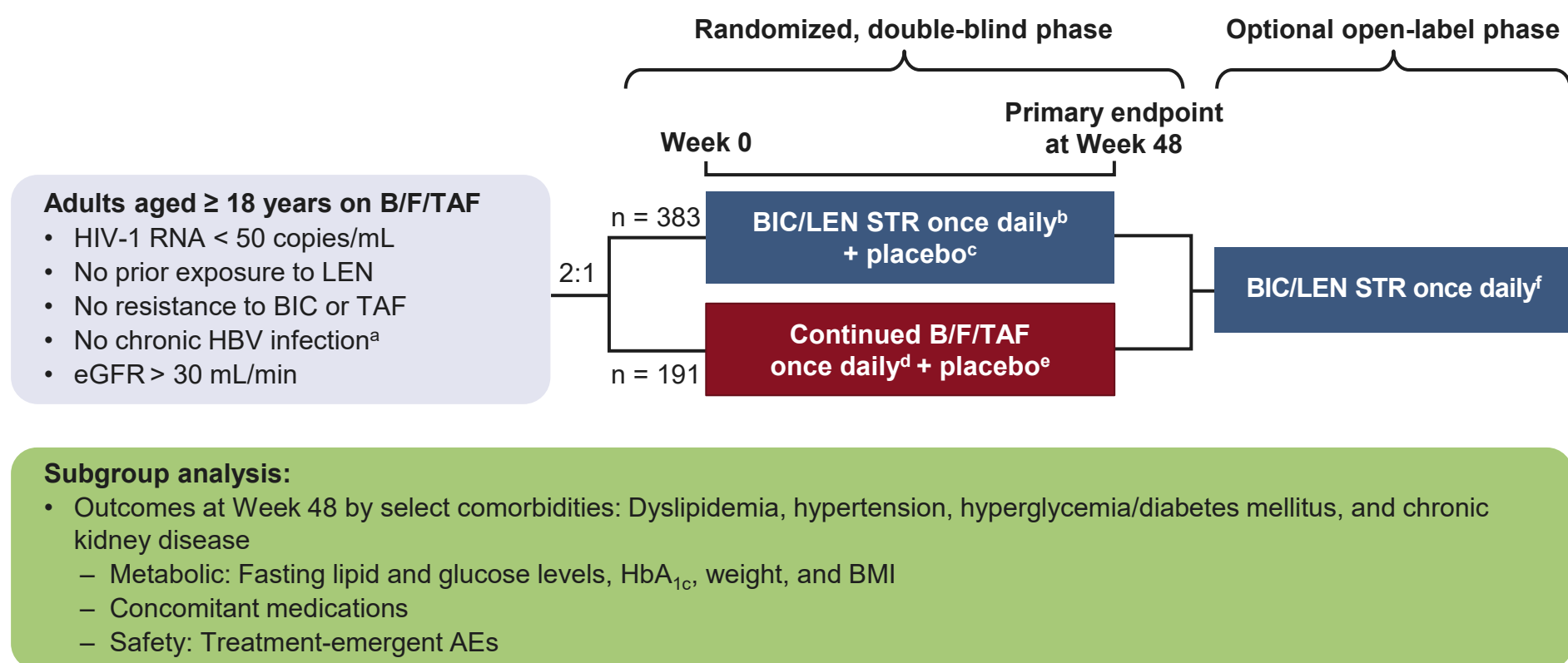
Objective

- To evaluate metabolic and safety outcomes in people with HIV and dyslipidemia, hypertension, hyperglycemia/diabetes mellitus, or chronic kidney disease through Week 48 of ARTISTRY-2

Methods

- ARTISTRY-2 is an ongoing, Phase 3, randomized, double-blind, active-controlled, multicenter clinical trial (NCT06333808)³ (**Figure 1**)

Figure 1. Phase 3 ARTISTRY-2 Study Design



^aDetermined by either of the following at the screening visit: 1) positive HBV surface antigen and negative HBV surface antibody results, regardless of HBV core antibody status; or 2) positive HBV core antibody and negative HBV surface antibody results, regardless of HBV surface antigen status. ^bBIC/LEN 75/50 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 75/50 mg. AE, adverse event; B/F/TAF, bicitegravir/emtricitabine/tenofovir alafenamide; BIC, bicitegravir; BMI, body mass index; eGFR, estimated glomerular filtration; HbA_{1c}, glycated hemoglobin; HBV, hepatitis B virus; LEN, lenacapavir; STR, single-tablet regimen; TAF, tenofovir alafenamide.

