GILEAD | Medical Information

Bixlenvo™ (bictegravir/lenacapavir) Treatment-Emergent RAMs

This document is in response to your request for information regarding Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) and treatment-emergent resistance-associated mutations (RAMs).

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_pi

Summary

Product Labeling[1]

BIC/LEN is indicated as a complete regimen for the treatment of HIV-1 in adults to replace the current ARV regimen in those who are VS (HIV-1 RNA <50 c/mL) on a stable ARV regimen with no known or suspected resistance to the individual components of BIC/LEN.

Concomitant administration of BIC/LEN is contraindicated with strong CYP3A inducers due to decreased plasma concentrations of BIC and LEN, which may result in the loss of therapeutic effect and development of resistance to BIC/LEN.

The concomitant use of BIC/LEN with certain other drugs may result in known or potentially significant drug interactions, some of which may lead to loss of therapeutic effect of BIC/LEN and possible development of resistance.

Counsel patients to take BIC/LEN on a regular dosing schedule with or without food and to avoid missing doses as it can result in development of resistance. Patients should contact their healthcare provider if >7 days have elapsed since their last dose of BIC/LEN.

Clinical Data on BIC/LEN and Treatment-Emergent RAMs

ARTISTRY-1: An ongoing phase 2/3 study is evaluating the efficacy and safety of switching to BIC/LEN vs continuing a complex ART regimen in VS PWH.[2]

Results from phase 2 through Week 96 have been reported.[2,3]

- The resistance analysis population at Week 48 consisted of 3 participants: 2 participants (3.9%) in the BIC 75 mg + LEN 25 mg group resuppressed without a change in ART, and 1 participant (1.9%) in the BIC 75 mg + LEN 50 mg group had HIV-1 RNA of 305 c/mL at Week 48 and was switched to DTG + MVC + LEN SUBQ; resistance analysis noted the N74T capsid mutation that did not confer resistance to LEN and caused no change in BIC sensitivity.[2,4]

Results from phase 3 through Week 48 have been reported.[5,6]

Treatment-emergent resistance was assessed in 2 participants (0.5%) in the BIC/LEN group and 1 participant (0.5%) in the complex ART regimen group who had virologic rebound.[6] One participant in the BIC/LEN group had transient emergence of a Q148R substitution in IN at low level (13% mutant) at Week 24 that is associated with a 1.2-fold reduction in BIC susceptibility; this substitution was not detected at Week 48.[1] The other participant in the BIC/LEN group had no detectable resistance to either capsid or IN. No treatment emergent resistance was detected in the participant in the complex ART regimen group.[6]

ARTISTRY-2: An ongoing phase 3 study is evaluating the efficacy and safety of switching from BIC/FTC/TAF to BIC/LEN STR 75 mg/50 mg vs continuing BIC/FTC/TAF in VS PWH.[7]

