Efficacy and Safety of BIC/LEN Single-Tablet Regimen in Virologically Suppressed People With HIV Aged ≥ 65 Years: Week 48 Analysis of Participants in the Phase 3 Portion of ARTISTRY-1

TUPEB096

ARTISTRY-1

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Conclusions

- In the Phase 3 portion of ARTISTRY-1, bictegravir/lenacapavir (BIC/LEN) single-tablet regimen (STR) maintained high rates of virologic suppression in people with HIV aged ≥ 65 years and < 65 years through Week 48
- Cluster of differentiation 4 (CD4) cell counts remained stable with BIC/LEN independent of age group
- BIC/LEN was generally well tolerated by participants in all age groups, with low rates of discontinuation due to adverse events (AEs)
  - The incidence of AEs with BIC/LEN was similar across age groups
- Renal function was stable across both age groups and treatments
- Treatment satisfaction increased after switching to BIC/LEN across both age groups and remained stable in the complex regimen group
- These data support BIC/LEN as a long-term treatment option for older people with HIV on complex regimens who have a high burden of cardiometabolic comorbidities, declining renal function, and high use of concomitant medications

Plain Language Summary

- Older people with human immunodeficiency virus (HIV) often have other health conditions that also require treatment
- Being older, having other health conditions, and taking other medications can make HIV more difficult to treat
- The ARTISTRY-1 clinical trial looked at two HIV medicines, bictegravir (BIC) and lenacapavir (LEN), taken together once a day as one tablet in people with HIV who switched from a complex HIV regimen
  - BIC/LEN worked equally well at treating HIV and was as well tolerated as continuing a complex multi-tablet HIV treatment
- In this analysis of the study, researchers wanted to find out if BIC/LEN was as effective and well tolerated in people who were aged 65 years or older as in younger people, and to compare it with complex multi-tablet HIV treatment
- BIC/LEN worked well to control HIV and was as well tolerated in people aged 65 or older as in younger people
  - Researchers saw similar results with BIC/LEN and complex multi-tablet treatment

Introduction

- Advances in HIV treatment have led to a growing proportion of people aging with HIV-1
- Many people with HIV, especially older individuals with a long history of antiretroviral therapy, multiple comorbidities, and concomitant medications, require complex multi-tablet antiretroviral regimens[1-3]
- A novel BIC/LEN STR could optimize treatment for people with virologic suppression on complex regimens who are unable to use available STRs due to virologic resistance, intolerance, contraindications, or drug-drug interactions
- ARTISTRY-1, a Phase 2/3, randomized, open-label, multicenter trial of once-daily oral BIC/LEN STR, included the oldest population to date in a registrational program for HIV treatment[4-6]
- In the primary analysis of Phase 3 of the trial, switching to BIC/LEN STR from complex regimens showed noninferior efficacy, comparable safety, and improved treatment satisfaction versus continuing complex regimens in people with HIV who were virologically suppressed[6]

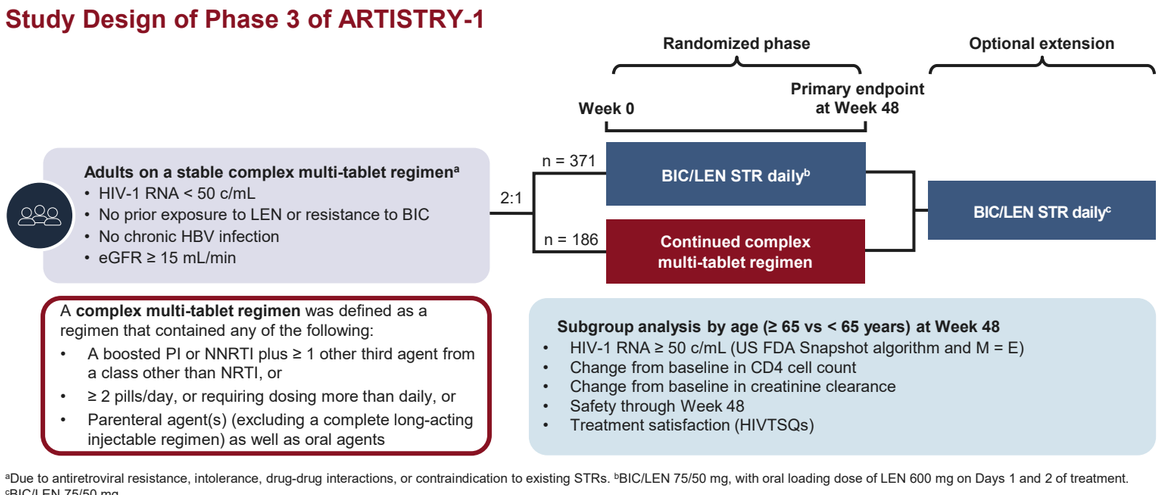
Objective

- To evaluate the efficacy and safety of switching from a complex regimen to BIC/LEN STR in people who are virologically suppressed in ARTISTRY-1, stratified by age subgroup (≥ 65 vs < 65 years)

