Characterizing Viremic Events in the ARTISTRY-1 and ARTISTRY-2 Trials

P062

ARTISTRY-1
ARTISTRY-2

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Conclusions

- The majority of participants in ARTISTRY-1 and ARTISTRY-2 remained virologically suppressed with no post-baseline viremic events (HIV-1 RNA ≥ 50 copies [c]/mL) through Week 48
  - Among those who experienced a post-baseline viremic event, most achieved virologic resuppression by Week 48 without regimen change
- Adherence to bictegravir/lenacapavir (BIC/LEN) was high in both studies
- Post-baseline viremia did not appear to be associated with low adherence or baseline resistance

Plain Language Summary

- A single tablet combining two medicines for human immunodeficiency virus (HIV) – bictegravir (BIC) and lenacapavir (LEN) – could simplify treatment for people with HIV
- In the ARTISTRY-1 and ARTISTRY-2 studies, researchers looked at how well BIC/LEN kept HIV levels in the blood undetectable (very low)
  - In the Phase 3 part of ARTISTRY-1, BIC/LEN worked as well as multiple tablets taken daily (known as a complex regimen)
  - In the ARTISTRY-2 study, BIC/LEN also worked as well as the commonly used HIV treatment bictegravir/emtricitabine/tenofovir alafenamide
- In this study, researchers looked at how many people in ARTISTRY-1 and ARTISTRY-2 had higher levels of HIV in their blood (known as viremia) and whether their levels decreased over time
- Very few people had higher levels of HIV in their blood. In most people who had higher levels, HIV-1 later returned to undetectable levels without any changes to their HIV treatment

Introduction

- BIC is a guideline-recommended integrase strand-transfer inhibitor with a high barrier to resistance,[1-4] and LEN is a first-in-class capsid inhibitor with no documented *de novo* resistance in the absence of prior exposure[5]
- A once-daily single-tablet regimen (STR) of BIC/LEN may expand treatment options for people with HIV who have virologic suppression, and has the potential to optimize treatment, particularly for those unable to take currently available STRs
- In the Phase 3 ARTISTRY-1 and ARTISTRY-2 studies, switching to BIC/LEN was noninferior to continuing complex antiretroviral regimen (CR) and the standard-of-care regimen bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF), respectively[1,2,6,7]

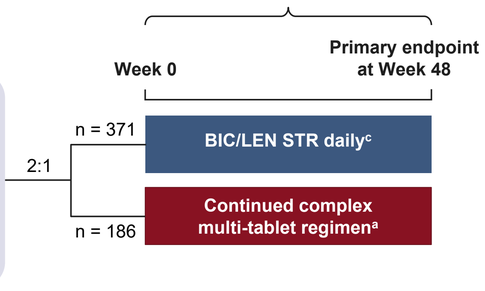
Objective

- To evaluate outcomes in a subgroup of participants from ARTISTRY-1 and ARTISTRY-2 who experienced post-baseline viremia through Week 48

Methods

Figure 1. ARTISTRY-1 and ARTISTRY-2 Study Design

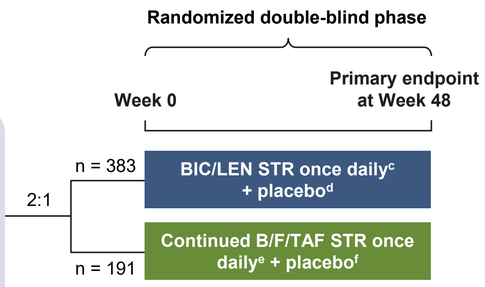
ARTISTRY-1[6]



Adults on a stable complex multi-tablet regimen[a]
- HIV-1 RNA < 50 c/mL for ≥ 6 months
- No prior exposure to LEN or resistance to BIC
- No chronic HBV infection[b]
- eGFR ≥ 15 mL/min

Endpoints
- **Primary:** HIV-1 RNA ≥ 50 c/mL (US FDA Snapshot algorithm) at Week 48
- **Secondary:** HIV-1 RNA < 50 c/mL at Week 48; change from baseline in CD4 cell count at Week 48; safety
- **Exploratory:** Treatment satisfaction

ARTISTRY-2[7]



Adults aged ≥ 18 years on B/F/TAF
- HIV-1 RNA < 50 c/mL for ≥ 6 months
- No prior exposure to LEN or resistance to BIC or TAF
- No chronic HBV infection[b]
- eGFR > 30 mL/min

Endpoints
- **Primary:** HIV-1 RNA ≥ 50 c/mL (US FDA Snapshot algorithm; 4% noninferiority margin) at Week 48
- **Secondary:** HIV-1 RNA < 50 c/mL at Week 48; change from baseline in CD4 cell count at Week 48; treatment-emergent AEs through Week 48

