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Bixlenvo™ (bictegravir/lenacapavir) Safety Overview

This document is in response to your request for information regarding Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) and a safety overview.

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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]

The primary safety assessment of BIC/LEN in VS adults with HIV-1 was based on 48-week data from participants in two phase 3 randomized active-controlled clinical trials, ARTISTRY-1 (N=557) and ARTISTRY-2 (N=574).

The most common adverse reactions (all grades) reported in ≥2% of participants in any treatment group from ARTISTRY-1 and ARTISTRY-2 through Week 48 were headache, nausea, and diarrhea.

Safety Overview of BIC/LEN

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]

Safety results from phase 2 through Week 96 have been reported.[2-4]

- Through Week 48, all commonly reported TEAEs (≥5% in any group) were Grade 1 or 2 in severity, except for 1 case of Grade 3 diarrhea unrelated to study drug. TEAEs led to treatment discontinuation in 2% of participants in the BIC 75 mg + LEN 25 mg group, 1.9% in the BIC 75 mg + LEN 50 mg group, and 0% in the complex ART regimen group.[2]
- Through Week 96, 46 participants (88.5%) experienced AEs, including 13 (25%) with Grade ≥3 AEs. Nine participants (17.3%) experienced SAEs, 3 (5.8%) TRAEs were reported (atrial conduction time prolongation, decreased BP, and nausea and vomiting), and no serious TRAEs were reported. No new AEs led to treatment discontinuations, and no deaths were reported between Week 48 and Week 96.[4]

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

- In the BIC/LEN and complex ART regimen groups, the rates of Grade ≥3 AEs (each, 14%) and discontinuations due to AEs (2% vs 1%) were similar.[5]
- In a subgroup analysis of safety outcomes by age (<65 years and ≥65 years), BIC/LEN was generally well tolerated, with low rates of BIC/LEN discontinuation across both age subgroups.[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.[7,8]

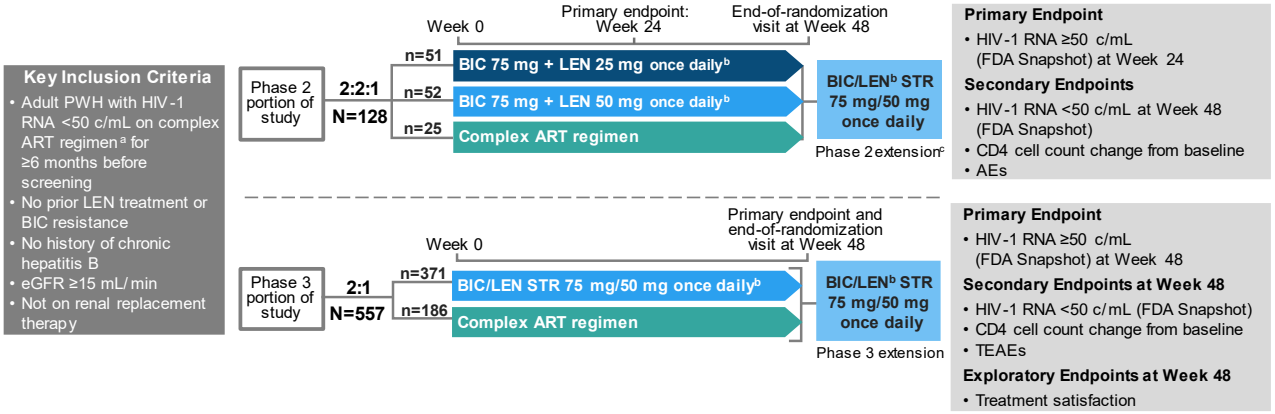
- Through Week 48, in the BIC/LEN and BIC/FTC/TAF groups, the rates of Grade ≥3 AEs (10% vs 8%, respectively) and discontinuations due to AEs (each, 2%) were similar.[7]
- Across various subgroups, the incidence of TRAEs was similar across assessed subgroups and treatment groups.[8]

Safety Overview of BIC/LEN

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]



Abbreviations: NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor; NRTI=nucleos(t)ide reverse transcriptase inhibitor; PI=protease inhibitor.
[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]

Safety results through Week 48

Through Week 48, the safety profile of BIC + LEN was similar regardless of LEN dose. Common TEAEs (≥5% in any group) were Grade 1 or 2 in severity, except for 1 case of Grade 3 diarrhea, which was deemed unrelated to study drug (Table 1).[2]