Methods

- ARTISTRY-1 (NCT05502341) is an open-label, randomized, multicenter, active-controlled trial[6]

Study Design of Phase 3 of ARTISTRY-1



[a]Due to antiretroviral resistance, intolerance, drug-drug interactions, or contraindication to existing STRs. [b]BIC/LEN 75/50 mg, with oral loading dose of LEN 600 mg on Days 1 and 2 of treatment. [c]BIC/LEN 75/50 mg.
BIC, bictegravir; c, copies; CD4, cluster of differentiation 4; eGFR, estimated glomerular filtration rate; FDA, Food and Drug Administration; HBV, hepatitis B virus; HIVTSQs, HIV Treatment Satisfaction Questionnaire: status version; LEN, lenacapavir; M = E, missing = excluded; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PI, protease inhibitor; STR, single-tablet regimen.

Results

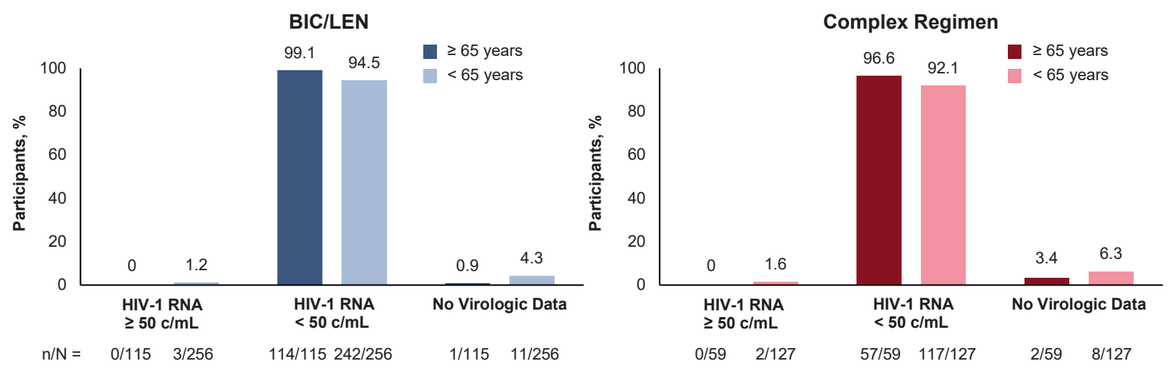
Baseline Demographics and Clinical Characteristics

	BIC/LEN		Complex Regimen	
	Aged ≥ 65 Years n = 115	Aged < 65 Years n = 256	Aged ≥ 65 Years n = 59	Aged < 65 Years n = 127
Age, years, median (range)	69 (65-84)	58 (22-64)	69 (65-75)	57 (24-64)
Male sex at birth, n (%)	104 (90.4)	203 (79.3)	57 (96.6)	93 (73.2)
Race, n (%)[a]				
White	83 (72.2)	177 (69.1)	49 (83.1)	75 (59.1)
Black	20 (17.4)	44 (17.2)	3 (5.1)	30 (23.6)
Asian	1 (0.9)	15 (5.9)	0	9 (7.1)
Other[b]	4 (3.5)	8 (3.1)	1 (1.7)	2 (1.6)
Hispanic or Latine, n (%)[c]	19 (16.5)	61 (23.8)	10 (16.9)	32 (25.2)
CD4 count, cells/µL, median (Q1, Q3)	614 (448, 808)	626 (463, 861)	595 (492, 711)	548 (426, 770)
CD4 count < 200 cells/µL, n (%)	3 (2.6)	9 (3.5)	1 (1.7)	4 (3.1)
Duration of HIV treatment, years, median (Q1, Q3)	30.4 (26.0, 34.8)	27.4 (19.6, 30.8)	30.3 (27.8, 34.5)	26.4 (16.5, 29.9)
Baseline ART, pills/day, median (range)	3.0 (2.0, 10.0)	3.0 (2.0, 11.0)	3.0 (2.0, 8.0)	3.0 (2.0, 9.0)
PI-containing regimen at baseline, n (%)	80 (69.6)	199 (77.7)	45 (76.3)	103 (81.1)
Reason for being on a complex regimen, n (%)				
History of resistance	90 (78.3)	207 (80.9)	52 (88.1)	101 (79.5)
Intolerance to components of STRs	24 (20.9)	65 (25.4)	16 (27.1)	23 (18.1)
Contraindication to STRs	11 (9.6)	12 (4.7)	4 (6.8)	6 (4.7)
Select comorbidities,[d] n (%)				
Dyslipidemia	96 (83.5)	148 (57.8)	50 (84.7)	83 (65.4)
Hypertension	69 (60.0)	121 (47.3)	40 (67.8)	50 (39.4)
Hyperglycemia/diabetes mellitus	46 (40.0)	45 (17.6)	24 (40.7)	18 (14.2)
Chronic kidney disease	24 (20.9)	25 (9.8)	11 (18.6)	18 (14.2)
≥ 2 of select comorbidities, n (%)	84 (73.0)	118 (46.1)	44 (74.6)	52 (40.9)
Select concomitant medications,[e] n (%)				
Antidiabetics	36 (31.3)	48 (18.8)	21 (35.6)	23 (18.1)
Antihypertensives	77 (67.0)	126 (49.2)	43 (72.9)	58 (45.7)
Lipid-lowering agents	101 (87.8)	161 (62.9)	50 (84.7)	84 (66.1)
≥ 2 of select concomitant medications, n (%)	90 (78.3)	147 (57.4)	44 (74.6)	58 (45.7)