Results

Table 1. Baseline Demographics and Select Clinical Characteristics

	BIC/LEN n = 383	B/F/TAF n = 191	Total N = 574
Age, years, median (range)	47 (23-77)	51 (26-77)	49 (23-77)
Assigned female at birth, n (%)	69 (18)	42 (22)	111 (19)
Race, n (%)			
White	199 (52)	111 (58)	310 (54)
Black	113 (30)	44 (23)	157 (27)
Asian	51 (13)	26 (14)	77 (13)
Other ^a	20 (5)	10 (5)	30 (5)
Hispanic or Latine ethnicity, ^b n (%)	106 (28)	49 (26)	155 (27)
Select comorbidities, ^{c,d} n (%)			
Dyslipidemia	158 (41)	79 (41)	237 (41)
Hypertension	141 (37)	63 (33)	204 (36)
Hyperglycemia/diabetes mellitus	68 (18)	31 (16)	99 (17)
Chronic kidney disease	20 (5)	12 (6)	32 (6)
≥ 2 of these comorbidities	121 (32)	52 (27)	173 (30)

^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. ^cCategories are not mutually exclusive. ^dGrouped terms on standardized MedDRA query narrow search. B/F/TAF, bicitegravir/emtricitabine/tenofovir alafenamide; BIC/LEN, bicitegravir/lenacapavir; MedDRA, Medical Dictionary for Regulatory Activities.

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Results (cont.)

Metabolic Outcomes

Table 2. Absolute Change From Baseline in Fasting Lipid Parameters at Week 48 in Participants With Dyslipidemia at Baseline

Median (Q1, Q3)	Overall		Dyslipidemia at Baseline	
	BIC/LEN n = 383	B/F/TAF n = 191	BIC/LEN n = 158	B/F/TAF n = 79
Fasting total cholesterol at baseline, mg/dL	172 (152, 197) n = 367	172 (150, 201) n = 187	168 (144, 194) n = 156	166 (148, 195) n = 77
Change at Week 48, mg/dL	0 (-16, 17) n = 343	1 (-11, 18) n = 162	-2 (-20, 17) n = 145	-1 (-12, 12) n = 70
Fasting LDL cholesterol at baseline, mg/dL	99 (80, 125) n = 367	99 (82, 124) n = 187	93 (74, 116) n = 156	95 (82, 116) n = 77
Change at Week 48, mg/dL	1 (-12, 15) n = 343	3 (-8, 16) n = 162	-1 (-13, 18) n = 145	1 (-9, 12) n = 70
Fasting HDL cholesterol at baseline, mg/dL	48 (41, 57) n = 366	47 (39, 58) n = 187	46 (41, 56) n = 155	46 (40, 58) n = 77
Change at Week 48, mg/dL	0 (-4, 5) n = 341	0 (-3, 5) n = 162	0 (-5, 5) n = 144	-1 (-3, 4) n = 70
Fasting total:HDL cholesterol ratio at baseline	3.5 (3.0, 4.4) n = 366	3.7 (3.0, 4.4) n = 187	3.5 (2.9, 4.3) n = 155	3.5 (3.0, 4.1) n = 77
Change at Week 48	-0.1 (-0.4, 0.3) n = 341	0.0 (-0.3, 0.3) n = 162	0.0 (-0.6, 0.5) n = 144	0.0 (-0.3, 0.3) n = 70
Fasting triglycerides at baseline, mg/dL	102 (74, 148) n = 366	101 (76, 151) n = 187	110 (78, 165) n = 155	100 (75, 155) n = 77
Change at Week 48, mg/dL	0 (-29, 25) n = 341	-5 (-27, 23) n = 162	-3 (-30, 27) n = 144	-6 (-33, 34) n = 70

Dyslipidemia was identified by MedDRA, version 28.0, using a standardized MedDRA query narrow search. B/F/TAF, bicitegravir/emtricitabine/tenofovir alafenamide; BIC/LEN, bicitegravir/lenacapavir; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MedDRA, Medical Dictionary for Regulatory Activities; Q, quartile.