Table 1. Phase 2 of ARTISTRY-1: TEAEs Through Week 48[9]

Safety Outcomes, n (%)		BIC 75 mg + LEN 25 mg (n=51)	BIC 75 mg + LEN 50 mg (n=52)	Complex ART Regimen (n=25)
Any TEAEs		42 (82.4)	41 (78.8)	19 (76)
Grade ≥3 TEAEs		7 (13.7)	4 (7.7)	1 (4)
Treatment-related TEAEs		9 (17.6)	3 (5.8)	0
Serious TEAEs		4 (7.8)[a]	3 (5.8)[a]	3 (12)[a]
TEAEs that led to study drug discontinuation		1 (2)[b]	1 (1.9)[c]	0
TEAEs in ≥5% in either LEN group	COVID-19	8 (15.7)	5 (9.6)	4 (16)
	Diarrhea	5 (9.8)	2 (3.8)	1 (4)
	Nasopharyngitis	5 (9.8)	0	1 (4)
	Cough	4 (7.8)	3 (5.8)	0
	URTI	3 (5.9)	4 (7.7)	2 (8)
	Arthralgia	3 (5.9)	4 (7.7)	0
	Constipation	3 (5.9)	2 (3.8)	0
	Nausea	3 (5.9)	2 (3.8)	0
	Vertigo	3 (5.9)	0	0
	HTN	1 (2)	5 (9.6)	1 (4)
	Pain in extremity	1 (2)	3 (5.8)	1 (4)
Death		0	1 (1.9)[d]	0

[a]Deemed unrelated to study treatment. [b]Grade 1 nausea was reported on Day 1.
[c]Grade 3 worsening of vomiting was reported in a participant with prior history of nausea and vomiting.
[d]Death was due to coronary artery disease and was deemed unrelated to study drug.

At Week 24, Grade 3 and 4 treatment-emergent laboratory abnormalities were experienced by 9.8% and 2% of participants, respectively, in the BIC 75 mg + LEN 25 mg group; by 17.3% and 5.8% in the BIC 75 mg + LEN 50 mg group; and by 32% and 0% in the complex ART regimen group.[10] Grade 3 or 4 laboratory abnormalities that occurred in ≥3 participants in any treatment group included low CrCl in participants with preexisting chronic kidney disease (BIC 75 mg + LEN 25 mg, n=1 [2%]; BIC 75 mg + LEN 50 mg, n=6 [11.5%]; complex ART regimen, n=2 [12%]) and urine glucose in participants with DM (BIC 75 mg + LEN 25 mg, n=2 [3.9%]; BIC 75 mg + LEN 50 mg, n=5 [9.6%]; complex ART regimen, n=1 [4%]).[11] Laboratory abnormalities were not reported at Week 48.[2,12]

Efficacy and safety through Week 96: participants initially randomized to the BIC 75 mg + LEN 50 mg group[4]

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.

Through Week 96, 46 participants (88.5%) reported an AE, including 13 (25%) with a Grade ≥3 AE. Nine participants (17.3%) reported SAEs, 3 (5.8%) TRAEs were reported (atrial conduction time prolongation, decreased BP, and nausea and vomiting), and no serious TRAEs were reported. No new AEs led to treatment discontinuations, and no deaths were reported between Week 48 and Week 96. The most common (≥10%) AEs reported through Week 96 were URTI (19.2%), COVID-19 (17.3%), HTN (13.5%), arthralgia (11.5%), and cough (11.5%). The median (Q1, Q3) change from baseline to Week 96 in weight was 0 (-3, 2.7) kg.

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 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.[5]

Safety outcomes through Week 48

Between groups, similar rates of AEs and SAEs were reported, most AEs were mild to moderate in severity, and the incidence of treatment discontinuation due to AEs was low (Table 2). The incidence of renal-related AEs was low, and the safety profile was similar between treatment groups regardless of the level of renal function.[5]

Table 2. Phase 3 of ARTISTRY-1: Safety Outcomes Through Week 48[5,13]