[a]Local regulators did not allow the collection of race information for participants receiving BIC/LEN (n = 7 in the ≥ 65 years group and n = 12 in the < 65 years group) and complex regimen (n = 6 and n = 11, respectively); percentages were calculated using total number of participants as the denominator. [b]Category includes American Indian or Alaska Native, Native Hawaiian, Pacific Islander, and Other. [c]Local regulators did not allow the collection of ethnicity information for participants receiving BIC/LEN (n = 8 in the ≥ 65 years group and n = 13 in the < 65 years group) and complex regimen (n = 5 and n = 11, respectively); percentages were calculated using total number of participants as the denominator. [d]Group terms based on SMQ narrow search. [e]Concomitant medications were those taken while on study drug or complex regimen.
ART, antiretroviral therapy; BIC, bictegravir; CD4, cluster of differentiation 4; LEN, lenacapavir; PI, protease inhibitor; Q, quartile; SMQ, Standardized Medical Dictionary for Regulatory Activities Query; STR, single-tablet regimen.

- Of 557 participants randomized and treated in ARTISTRY-1, 174 (31%) were aged ≥ 65 years and 383 (69%) were aged < 65 years
- Older participants had a higher prevalence of select comorbidities at baseline and a higher proportion were taking ≥ 2 select concomitant medications compared with younger participants

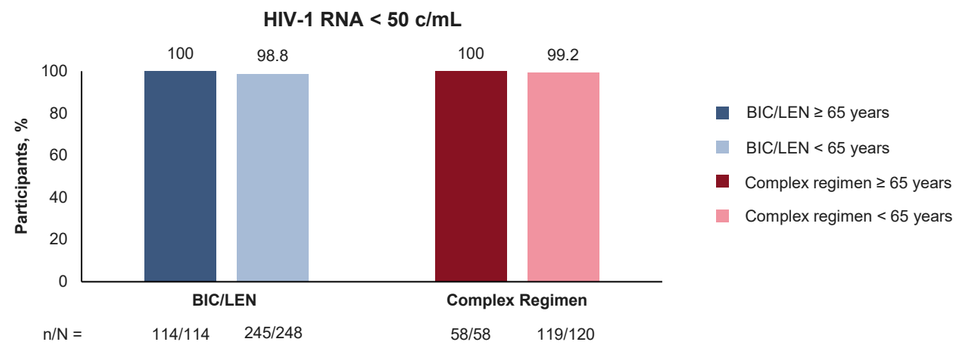
Virologic Outcomes at Week 48 (US FDA Snapshot Analysis)



BIC, bictegravir; c, copies; FDA, Food and Drug Administration; LEN, lenacapavir.