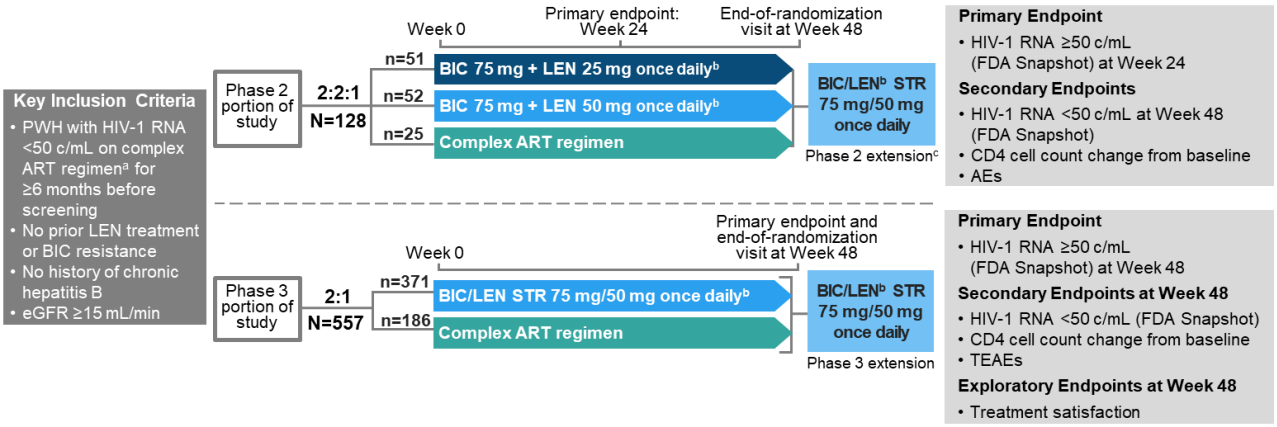
- Of the 2 participants in each group who underwent resistance analysis, 1 participant in the BIC/LEN group and both participants in the BIC/FTC/TAF group had no treatment-emergent RAMs. The other participant in the BIC/LEN group had a history of RAL and DTG exposure, and an isolated R263K IN substitution at Week 36 was detected. The participant was switched to DRV/c/FTC/TAF at Week 48 with a maximum HIV-1 RNA of 208 c/mL at Week 36.

Clinical Data on BIC/LEN and Treatment-Emergent RAMs

ARTISTRY-1: Switching to BIC/LEN vs Complex ART

An ongoing, randomized, multicenter, open-label, phase 2/3 study (NCT05502341) is evaluating the efficacy and safety of switching to BIC/LEN vs continuing their ART regimen in PWH who were receiving a complex ART regimen.[2,3]

Figure 1. ARTISTRY-1 Phase 2/3: Study Design[3,5,9]



[a]Due to viral resistance, intolerance, or contraindication to existing STRs. Regimens contained the following: a boosted PI or NNRTI + ≥1 other third agent from a class other than NRTIs, or ≥2 pills/day or a dosing frequency >once daily, or parenteral ART (excluding a complete long-acting injectable regimen) plus oral ART.
[b]Oral loading doses of LEN (600 mg for 2 days) were given after participants switched from their complex ART regimen.
[c]All participants reached the Week 48 timepoint and completed the end-of-randomization visit before entering the OLE phase.

Phase 2 of ARTISTRY-1

During the phase 2 portion of the study, participants were randomly assigned to switch to BIC 75 mg + LEN (25 or 50 mg; oral) or to continue their complex ART regimen. After the randomized period, participants could continue on to the extension period and receive BIC/LEN STR (Figure 1).[2]

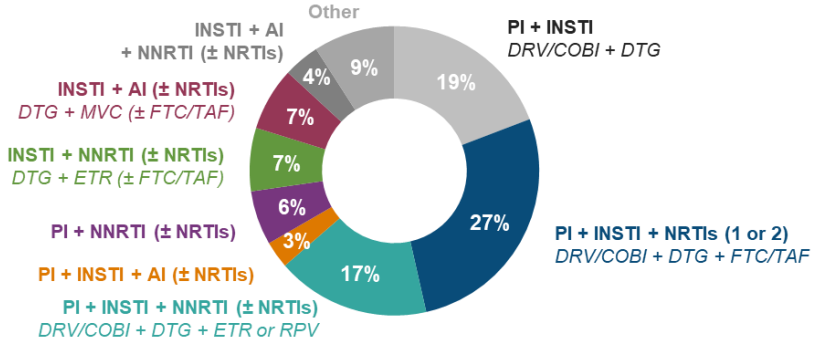
Table 1. Phase 2 of ARTISTRY-1: Baseline Demographics, Disease Characteristics, and Historical RAMs[3]

