Increased Treatment Satisfaction and Maintained Health-Related Quality of Life Among People With HIV Switching to a Bictegravir/Lenacapavir Single-Tablet Regimen From Complex Regimens: Results From the Phase 3 ARTISTRY-1 Trial

TUPEB099

ARTISTRY-1

Chloe Orkin[1], Andrea Antinori[2], Christian Hoffmann[3], Manuel Pardo[4], Isabel Cassetti[5], Po-Liang Lu[6], Andrew Carr[7], Jose I Bernardino[8], Saeid Shahraz[9], Caroline Burk[9], Ying Guo[9], Jairo M Montezuma-Rusca[9], Peter Sklar[9], Kwanza Price[9], Benoit Trottier[10]

[1]SHARE Collaborative, Blizard Institute, Queen Mary University of London, London, UK; [2]National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy; [3]Infektionsmedizinisches Centrum Hamburg, Hamburg, Germany; [4]Men's Health Foundation, West Hollywood, CA, USA; [5]Helios Salud, Buenos Aires, Argentina; [6]Kaohsiung Medical University Chung-Ho Memorial Hospital, Kaohsiung, Taiwan; [7]St Vincent's Hospital, Sydney, NSW, Australia; [8]Hospital Universitario La Paz, Madrid, Spain; [9]Gilead Sciences, Inc., Foster City, CA, USA; [10]Clinique de Médecine Urbaine du Quartier Latin, Montreal, QC, Canada

Conclusions

- In Phase 3 of ARTISTRY-1, treatment satisfaction improved in people with HIV (PWH) who switched to bictegravir/lenacapavir (BIC/LEN) single-tablet regimen (STR) from multi-tablet complex regimens (CRs) versus those continuing CRs
  - Treatment satisfaction increased within 4 weeks after switching to BIC/LEN and remained high through Week 48
- Participants with the highest pill burden at baseline reported the greatest increase in treatment satisfaction at Week 48 after switching to BIC/LEN
- Most participants who switched to BIC/LEN indicated that they would continue BIC/LEN and would recommend it to others
- Health-related quality of life (HRQoL) was high at baseline and was maintained through Week 48
- The results of this analysis support the novel BIC/LEN STR as a person-centered option for optimizing HIV treatment for people on CRs

Plain Language Summary

For an infographic summary of the poster, please scan the QR code

- Some people with human immunodeficiency virus (HIV) need to take multiple tablets a day (called a complex regimen) because single-tablet treatments do not work for them or may cause side effects
- People with HIV who are satisfied with their treatment are more likely to take it regularly and as prescribed
- The ARTISTRY-1 study looked at two HIV medicines, bictegravir (BIC) and lenacapavir (LEN), taken together 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 safe as continuing the complex regimen
- In this study, researchers asked people how satisfied they were with their HIV treatment and how their health affected their everyday life after switching to BIC/LEN or if they had continued their complex regimen
- People who switched their treatment to BIC/LEN were more satisfied with their treatment than people who continued their complex regimen
  - Most people who switched to BIC/LEN said they would continue taking it and would recommend it to others with HIV

Introduction

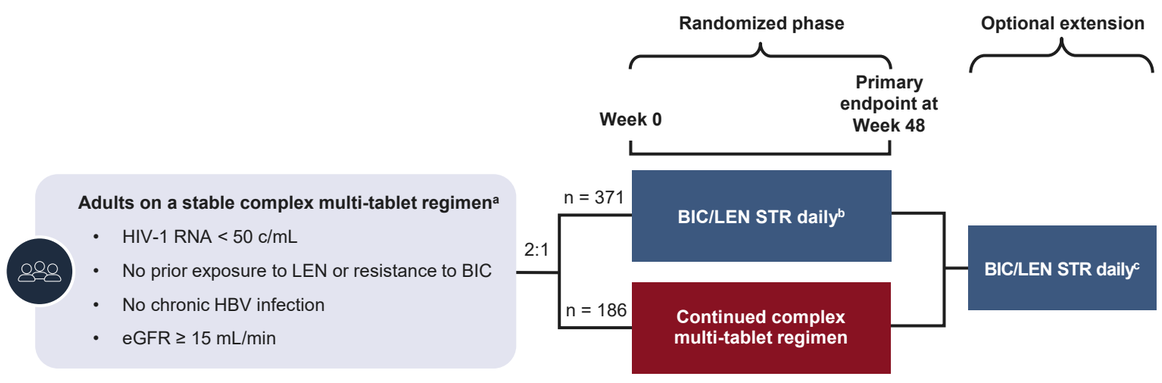
- High HIV treatment satisfaction and HRQoL are associated with improved adherence and sustained virologic suppression in PWH[1,2]
- STRs are the standard of care for HIV treatment; however, some people need to take CRs due to viral resistance, intolerance, contraindications, or drug-drug interactions with existing STRs[3-6]
- The novel BIC/LEN STR is a once-daily tablet with the potential to optimize HIV treatment
  - BIC is the guideline-recommended integrase strand-transfer inhibitor with a high barrier to resistance[3,7-9]
  - LEN is a first-in-class capsid inhibitor with no documented *de novo* resistance in the absence of prior exposure[10]
- In Phase 3 of the randomized, open-label, Phase 2/3 ARTISTRY-1 trial (NCT05502341), switching to BIC/LEN STR from CRs showed noninferior efficacy and comparable safety versus continuing CRs in PWH who were virologically suppressed[11]
- With a median age of 60 years, participants in Phase 3 were the oldest enrolled in a registrational trial to date, and had a high daily pill burden at enrollment