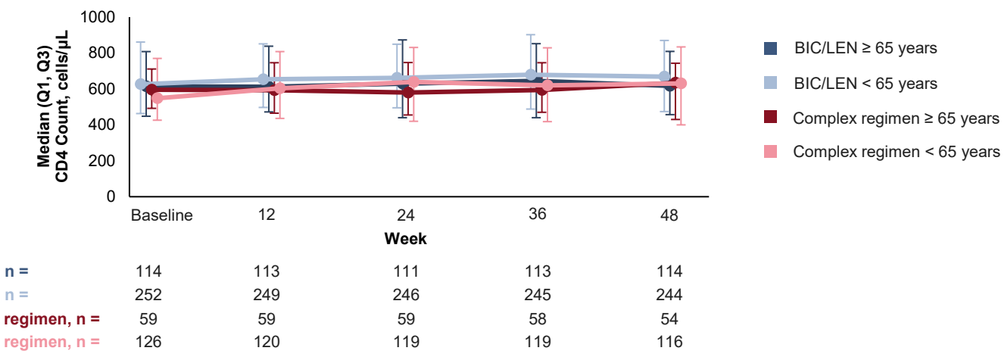
- Rates of virologic suppression with BIC/LEN remained high and were similar between participants aged ≥ 65 and < 65 years

Virologic Outcomes at Week 48 (M = E Analysis)



The denominators for the percentage calculations were the numbers of participants in the full analysis set with non-missing HIV-1 RNA values at Week 48.
BIC, bictegravir; c, copies; LEN, lenacapavir; M = E, missing = excluded.

CD4 Cell Count Over Time



	Baseline	12	24	36	48
			Week		
BIC/LEN, n =	114	113	111	113	114
BIC/LEN, n =	252	249	246	245	244
Complex regimen, n =	59	59	59	58	54
Complex regimen, n =	126	120	119	119	116

BIC, bictegravir; CD4, cluster of differentiation 4; LEN, lenacapavir; Q, quartile.

- CD4 cell count remained stable through 48 weeks in participants aged ≥ 65 and < 65 years in both treatment groups

Summary of Adverse Events Through 48 Weeks

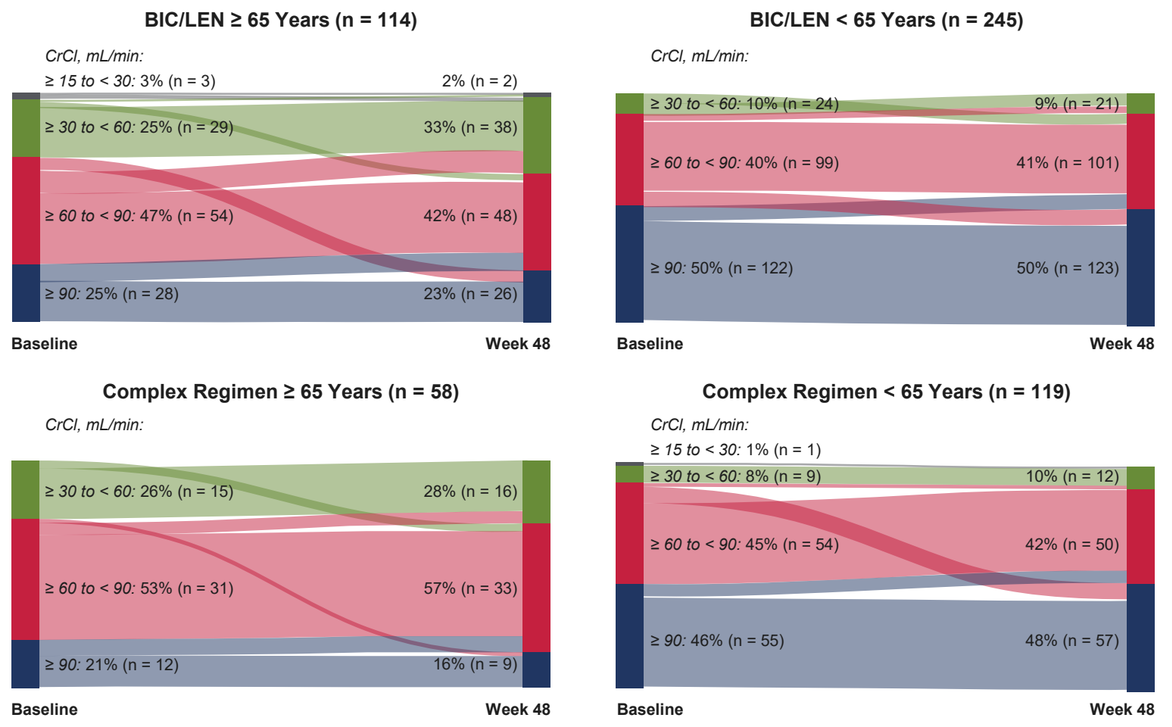
	BIC/LEN		Complex Regimen	
	Aged ≥ 65 Years n = 115	Aged < 65 Years n = 256	Aged ≥ 65 Years n = 59	Aged < 65 Years n = 127
AE, n (%)	93 (80.9)	212 (82.8)	55 (93.2)	102 (80.3)
AE of Grade ≥ 3	18 (15.7)	33 (12.9)	10 (16.9)	16 (12.6)
Serious AE	19 (16.5)	33 (12.9)	9 (15.3)	13 (10.2)
Drug-related AE, n (%)	11 (9.6)	42 (16.4)	0	3 (2.4)
Drug-related AE of Grade ≥ 3	0	2 (0.8)[a]	0	0
Serious drug-related AE	0	1 (0.4)[b]	0	0
AE leading to premature study drug discontinuation	1 (0.9)[c]	5 (2.0)[d]	0	1 (0.8)[e]
Death	0	5 (2.0)[f]	0	0