Key Demographics and Characteristics		BIC 75 mg + LEN 25 mg (n=51)	BIC 75 mg + LEN 50 mg (n=52)	Complex ART Regimen (n=25)	Total (N=128)
Age, median (range), years		62 (26–79)	62 (34–76)	58 (41–70)	60 (26–79)
Female sex assigned at birth, n (%)		13 (25.5)	7 (13.5)	4 (16)	24 (19)
Race, White/Black/Asian/other, %		56.9/35.3/3.9/3.9	65.4/30.8/3.8/0	80/20/0/0	64.8/30.5/3.1/1.6
Hispanic/Latinx,[a] n (%)		7 (14)	9 (17.6)	4 (16)	20 (15.9)
CD4 count, median (IQR), cells/mcL		583 (460–764)	624 (517–791)	585 (285–733)	610 (435–766)
<200 cells/mcL, n (%)		1 (2)	1 (1.9)	2 (8)	4 (3.1)
Duration of HIV treatment,[b] median (IQR), years		27.8 (22.7–32.4)[c]	27 (18.9–31.5)	26.9 (19.8–31.9)	27 (19.9–32)
Prior ARTs,[d] median (IQR), n		4 (2–9)	7 (3–11)	8 (3–13)	6 (3–11)
Reasons for complex regimen,[e] n (%)	History of resistance	44 (86.3)	40 (76.9)	20 (80)	104 (81.3)
	Intolerance of STR components	20 (39.2)	11 (21.2)	7 (28)	38 (29.7)
	Contraindications to STRs	7 (13.7)	4 (7.7)	1 (4)	12 (9.4)
ARTs,[d] median (range), n		2 (2–5)	2.5 (2–5)	3 (2–5)	2 (1–5)
Pills/day, median (range)		2 (2–8)	3 (2–9)	3 (2–8)	3 (2–9)
Historical RAMs,[e] n (%) INSTI/NNRTI/NRTI/PI		0/49/60.8/ 35.3	0/53.8/67.3/ 32.7	0/56/64/44	0/52.3/64.1/ 35.9

[a]Ethnicity data were not permitted to be collected for 1 patient each in the BIC 75 mg +LEN 25 mg and BIC 75 mg + LEN 50 mg arms.
[b]Calculated with the following equation: (date of first dose – start date of first HIV treatment + 1 day)/365.25.
[c]n=50.
[d]Defined as ARTs taken on Day 1 or up to 14 days before Day 1. If participants received multiple ARTs, they were counted once per participant for each drug name and ART class.
[e]Categories were not mutually exclusive. An alternative response was "no" or "not available."

Refer to Figure 2 for a summary of complex ART regimens at baseline; 53 participants (41.4%) in the overall population were taking twice-daily ART, and 43%, 18.8%, 10.9%, and 27.3% were taking 2, 3, 4, or ≥5 pills/day, respectively.[3]

Figure 2. Phase 2 of ARTISTRY-1: Complex ART Regimens at Baseline (N=128)[3]



Abbreviations: AI=attachment inhibitor; RPV=rilpivirine.
Note: Regimens in italics were the most common regimen in each category; not all regimens are shown here.
Percentages do not equal 100% due to rounding.

Efficacy outcomes through Week 48

At Week 24, 1 participant (1.9%) in the BIC 75 mg + LEN 50 mg group and no participants in the BIC 75 mg + LEN 25 mg group or complex ART regimen group had HIV-1 RNA ≥50 c/mL (primary endpoint; FDA Snapshot algorithm).[3] At Week 48, similarly high rates of virologic suppression were maintained in each group (Table 2).[2]

Table 2. Phase 2 of ARTISTRY-1: Rates of HIV RNA <50 c/mL (FDA Snapshot) and HIV RNA ≥50 c/mL at Week 48[2]