Table 3. Absolute Change From Baseline in Metabolic Outcomes at Week 48 in Participants With Hyperglycemia/Diabetes Mellitus at Baseline

Median (Q1, Q3)	Overall		Hyperglycemia/ Diabetes Mellitus at Baseline	
	BIC/LEN n = 383	B/F/TAF n = 191	BIC/LEN n = 68	B/F/TAF n = 31
HbA_{1c} at baseline, %	5.3 (5.1, 5.7) n = 377	5.3 (5.0, 5.7) n = 188	6.2 (5.6, 6.7) n = 67	5.9 (5.6, 6.5) n=31
Change at Week 48, %	0.1 (-0.1, 0.3) n = 354	0.1 (-0.1, 0.3) n = 170	0.1 (-0.2, 0.3) n = 66	0.0 (-0.2, 0.5) n = 29
Fasting glucose at baseline, mg/dL	93 (86, 102) n = 375	94 (87, 102) n = 190	108 (94, 126) n = 66	109 (95, 124) n = 29
Change at Week 48, mg/dL	0 (-7, 6) n = 354	-1 (-7, 7) n = 172	1 (-13, 12) n = 66	-1 (-7, 11) n = 29
Weight at baseline, kg	81.1 (71.7, 92.4) n = 361	81.1 (72.0, 94.1) n = 173	88.5 (79.4, 111.1) n = 67	95.6 (83.5, 108.0) n = 29
Change at Week 48, kg	-0.2 (-2.5, 1.8) n = 361	0.0 (-2.2, 2.3) n = 173	-0.2 (-3.1, 1.9) n = 67	0.0 (-3.8, 2.8) n = 29
BMI at baseline, kg/m²	26.8 (24.2, 30.3) n = 361	27.1 (24.1, 31.2) n = 173	29.8 (27.0, 38.2) n = 67	33.2 (30.4, 36.0) n = 29
Change at Week 48, kg/m ²	-0.1 (-0.8, 0.6) n = 361	0.0 (-0.7, 0.7) n = 173	-0.1 (-1.2, 0.6) n = 67	0.0 (-1.4, 1.1) n = 29

Hyperglycemia/diabetes mellitus was identified by MedDRA, version 28.0, using a standardized MedDRA query narrow search. Participant numbers are shown only if they differ from the column headers. B/F/TAF, bicitegravir/emtricitabine/tenofovir alafenamide; BIC/LEN, bicitegravir/lenacapavir; BMI, body mass index; HbA_{1c}, glycated hemoglobin; MedDRA, Medical Dictionary for Regulatory Activities; Q, quartile.

- There were no clinically significant changes from baseline to Week 48 in fasting lipid levels with either BIC/LEN or B/F/TAF in participants with dyslipidemia at baseline and in the overall population (**Table 2**)
- There were no clinically significant changes in fasting glucose levels or body weight from baseline to Week 48 in participants with hyperglycemia/diabetes mellitus at baseline in both treatment groups and in the overall population (**Table 3**)