Objective

- To describe patient-reported treatment satisfaction and HRQoL at baseline through Week 48 of Phase 3 of ARTISTRY-1

Methods

Phase 3 ARTISTRY-1 Study Design



A **complex multi-tablet regimen** was defined as a regimen that contained any of the following:

- A boosted PI or NNRTI plus ≥ 1 other third agent from a class other than NRTI, or
- ≥ 2 pills/day, or requiring dosing more than daily, or
- Parenteral agent(s) (excluding a complete long-acting injectable regimen) as well as oral agents

Endpoints:

- **Primary (previously reported)[10]:** HIV-1 RNA ≥ 50 c/mL (US FDA Snapshot algorithm) at Week 48
- **Secondary (previously reported)[10]:** HIV-1 RNA < 50 c/mL at Week 48; change from baseline in CD4 cell count at Week 48; safety
- **Exploratory:** Change from baseline in HIV treatment satisfaction (HIVTSQs/c), and HRQoL at baseline and Week 48 (PozQoL)

[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/c, HIV Treatment Satisfaction Questionnaire: status/change version; HRQoL, health-related quality of life; LEN, lenacapavir; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PI, protease inhibitor; STR, single-tablet regimen.

Patient-Reported Outcome Measures

- All participants who took ≥ 1 dose of BIC/LEN or CR were included in the patient-reported outcomes analysis (full analysis set)
- HIV Treatment Satisfaction Questionnaire: status version (HIVTSQs) was used to assess satisfaction with HIV treatment at baseline and Weeks 4, 12, 24, and 48
  - HIVTSQs scores range from 0 to 66, with higher scores indicating greater satisfaction
  - The difference in mean change between participants switching to BIC/LEN and those continuing CRs was calculated using a mixed model for repeated measures
- HIV Treatment Satisfaction Questionnaire: change version (HIVTSQc) was used to capture the impact of switching to BIC/LEN at Week 48 (completed only by participants who switched to BIC/LEN)
  - HIVTSQc scores range from -33 to +33, with a score of > 0 indicating improvement
- The PozQoL questionnaire was used to assess HRQoL at baseline and Week 48
  - PozQoL scores of ≥ 14 (psychological domain), ≥ 10 (social and health concerns domains), and ≥ 12 (functional domain) indicate high or very high HRQoL
- Outcomes were reported descriptively