n = number of participants. [a]Diabetes mellitus and maculopapular rash. [b]Diabetes mellitus. [c]Hepatitis B reactivation. [d]Diabetes mellitus (n = 1); stroke (n = 1); erectile dysfunction and hypertension (both in 1 participant); headache and hypoesthesia (both in 1 participant); nausea, dizziness, headache, alopecia, and fatigue (all in 1 participant). [e]Pulmonary embolism. [f]Unknown cause (n = 2), metastatic neoplasm (n = 1), cardiac arrest (n = 1), respiratory failure (n = 1) – all deemed unrelated to study treatment.
AE, adverse event; BIC, bictegravir; LEN, lenacapavir.

- BIC/LEN was generally well tolerated, with similar rates of AEs and low rates of discontinuation due to AEs in participants aged ≥ 65 years and those who were younger

Shift From Baseline at Week 48 in Creatinine Clearance[a] Category

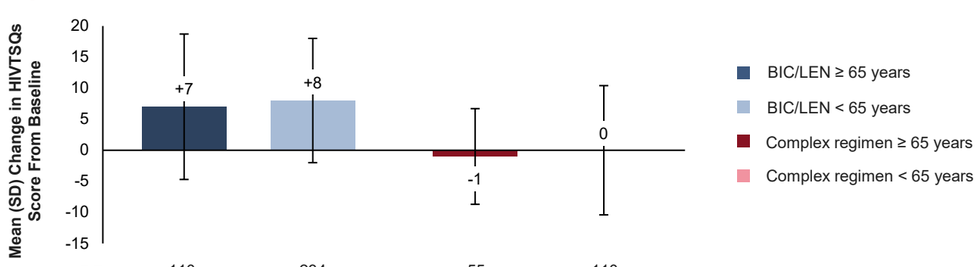
For changes in CrCl over time, please scan the QR code



Values are shown as % (n) of participants in each CrCl category. Participants with non-missing data at baseline and Week 48 were included in the denominators for the percentage calculations for each baseline CrCl category. Participants with missing data at Week 48 (BIC/LEN ≥ 65 years: n = 1; BIC/LEN < 65 years: n = 11; complex regimen ≥ 65 years: n = 1; complex regimen < 65 years: n = 8) were excluded from the Sankey plots. [a]Estimated using the Cockcroft-Gault formula.
BIC, bictegravir; CrCl, creatinine clearance; LEN, lenacapavir.

- Most participants remained in the same creatinine clearance category from baseline to Week 48, with only small shifts between adjacent categories in both treatment groups

Patient-Reported Treatment Satisfaction at 48 Weeks



BIC, bictegravir; HIVTSQs, HIV Treatment Satisfaction Questionnaire: status version; LEN, lenacapavir.

- At baseline, mean (SD) HIVTSQs scores were similar between age groups for both treatments
  - BIC/LEN: 56 (10.5) for those aged ≥ 65 years and 55 (10.3) for those aged < 65 years
  - Complex regimen: 56 (10.1) for those aged ≥ 65 years and 55 (9.1) for those aged < 65 years
- At Week 48, treatment satisfaction increased after switching to BIC/LEN across both age groups and remained stable in the complex regimen group

References: **1.** Department of Health and Human Services. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf (accessed April 28, 2026). **2.** Verheij E, et al. *Lancet HIV*. 2023;10:e164-74. **3.** DerSarkissian M, et al. *Curr Med Res Opin*. 2020;36:781-8. **4.** Mounzer K, et al. *Clin Infect Dis*. 2025;80:881-8. **5.** Mounzer K, et al. *Open Forum Infect Dis*. 2025;12:ofaf615. **6.** Orkin C, et al. *Lancet*. 2026;407:1249-58.

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