Efficacy Endpoints	BIC 75 mg + LEN 25 mg	BIC 75 mg + LEN 50 mg	Complex ART Regimen
HIV-1 RNA ≥50 c/mL, % (n/N)	3.9 (2/51)	1.9 (1/52)	0 (0/25)
Difference, % (95% CI); *P*-value	3.9 (−10.7, 13.9); 1	1.9 (−12.2, 10.7); 1	–
HIV-1 RNA <50 c/mL, % (n/N)	92.2 (47/51[a])	90.4 (47/52[b])	100 (25/25)
Difference, % (95% CI); *P*−value	−7.8 (−19.2, 7); 0.3	−9.6 (−21, 5.3); 0.17	–

[a]Reasons for DC before Week 48: AE and participant decision (each, n=1).
[b]Reasons for DC before Week 48: AE, death, participant decision, and investigator decision (each, n=1).
Note: *P*-values were for comparisons vs the complex ART regimen and are reported for descriptive purposes.

Week 48 resistance analysis[4]

Resistance testing was performed in participants with confirmed virologic rebound (HIV-1 RNA ≥200 c/mL). Three participants had HIV RNA levels ≥50 c/mL: 2 participants (3.9%) in the BIC 75 mg + LEN 25 mg group were resuppressed at their next study visit without a change in ART (HIV-1 RNA at Week 48: 50 c/mL and 98 c/mL, respectively), and 1 participant (1.9%) in the BIC 75 mg + LEN 50 mg group (HIV-1 RNA at Week 48: 305 c/mL) was resuppressed after switching treatment to DTG (twice daily) + MVC (twice daily) + LEN SUBQ. The third participant had a history of extensive ART exposure and had documented resistance to NRTIs, NNRTIs, and PIs. The participant underwent a resistance analysis, and the N74T capsid mutation was noted with DeepTypeHIV assay. This novel capsid polymorphism did not confer resistance to LEN, and no change in BIC sensitivity occurred.

Efficacy through Week 96: participants initially randomized to the BIC 75 mg + LEN 50 mg group[10]

Efficacy and safety outcomes through Week 96 were analyzed for participants who were initially randomized to the BIC 75 mg + LEN 50 mg group (n=52). Of these participants, 5 discontinued from the study during the randomized phase and 47 continued in the OLE on an STR of BIC/LEN 75 mg/50 mg.

Virologic suppression was maintained in 96% of participants (45/47; missing=excluded) through Week 96. The 2 participants with HIV-1 RNA ≥50 c/mL had low-level viremia (defined as HIV-1 RNA <500 c/mL) and were later resuppressed without requiring a change in their ART regimen. One of these participants met criteria for resistance testing and had assay failures for all genes.

Safety outcomes through Week 48

Safety outcomes were not reported in the subgroup of participants with treatment-emergent RAMs. In the overall population through Week 48, TRAEs occurred in 17.6% of participants (9/51) in the BIC 75 mg + 25 mg group, 5.8% of participants (3/52) in the BIC 75 mg + 50 mg group, and in none of the participants in the complex ART regimen group.[8] Two participants discontinued treatment due to TEAEs that were considered related to the

study drugs through Week 48: 1 participant in the BIC 75 mg + LEN 25 mg group (Grade 1 nausea) and 1 participant in the BIC 75 mg + LEN 50 mg group with a history of nausea and vomiting (Grade 3 worsening vomiting).[2,3]

Phase 3 of ARTISTRY-1

For the phase 3 portion of the study, participants were randomly assigned (2:1) to receive an STR of BIC/LEN 75 mg/50 mg (n=371) or to continue their stable complex ART regimen (n=186) for 48 weeks (Figure 1). At baseline, participants had a history of resistance to multiple drug classes (Table 3).[5]