Endpoints in this analysis
- Virologic outcomes and adherence in ARTISTRY-1 and ARTISTRY-2 participants with post-baseline viremia

[a]Defined as a regimen that contained any of the following: (1) a boosted PI or NNRTI plus ≥ 1 other third agent from a class other than NRTI; (2) ≥ 2 pills/day or requiring dosing more than once daily; or (3) parenteral agent(s) (excluding a complete long-acting injectable regimen) as well as oral agents. Due to antiretroviral resistance, intolerance, drug-drug interactions, or contraindication to existing STRs.
[b]Determined 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.
[c]BIC/LEN 75/50 mg, with oral loading dose of LEN 600 mg on Days 1 and 2 of treatment.
[d]Placebo-to-match B/F/TAF.
[e]B/F/TAF 50/200/25 mg; participants received placebo-to-match LEN on Days 1 and 2 of treatment.
[f]Placebo-to-match BIC/LEN.
AE, adverse event; BIC, bictegravir; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; c, copies; CD4, cluster of differentiation 4; eGFR, estimated glomerular filtration rate; FDA, Food and Drug Administration; HBV, hepatitis B virus; LEN, lenacapavir; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PI, protease inhibitor; STR, single-tablet regimen.

- The study designs for ARTISTRY-1 and ARTISTRY-2 are shown in **Figure 1**
- Randomized participants who took at least one dose of study treatment were included in this analysis
- Viremia was defined as having at least one HIV-1 RNA result ≥ 50 c/mL at post-baseline visit(s) after being suppressed on BIC/LEN or comparator
  - Viremia with HIV-1 RNA ≥ 200 c/mL was also summarized
  - A viremic event was considered a single event until the participant resuppressed
- All data available through Week 48 were used
- Although not trial mandated, all participants with post-baseline viremia could change regimen at the investigator's discretion or per local guidelines

Results

Post-Baseline Viremic Events

Table 1. Participants Experiencing Viremic Events

	ARTISTRY-1				ARTISTRY-2			
	BIC/LEN n = 371		CR n = 186		BIC/LEN n = 383		B/F/TAF n = 191	
	HIV-1 RNA ≥ 50 c/mL	HIV-1 RNA ≥ 200 c/mL	HIV-1 RNA ≥ 50 c/mL	HIV-1 RNA ≥ 200 c/mL	HIV-1 RNA ≥ 50 c/mL	HIV-1 RNA ≥ 200 c/mL	HIV-1 RNA ≥ 50 c/mL	HIV-1 RNA ≥ 200 c/mL
Participants with ≥ 1 post-baseline viremic event, n (%)	26 (7)	10 (3)	17 (9)	6 (3)	26 (7)	11 (3)	15 (8)	4 (2)
Resuppressed[a] while continuing study drug, n (%)	23 (6)	7 (2)	15 (8)	4 (2)	21 (5)	7 (2)	13 (7)	2 (1)
Resuppressed without LEN reload,[b] n (%)	23 (6)	7 (2)	NA	NA	20 (5)	7 (2)	NA	NA
Participants with no post-baseline viremic event, n (%)	345 (93)	361 (97)	169 (91)	180 (97)	357 (93)	372 (97)	176 (92)	187 (98)

[a]HIV-1 RNA < 50 c/mL.
[b]If more than 7 days of daily dosing were missed, participants were recommended to reload by dosing 2-day oral loading regimen of LEN (or placebo-to-match for participants taking B/F/TAF in ARTISTRY-2) on Day 1 and 2 of regimen re-initiation.
BIC, bictegravir; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; c, copies; CR, complex regimen; LEN, lenacapavir; NA, not applicable.

- Most participants with post-baseline viremia resuppressed without regimen change (**Table 1**)
- Baseline demographics and disease characteristics for people with post-baseline viremia are shown in **Table 2**

Table 2. Baseline Demographics and Clinical Characteristics in Participants With Post-Baseline Viremia