Safety Outcomes, n or n/N (%)		BIC/LEN 75 mg/50 mg (n=371)	Complex ART Regimen (n=186)
AEs		305 (82)	157 (84)
TRAEs		53 (14)	3 (2)
Grade ≥3 AEs		51 (14)	26 (14)
Grade ≥3 TRAEs		2 (1)[a]	0
SAEs		52 (14)	22 (12)
Treatment-related SAEs		1 (<1)[b]	0
AEs that led to study drug discontinuation		6 (2)[c]	1 (1)[d]
AEs with ≥5% frequency in the BIC/LEN group	URTI	34 (9)	24 (13)
	Headache	28 (8)	4 (2)
	Nasopharyngitis	26 (7)	17 (9)
	Diarrhea	22 (6)	11 (6)
	HTN	21 (6)	6 (3)
	COVID-19	20 (5)	6 (3)
	Arthralgia	19 (5)	8 (4)
	Cough	18 (5)	11 (6)
TRAEs with ≥2% frequency in the BIC/LEN group[e]	Headache	13 (4)	0
	Nausea	10 (3)	0
	Diarrhea	8 (2)	1 (1)
Death		5 (1)[f]	0
Any-grade laboratory abnormality		341 (92)	178/183 (97)
Grade ≥3 laboratory abnormality		124 (33)	64/183 (35)
Grade ≥3 laboratory abnormalities in ≥2% of participants in any group	Decreased CrCl	46 (12)	29/183 (16)
	Increased direct bilirubin[g]	36 (10)	11/183 (6)
	Glycosuria[g]	21/368 (6)	6/182 (3)
	Increased Cr	11 (3)	11/183 (6)
	Increased fasting triglycerides	10/365 (3)	6/181 (3)
	Increased fasting LDL[g]	8/365 (2)	9/181 (5)
	Increased lipase	10 (3)	5/183 (3)
	Hyperglycemia (non-fasting)[g]	5/228 (2)	2/123 (2)
	Hypercholesterolemia (fasting)[g]	5/365 (1)	4/181 (2)

Abbreviations: DRV=darunavir; EFV=efavirenz; RTV=ritonavir.
[a]DM and maculopapular rash. [b]DM was newly diagnosed in a participant who had a high fasting glucose level at baseline. This resolved on Day 173 after a switch in ART to EFV + DRV/RTV on Day 103.
[c]Cerebrovascular accident; DM; erectile dysfunction and worsened HTN; headache and hypoesthesia; HBV viremia; and alopecia, dizziness, worsened fatigue, headache, and nausea (each, n=1). All AEs except for hypoesthesia, HBV viremia, and cerebrovascular accident were related to BIC/LEN.
[d]Pulmonary embolism; unrelated to study drug.
[e]All were Grade 1 or 2 in severity.

[f]None of the deaths were deemed related to BIC/LEN: unknown cause (n=2), metastatic neoplasm (n=1), cardiac arrest (n=1), and respiratory failure (n=1).
[g]All laboratory abnormalities in both treatment groups were Grade 3 in severity.

Safety outcomes by age subgroup (<65 years and ≥65 years)

A subgroup analysis assessed the safety of VS PWH switching to BIC/LEN by age subgroup (<65 years and ≥65 years). Through Week 48, BIC/LEN was generally well tolerated, with low rates of BIC/LEN discontinuation across both age subgroups (Table 3).[6] In both treatment groups at baseline, CrCl was lower in participants aged ≥65 years than in those aged <65 years; however, through 48 weeks of treatment, CrCl generally remained stable in both age and treatment groups, with small changes to adjacent CrCl categories (ie, ≥15 to <30 mL/min, ≥30 to <60 mL/min, ≥60 to <90 mL/min, and ≥90 mL/min).[6,14]

Table 3. Phase 3 of ARTISTRY-1: Safety Outcomes Through Week 48 by Age Subgroup (<65 Years vs ≥65 Years)[6]

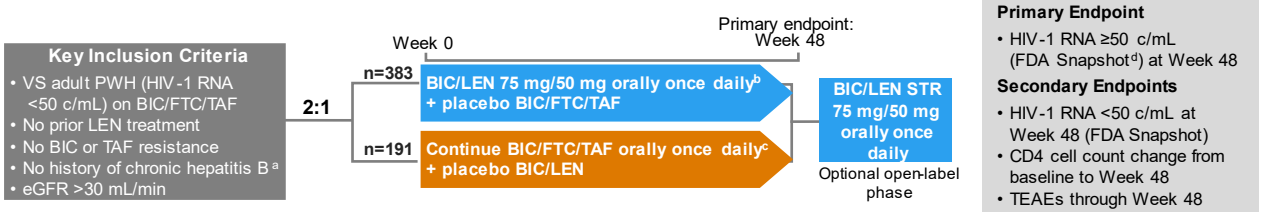
Parameter, n (%)	Age <65 Years		Age ≥65 Years	
	BIC/LEN (n=256)	Complex ART Regimen (n=127)	BIC/LEN (n=115)	Complex ART Regimen (n=59)
Any-grade AE	212 (82.8)	102 (80.3)	93 (80.9)	55 (93.2)
Grade ≥3 AE	33 (12.9)	16 (12.6)	18 (15.7)	10 (16.9)
SAE	33 (12.9)	13 (10.2)	19 (16.5)	9 (15.3)
TRAE	42 (16.4)	3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