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Concomitant Medications

Table 4. Select Concomitant Medication Use

n (%)	BIC/LEN n = 383	B/F/TAF n = 191	Total N = 574
Lipid-lowering agents	157 (41)	77 (40)	234 (41)
Use at baseline	139 (36)	73 (38)	212 (37)
Use at Week 48	155 (41)	76 (40)	231 (40)
Initiated during the study ^a	18 (5)	4 (2)	22 (4)
Stopped during the study ^b	3 (1)	3 (2)	6 (1)
Antihypertensive agents	160 (42)	68 (36)	228 (40)
Use at baseline	140 (37)	62 (33)	202 (35)
Use at Week 48	152 (40)	66 (35)	218 (38)
Initiated during the study ^a	20 (5)	6 (3)	26 (5)
Stopped during the study ^b	3 (1)	2 (1)	5 (1)
Antidiabetic agents	71 (19)	24 (13)	95 (17)
Use at baseline	58 (15)	20 (11)	78 (14)
Use at Week 48	70 (18)	23 (12)	93 (16)
Initiated during the study ^a	13 (3)	4 (2)	17 (3)
Stopped during the study ^b	1 (< 1)	3 (2)	4 (1)
GLP-1 agents	45 (12)	13 (7)	58 (10)
Use at baseline	27 (7)	10 (5)	37 (6)
Use at Week 48	42 (11)	11 (6)	53 (9)
Initiated during the study ^a	18 (5)	3 (2)	21 (4)
Stopped during the study ^b	4 (1)	3 (2)	7 (1)

Medications were coded using WHODrug Dictionary (BMAR25 update). ^a"Initiated during the study" refers to participants who did not take that class of medication at baseline but who started it during the study. ^b"Stopped during the study" refers to participants who took that class of medication at baseline and stopped all medications of this class during study. B/F/TAF, bicitegravir/emtricitabine/tenofovir alafenamide; BIC/LEN, bicitegravir/lenacapavir; GLP-1, glucagon-like peptide 1.

- Across lipid-lowering, antihypertensive, antidiabetic, and GLP-1 agent medication classes, medication use over 48 weeks remained generally stable and comparable between the BIC/LEN and B/F/TAF groups (**Table 4**)

Safety

Table 5. Safety Outcomes Through Week 48 Stratified by Select Comorbidities at Baseline and in the Overall Population

Participants, n (%)	Overall		Dyslipidemia		Hypertension		Hyperglycemia/ Diabetes Mellitus		Chronic Kidney Disease	
	BIC/LEN n = 383	B/F/TAF n = 191	BIC/LEN n = 158	B/F/TAF n = 79	BIC/LEN n = 141	B/F/TAF n = 63	BIC/LEN n = 68	B/F/TAF n = 31	BIC/LEN n = 20	B/F/TAF n = 12
AEs – any grade	288 (75)	141 (74)	122 (77)	63 (80)	110 (78)	43 (68)	57 (84)	18 (58)	16 (80)	8 (67)
Grade ≥ 3	38 (10)	15 (8)	16 (10)	7 (9)	15 (11)	6 (10)	8 (12)	3 (10)	2 (10)	1 (8)
Serious	27 (7)	13 (7)	9 (6)	7 (9)	10 (7)	5 (8)	6 (9)	2 (7)	1 (5)	0
DRAEs – any grade	40 (10)	23 (12)	15 (10)	7 (9)	10 (7)	4 (6)	4 (6)	5 (16)	5 (25)	0
Grade ≥ 3	1 (< 1) ^a	0	1 (1) ^a	0	0	0	0	0	0	0
Serious	0	0	0	0	0	0	0	0	0	0
AEs leading to treatment discontinuation	6 (2)	3 (2)	3 (2)	0	2 (1)	1 (2)	1 (2)	0	1 (5)	1 (8)
Deaths	0	1 (1)	0	1 (1)	0	1 (2)	0	1 (3)	0	0

Severity grades were defined by the Division of AIDS Toxicity Grading Scale, version 2.1. ^aOne participant in the BIC/LEN group had drug-related Grade 3 rhabdomyolysis, which resolved without a dose change or interruption and was subsequently revised to Grade 1 after the cutoff date for this analysis. AE, adverse event; B/F/TAF, bicitegravir/emtricitabine/tenofovir alafenamide; BIC/LEN, bicitegravir/lenacapavir; DRAE, drug-related adverse event.

- The incidences of drug-related AEs were low and generally similar in the BIC/LEN and B/F/TAF groups, for each of the selected comorbidities and for the overall population (**Table 5**)
 - Most drug-related AEs were Grade 1/2
 - There were no serious drug-related AEs
- Few participants discontinued treatment due to drug-related AEs

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