	ARTISTRY-1				ARTISTRY-2			
	BIC/LEN n = 371		CR n = 186		BIC/LEN n = 383		B/F/TAF n = 191	
	HIV-1 RNA ≥ 50 c/mL (n = 26)	HIV-1 RNA ≥ 200 c/mL (n = 10)	HIV-1 RNA ≥ 50 c/mL (n = 17)	HIV-1 RNA ≥ 200 c/mL (n = 6)	HIV-1 RNA ≥ 50 c/mL (n = 26)	HIV-1 RNA ≥ 200 c/mL (n = 11)	HIV-1 RNA ≥ 50 c/mL (n = 15)	HIV-1 RNA ≥ 200 c/mL (n = 4)
Age, median (range), years	61 (28-71)	60 (47-71)	60 (38-72)	60 (51-72)	43 (25-76)	39 (25-69)	51 (32-74)	55 (50-74)
Female at birth, n (%)	2 (8)	1 (10)	0	0	4 (15)	2 (18)	3 (20)	1 (25)
Race, n (%)[a]								
White	20 (77)	9 (90)	10 (59)	3 (50)	15 (58)	7 (64)	9 (60)	3 (75)
Black	3 (12)	0	3 (18)	1 (17)	6 (23)	2 (18)	6 (40)	1 (25)
Asian	2 (8)	1 (10)	1 (6)	0	1 (4)	1 (9)	0	0
Other[b]	0	0	0	0	4 (15)	1 (9)	0	0
Hispanic/Latine, n (%)[c]	6 (23)	0	4 (24)	1 (17)	11 (42)	4 (36)	2 (13)	0
HIV-1 RNA ≥ 50 c/mL at baseline, n (%)	5 (19)	3 (30)	2 (12)	1 (17)	2 (8)	1 (9)	1 (7)	0
CD4 cell count, median (Q1, Q3), cells/μL	634 (457, 900)	812 (627, 910)	516 (465, 812)	493 (468, 812)	675 (489, 891)	615 (444, 788)	638 (522, 853)	662 (466, 915)
Preexisting resistance mutations, n (%)[d]								
NRTI	20 (77)	9 (90)	13 (76)	5 (83)	1 (4)	0	1 (7)	1 (25)
NNRTI	14 (54)	8 (80)	10 (59)	3 (50)	5 (19)	3 (27)	0	0
PI	9 (35)	3 (30)	7 (41)	3 (50)	0	0	1 (7)	1 (25)
INSTI	2 (8)	0	2 (12)	1 (17)	0	0	0	0

The denominator for percentage calculations of post-baseline viremia events was the number of participants in the treatment group; for remaining categories, the number of participants with post-baseline viremia in a given subgroup was used.
[a]In ARTISTRY-1, local regulations did not allow collection of data for race for 1 BIC/LEN and 3 CR participants with HIV-1 RNA ≥ 50 c/mL, and 2 CR participants with HIV-1 RNA ≥ 200 c/mL.
[b]Includes American Indian, Alaska Native, Native Hawaiian, Pacific Islander, and other.
[c]In ARTISTRY-1, local regulations did not allow collection of data for ethnicity for 1 BIC/LEN and 2 CR participants with HIV-1 RNA ≥ 50 c/mL, and 2 CR participants with HIV-1 RNA ≥ 200 c/mL.
[d]In ARTISTRY-1, resistance data were not available for NRTI and NNRTI: 5 BIC/LEN and 4 CR participants with HIV-1 RNA ≥ 50 c/mL, and 1 CR participant with HIV-1 RNA ≥ 200 c/mL; for PI: 6 BIC/LEN and 5 CR participants with HIV-1 RNA ≥ 50 c/mL, and 1 CR participant with HIV-1 RNA ≥ 200 c/mL; for INSTI: 14 BIC/LEN and 12 CR participants with HIV-1 RNA ≥ 50 c/mL, and 6 BIC/LEN and 3 CR participants with HIV-1 RNA ≥ 200 c/mL. In ARTISTRY-2, resistance data were not available for NRTI and NNRTI: 17 BIC/LEN and 8 B/F/TAF participants with HIV-1 RNA ≥ 50 c/mL, and 5 BIC/LEN and 1 B/F/TAF participants with HIV-1 RNA ≥ 200 c/mL; for PI: 17 BIC/LEN and 9 B/F/TAF participants with HIV-1 RNA ≥ 50 c/mL, and 5 BIC/LEN and 1 B/F/TAF participants with HIV-1 RNA ≥ 200 c/mL; for INSTI: 23 BIC/LEN and 12 B/F/TAF participants with HIV-1 RNA ≥ 50 c/mL, and 9 BIC/LEN and 3 B/F/TAF participants with HIV-1 RNA ≥ 200 c/mL.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BIC, bictegravir; c, copies; CD4, cluster of differentiation 4; CR, complex regimen; INSTI, integrase strand-transfer inhibitor; LEN, lenacapavir; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PI, protease inhibitor; Q, quartile.

Resistance

- Baseline resistance-associated mutations (RAMs) were common in ARTISTRY-1 study participants, with a similar distribution in both treatment groups (**Table 2**)
  - The frequency of RAMs was also similar in participants with events of post-baseline viremia at ≥ 50 c/mL and ≥ 200 c/mL
- Consistent with eligibility criteria, RAMs were less common in both treatment groups of ARTISTRY-2

Adherence

- Through Week 48, median (quartile [Q]1, Q3) adherence for the overall population was:
  - BIC/LEN: 99% (98%, 100%) in ARTISTRY-1[a] and 99% (97%, 100%) in ARTISTRY-2
  - B/F/TAF: 99% (97%, 100%) in ARTISTRY-2

[a]Data for adherence to CRs are not available due to the different combinations of regimens participants were taking.

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