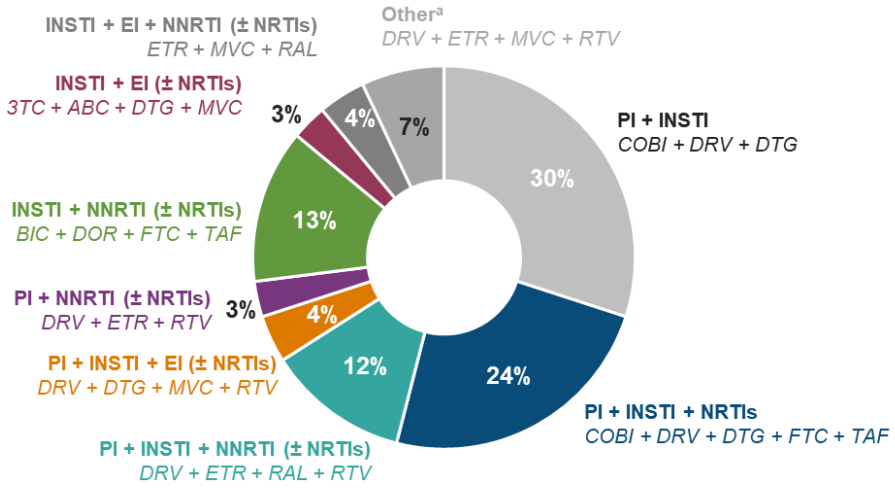
Table 3. Phase 3 of ARTISTRY-1: Baseline Demographics, Disease Characteristics, and Preexisting RAMs[5]

Key Demographics and Characteristics		BIC/LEN 75 mg/50 mg (n=371)	Complex ART Regimen (n=186)	Overall (N=557)
Age, median (range), years		60 (22–84)	60 (24–75)	60 (22–84)
Female sex assigned at birth, n (%)		64 (17)	36 (19)	100 (18)
Race, White/Black/Asian/other,[a] %		70/17/4/3	67/18/5/2	69/17/4/3
Hispanic/Latinx,[b] n (%)		80 (22)	42 (23)	122 (22)
CD4 count, median (IQR), cells/mcL		626 (457–836)[c]	579 (450–747)[d]	612 (456–809)[e]
Duration of HIV treatment, median (IQR), years		28.3 (21.6–32.3)[f]	28.3 (21.4–31.8)[g]	28.3 (21.6–32.1)[h]
Antiretroviral pills/day, median (range), n		3 (2–11)	3 (2–9)	3 (2–11)
Reasons for taking complex regimen,[i] n (%)	History of resistance	297 (80)	153 (82)	450 (81)
	Intolerance to STR components	89 (24)	39 (21)	128 (23)
	Contraindications to STR components	23 (6)	10 (5)	33 (6)
History of selected comorbidities,[i,j] dyslipidemia/HTN/DM or hyperglycemia/CKD, %		66/51/25/13	72/48/23/16	68/50/24/14
Historical drug class resistance,[i,k] n (%)	NRTI	247 (67)	128 (69)	375 (67)
	NNRTI	203 (55)	104 (56)	307 (55)
	PI	151 (41)	77 (41)	228 (41)
	INSTI	1 (<1)	2 (1)	3 (1)

[a]Local regulations did not permit the collection of race data for 19 participants in the BIC/LEN group and 17 in the complex ART regimen group. The "other" category included participants who were American Indian or Alaska Native, Native Hawaiian, Pacific Islander, or other.
[b]Local regulations did not permit the collection of ethnicity data for 21 participants in the BIC/LEN group and 16 in the complex ART regimen group.
[c]n=366. [d]n=185. [e]n=551.
[f]n=358. [g]n=183. [h]n=541.
[i]Not mutually exclusive.
[j]Grouped terms per MedDRA.
[k]NRTI, NNRTI, PI, and INSTI data were not available for 75, 79, 78, and 197 participants in the BIC/LEN group, respectively, and 44, 46, 50, and 100 participants in the complex ART regimen group. The denominator used for percentage calculations was the total number of participants.