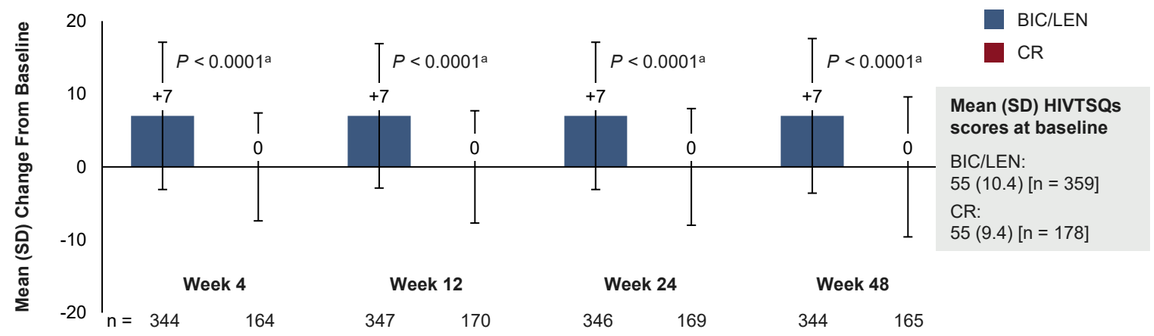
Results

Baseline Demographic and Clinical Characteristics

	BIC/LEN n = 371	CR n = 186
Age, years, median (range)	60 (22-84)	60 (24-75)
Assigned female at birth, n (%)	64 (17.3)	36 (19.4)
Race,[a] n (%)		
White	260 (70.1)	124 (66.7)
Black	64 (17.3)	33 (17.7)
Asian	16 (4.3)	9 (4.8)
Other[b]	12 (3.2)	3 (1.6)
Hispanic or Latine,[c] n (%)	80 (21.6)	42 (22.6)
Duration of HIV treatment, years, median (Q1, Q3)	28.3 (21.6, 32.3)	28.3 (21.4, 31.8)
Number of antiretroviral pills/day, median (range)	3 (2, 11)	3 (2, 9)
2-3, n (%)	248 (66.8)	122 (65.6)
≥ 4, n (%)	123 (33.2)	64 (34.4)
Twice-daily dosing, n (%)	152 (41.0)	66 (35.5)
PI-containing regimen, n (%)	279 (75.2)	148 (79.6)
Select comorbidities,[d,e] n (%)		
Dyslipidemia	244 (65.8)	133 (71.5)
Hypertension	190 (51.2)	90 (48.4)
Hyperglycemia/diabetes mellitus	91 (24.5)	42 (22.6)
Chronic kidney disease	49 (13.2)	29 (15.6)
Number of select concomitant medications,[f] n (%)		
1	62 (16.7)	50 (26.9)
≥ 2	237 (63.9)	102 (54.8)

[a]Local regulators did not allow the collection of race information for 19 participants in the BIC/LEN group and 17 in the CR group; 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 21 participants in the BIC/LEN group and 16 in the CR group; percentages were calculated using total number of participants as the denominator. [d]Categories are not mutually exclusive. [e]Grouped terms on standardized MedDRA query narrow search. [f]Includes antidiabetic, antihypertensive, and lipid-lowering agents.
BIC/LEN, bictegravir/lenacapavir; CR, complex regimen; MedDRA, Medical Dictionary for Regulatory Activities; PI, protease inhibitor; Q, quartile.

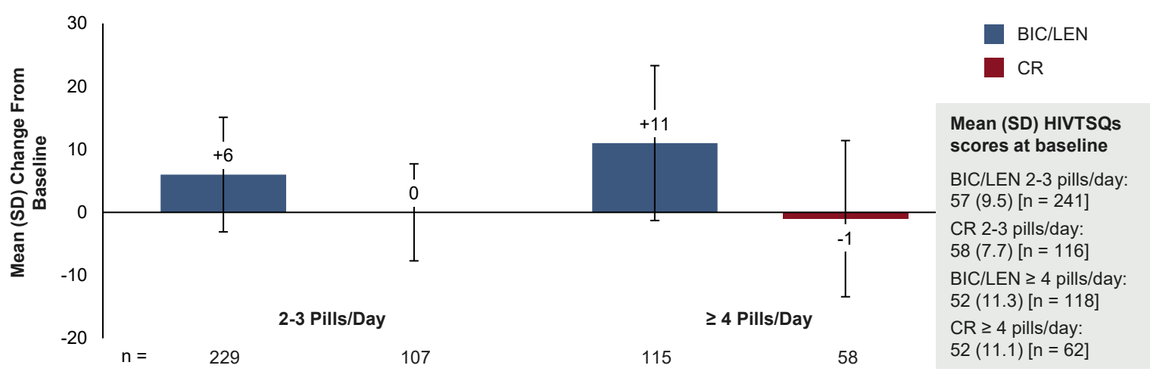
Change in HIVTSQs Total Scores From Baseline Through Week 48



Adapted from Orkin C, et al. Oral Presentation 181, 33rd Conference on Retroviruses and Opportunistic Infections (CROI); February 22-25, 2026; Denver, CO, USA.
HIVTSQs total score was calculated as the sum of responses ranging from 0 to 66. Higher scores indicate higher satisfaction. n-values represent participants with available data.
[a]*P* values for the difference in mean change from baseline between BIC/LEN and CR were calculated from the MMRM, including baseline value, region, treatment, visit, and treatment by visit interaction as fixed effects and participants as random effect. Given exploratory analyses, the nominal *P* values are provided without multiplicity adjustment.
BIC/LEN, bictegravir/lenacapavir; CR, complex regimen; HIVTSQs, HIV Treatment Satisfaction Questionnaire: status version; MMRM, mixed model for repeated measures.