Refer to Figure 3 for a summary of complex ART regimens; 77% of participants (n=427) were receiving a PI at baseline, and 75% of those participants (n=419) received a boosted PI-based regimen. At baseline, 39% of overall participants were receiving twice-daily ART, and 41%, 26%, 11%, and 22% were taking 2, 3, 4, or ≥5 pills/day, respectively.[5,11]

Figure 3. Phase 3 of ARTISTRY-1: Complex ART Regimens at Baseline[5]



Abbreviations: 3TC=lamivudine; ABC=abacavir; DOR=doravirine; EI=entry inhibitor; RTV=ritonavir.
[a]Other regimens could have contained a PI.
Note: Regimens in italics were the most common regimen in each category.

Efficacy outcomes through Week 48

BIC/LEN was non-inferior to complex ART regimens in maintaining virologic suppression at Week 48 (Table 4).[5] Each of the participants in the BIC/LEN group with HIV-1 RNA ≥50 c/mL at Week 48 achieved virologic resuppression or had low-level viremia without changes in their ART regimen.[11]

Table 4. Phase 3 of ARTISTRY-1: Rates of HIV RNA ≥50 c/mL and HIV RNA <50 c/mL (FDA Snapshot) at Week 48 in the Full Analysis Set[5]

Efficacy Endpoints	BIC/LEN 75 mg/50 mg	Complex ART Regimen
HIV-1 RNA ≥50 c/mL, % (n/N)	1 (3/371)	1 (2/186)
Difference,[a] % (95.002% CI)	−0.3 (−2.3, 1.8)	
HIV-1 RNA <50 c/mL, % (n/N)	96 (356/371)	94 (174/186)
Difference, % (95.002% CI)	2.4 (-1.8 to 6.6)	
No virologic data, % (n/N)	3 (12/371)[b]	5 (10/186)[c]

[a]Two-sided CI was based on Mantel-Haenszel stratum weights and Koch variance estimator and was adjusted by geographic region (US vs non-US).
[b]Reasons for DC before Week 48: AE or death, n=7 (AEs, n=5; deaths, n=2); other reasons and last HIV-1 RNA <50 c/mL, n=5.
[c]Reasons for DC before Week 48: other reasons and last HIV-1 RNA <50 c/mL, n=8; AE or death, n=1; and missing data but still on study drug, n=1.

Week 48 resistance analysis

Resistance testing was performed in participants with confirmed virologic rebound (HIV-1 RNA ≥50 c/mL at any visit after Day 1, followed by HIV-1 RNA ≥200 c/mL at the subsequent visit) or with HIV-1 RNA ≥200 c/mL at the last on-treatment visit through Week 48, including instances of early DC or loss to follow-up. Treatment-emergent resistance was assessed in 2 participants (0.5%) in the BIC/LEN group and 1 participant (0.5%) in the complex ART regimen group who experienced virologic rebound (confirmed HIV-1 RNA ≥50 c/mL or with HIV-1 RNA ≥50 c/mL at the last visit) through Week 48. In the BIC/LEN group, 1 participant had baseline RAMs in RT (M41L, K65R, L741, K103N, M184V, Y188L, T210W, T215Y, K219N, and H22IY) and protease (M46I/L, 154V, I84V, L90M).[6] This participant had

no detectable resistance in capsid and had transient emergence of a Q148R substitution in IN at low level (13% mutant) at Week 24 that is associated with a 1.2-fold reduction in BIC susceptibility; however, this substitution was not detected at Week 48.[1] The other participant in the BIC/LEN group had baseline RAMs in RT (D67N, K70R, K103N, V108I, M184V, L210W, T215Y, and K219E); the participant achieved resuppression, and no resistance was detected in CA or IN at virologic rebound. The participant in the complex ART regimen group had baseline RAMs in RT (M41L, M184V, and T215Y), PR (D30N), and IN (E92M/V) and was switched to BIC/FTC/TAF + LEN SUBQ with no detected resistance.[6]

Safety outcomes through Week 48[5]

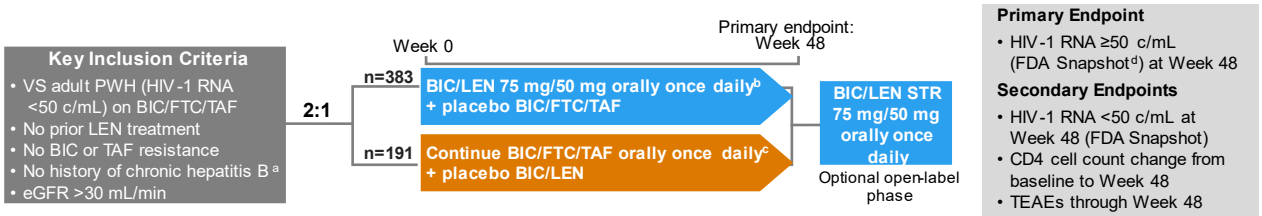
Safety outcomes were not reported in the subgroup of participants with treatment-emergent RAMs. In the overall population through Week 48, TRAEs were reported in 14% of participants (53/371) in the BIC/LEN group and in 2% of participants (3/186) in the complex ART group. AEs that led to DC of study drug occurred in 2% of participants (6/371) in the BIC/LEN group and in 1% of participants (1/186) in the complex ART group.

ARTISTRY-2: Switching to BIC/LEN vs BIC/FTC/TAF[7]

Study design and demographics

An ongoing, randomized, multicenter, double-blind, active-controlled, phase 3 study (NCT06333808) is evaluating the efficacy and safety of switching from BIC/FTC/TAF to STR BIC/LEN 75 mg/50 mg vs continuing BIC/FTC/TAF in VS PWH. After the randomized period, participants could continue in the OLE phase and receive BIC/LEN.

Figure 4. ARTISTRY-2: Study Design[7]



Abbreviations: HBcAb=HBV core antibody; HBsAb=HBV surface antibody; HBsAg=HBV surface antigen.
[a]Determined by the following at the screening visit: either HBsAg+ status or HBcAb+ and HBsAb status.
[b]Oral loading doses of LEN 600 mg on Days 1 and 2 were given.
[c]Participants were given placebo to match LEN on Days 1 and 2 of treatment.
[d]Non-inferiority margin: 4%.

Table 5. ARTISTRY-2: Baseline Demographics and Disease Characteristics[7]

Key Demographics and Characteristics	BIC/LEN 75 mg/50 mg (n=383)	BIC/FTC/TAF (n=191)	Total (N=574)
Age, median (range), years	47 (23–77)	51 (26–77)	49 (23–77)
Male sex assigned at birth, n (%)	314 (82)	149 (78)	463 (81)
Race, White/Black/Asian/American Indian or Alaska Native/Native Hawaiian or Pacific Islander/other, %	52/30/13/<1/<1/5	58/23/14/1/0/5	54/27/13/<1/<1/5
Hispanic/Latinx,[a] n (%)	106 (28)	49 (26)	155 (27)
CD4 count, median (IQR), cells/mcL	711 (547–914)	663 (522–873)	695 (541–902)
History of select comorbidities,[b,c] dyslipidemia/HTN/DM or hyperglycemia/CKD, %	41/37/18/5	41/33/16/6	41/36/17/6

Key Demographics and Characteristics		BIC/LEN 75 mg/50 mg (n=383)	BIC/FTC/TAF (n=191)	Total (N=574)
Number of select comorbidities, 1/≥2, n (%)		94 (25)/ 121 (32)	57 (30)/ 52 (27)	151 (26)/ 173 (30)
Historical primary resistance mutations,[c] n (%) or n/N (%)	NNRTI	25/144 (17)	14/80 (18)	39 (17)
	NRTI	14/144 (10)	15/80 (19)	29 (13)
	PI	7/144 (5)	7/79 (9)	14 (6)
	INSTI	0/83	0/41	0

[a]Local regulations did not permit the collection of ethnicity data for 1 participant in the BIC/FTC/TAF group.
[b]Grouped terms (per MedDRA).
[c]Categories were not mutually exclusive.