- HIVTSQs scores increased at Week 4 following switch to BIC/LEN and remained high through Week 48
- The difference in least squares mean (95% confidence interval) change from baseline in participants who switched to BIC/LEN versus those continuing CRs was 6.7 (5.4, 8.0) at Week 4, 6.8 (5.6, 7.9) at Week 12, 7.6 (6.2, 8.6) at Week 24, and 7.7 (6.2, 9.1) at Week 48
  - The difference in least squares mean change from baseline between the two groups was statistically significant (nominal $P < 0.0001$) at each timepoint

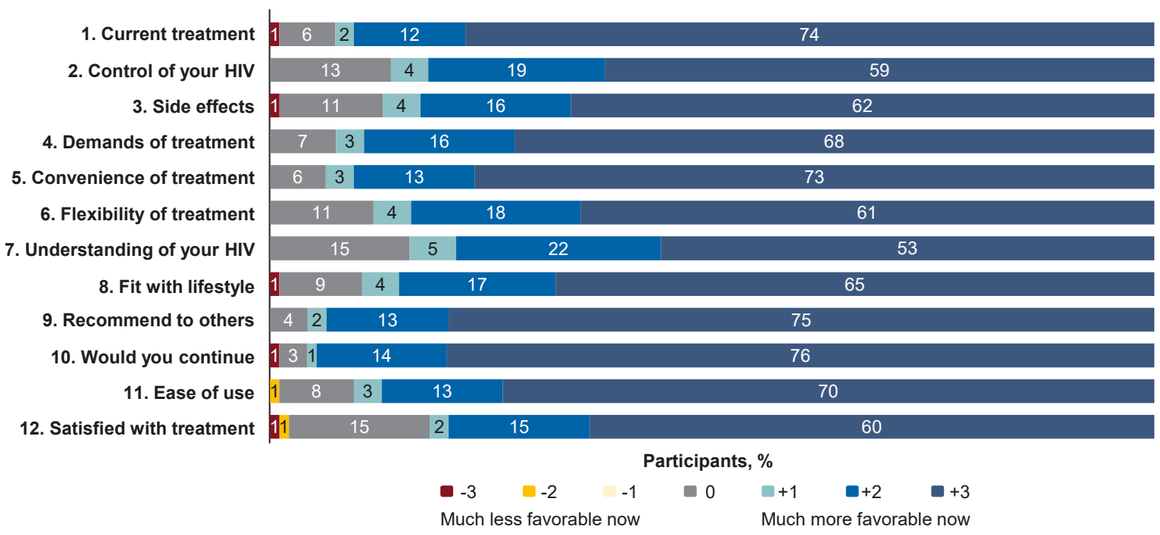
Change in HIVTSQs Total Scores From Baseline at Week 48 by Number of Pills Per Day



HIVTSQs total score was calculated as the sum of responses ranging from 0 to 66. Higher scores indicate higher satisfaction. N-values represent participants with available data.
BIC/LEN, bictegravir/lenacapavir; CR, complex regimen; HIVTSQs, HIV Treatment Satisfaction Questionnaire: status version.

- Participants taking ≥ 4 pills per day at baseline reported a greater increase in HIVTSQs scores from baseline to Week 48 following switch to BIC/LEN than those taking fewer pills

HIVTSQc Scores by Item at Week 48 in Participants Who Switched to BIC/LEN



Numbers indicate the question numbers in the HIVTSQc. The denominator includes the full analysis set (n = 371). Data were missing for n = 17 (5%) participants. Reponses in categories with only a single participant (0.3%) are not shown due to rounding.
BIC/LEN, bictegravir/lenacapavir; HIVTSQc, HIV Treatment Satisfaction Questionnaire: change version.

- Mean (SD) HIVTSQc score at Week 48 after switching to BIC/LEN was +27 (9.1)
  - HIVTSQc scores range from -33 to +33; a score of > 0 indicates improvement
- At Week 48, most participants reported more favorable outcomes across all domains of the HIVTSQc after switching to BIC/LEN
  - Over three-quarters of participants said they would continue to take BIC/LEN and recommend BIC/LEN to others

PozQoL by Domain at Baseline and Week 48

PozQoL scores of ≥ 14 (psychological domain), ≥ 10 (social and health concerns domains), and ≥ 12 (functional domain) indicate high or very high health-related quality of life.
N-values represent participants with available data.
BIC/LEN, bictegravir/lenacapavir; BL, baseline; CR, complex regimen; W, Week.

- HRQoL assessed using PozQoL domain scores was high at baseline and maintained at Week 48

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Correspondence: Chloe Orkin, c.m.orkin@qmul.ac.uk.