Efficacy outcomes through Week 48

BIC/LEN was non-inferior to BIC/FTC/TAF in maintaining virologic suppression at Week 48 (Table 6).

Table 6. ARTISTRY-2: Rates of HIV RNA ≥50 c/mL and HIV RNA <50 c/mL (FDA Snapshot) at Week 48[7]

Efficacy Endpoints	BIC/LEN 75 mg/50 mg	BIC/FTC/TAF
HIV-1 RNA ≥50 c/mL, n/N (%)	5/383 (1)[a]	2/191 (1)
Difference,[b] % (95.002% CI)	0.3 (-1.9 to 2.4)	
HIV-1 RNA <50 c/mL, n/N (%)	358/383 (93)	173/191 (91)
Difference,[b] % (95.002% CI)	3.1 (-1.8 to 8)	
No virologic data, n/N (%)	20/383 (5)[c]	16/191 (8)[d]

[a]Four of the 5 participants had HIV-1 RNA between 56 and 147 c/mL.
[b]Two-sided CI was based on Mantel-Haenszel stratum weights and the Koch variance estimator and was adjusted by geographic region (US vs non-US).
[c]Reasons for DC before Week 48: other reasons and last HIV-1 RNA was <50 c/mL, n=14; AE or death, n=6; other reasons and last HIV-1 RNA was ≥50 c/mL, n=3.
[d]Reasons for DC before Week 48: other reasons and last HIV-1 RNA was <50 c/mL, n=12; AE or death, n=4; other reasons and last HIV-1 RNA was ≥50 c/mL, n=2.

Week 48 resistance analysis

Two participants in each group met criteria for resistance testing (virologic failure and HIV-1 ≥200 c/mL). No treatment-emergent RAMs were noted for 1 participant in the BIC/LEN group or for either participant in the BIC/FTC/TAF group. The other participant in the BIC/LEN group had a history of RAL and DTG exposure, had polymorphic secondary mutations in IN (M501 and S119P) that were detected in plasma and proviral DNA before study entry, and had an isolated R263K IN substitution recorded at Week 36; the R263K isolate was susceptible to BIC, and no capsid mutations were detected. The maximum HIV-1 RNA was 208 c/mL at Week 36, which declined to 146 c/mL at Week 48; the participant was switched to DRV/c/FTC/TAF at Week 48.

Safety outcomes through Week 48

Safety outcomes were not reported in the subgroup of participants with treatment-emergent RAMs. In the overall population through Week 48, TRAEs occurred in 10% of participants (40/383) in the BIC/LEN group and in 12% of participants (23/191) in the BIC/FTC/TAF group. TRAEs led to DC of study drug in 2 (<1%) and 1 (<1%) participants in the BIC/LEN and BIC/FTC/TAF groups, respectively.

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Abbreviations

AE=adverse event
ART=antiretroviral therapy
ARV=antiretroviral
BIC=bictegravir
c/mL=copies per mL
CD4=cluster of differentiation
CKD=chronic kidney disease
COBI=cobicistat
DC=discontinuation
DM=diabetes mellitus
DRV=darunavir
DTG=dolutegravir
ETR=etravirine
FTC=emtricitabine
HTN=hypertension
IN=integrase
INSTI=integrase strand transfer inhibitor
LEN=lenacapavir
MedDRA=Medical Dictionary for Regulatory Activities
MVC=maraviroc
NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor
NRTI=nucleos(t)ide reverse transcriptase inhibitor
OLE=open-label extension
PI=protease inhibitor
PWH=people with HIV
RAL=raltegravir
RAM=resistance-associated mutation
RT=reverse transcriptase
STR=single-tablet regimen
SUBQ=subcutaneous
TAF=tenofovir alafenamide
TEAE=treatment-emergent adverse event
VS=virologically suppressed

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Bixlenvo US Prescribing Information available at:
www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_pi

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

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Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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