[a]DM and maculopapular rash. [b]DM.
[c]DM, stroke (each, n=1); erectile dysfunction and HTN (both in 1 participant); headache and hypoesthesia (both in 1 participant); nausea, dizziness, headache, alopecia, and fatigue (all in 1 participant).
[d]Pulmonary embolism. [e]HBV reactivation.

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

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.[7]

Figure 2. 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%.

Safety outcomes through Week 48

Similar rates of AEs and TRAEs were reported in both groups, and the overall incidence of treatment discontinuation due to AEs was low (Table 4).[7]

Table 4. ARTISTRY-2: Safety Outcomes Through Week 48[7,15]

Safety Outcomes, n (%)		BIC/LEN 75 mg/50 mg (n=383)	BIC/FTC/TAF (n=191)
Any-grade AEs		288 (75)	141 (74)
Grade ≥3 AEs		38 (10)	15 (8)
Any-grade TRAEs		40 (10)	23 (12)
Grade ≥3 TRAE		1 (<1)[a]	0
SAEs		27 (7)	13 (7)
Treatment-related SAEs		0	0
AEs that led to study drug discontinuation		6 (2)[b]	3 (2)[c]
AEs that occurred in ≥5% in either group	Diarrhea	31 (8)	9 (5)
	Nasopharyngitis	30 (8)	13 (7)
	URTI	29 (8)	9 (5)
	Headache	22 (6)	6 (3)
	Nausea	20 (5)	11 (6)
	COVID-19	5 (1)	10 (5)
Death		0	1 (<1)[d]
Any-grade laboratory abnormalities		346/382 (91)	174/190 (92)
Grade ≥3 laboratory abnormalities		93/382 (24)	44/190 (23)
Grade ≥3 laboratory abnormalities in ≥2% of participants in any group	Increased direct bilirubin	36/382 (9)	7/190 (4)
	Decreased CrCl	23/382 (6)	21/190 (11)
	Increased creatinine kinase	10/382 (3)	5/190 (3)
	Increased fasting serum glucose	10/381 (3)	2/189 (1)
	Increased lipase	8/382 (2)	2/190 (1)
	Glycosuria	7/379 (2)	4/181 (2)
	Increased fasting triglycerides	5/377 (1)	4/180 (2)
	Increased Cr	4/382 (1)	6/190 (3)
	Increased non-fasting serum glucose	3/235 (1)	3/126 (2)

[a]Grade 3 rhabdomyolysis that was revised to Grade 1 after data cutoff.
[b]The following were deemed unrelated to BIC/LEN (each, n=1): anxiety; colon cancer; decreased libido; and encephalopathy and intracranial mass. The following were deemed related to BIC/LEN (each, n=1): alopecia and fatigue; and rash, restless leg syndrome, and trismus.
[c]The following were deemed unrelated to BIC/FTC/TAF (each, n=1): abdominal discomfort; road traffic accident. Dry mouth was deemed related to BIC/FTC/TAF treatment.
[d]Due to coronary artery disease and was deemed unrelated to study treatment.

Subgroup analyses[8]

The efficacy and safety of switching from BIC/FTC/TAF to BIC/LEN were assessed in the following subgroups: age (<55 years and ≥55 years), sex, race (White and non-White), and geographic region (US and ex-US). Baseline demographics and disease characteristics were similar between treatment groups and subgroups.

The incidence of TRAEs was similar between BIC/LEN and BIC/FTC/TAF across assessed subgroups. Most TRAEs were Grade 1 or 2 in severity, and no serious TRAEs were reported. Study drug discontinuations due to AEs occurred at low rates (0–4.3%) across assessed subgroups and treatment groups.

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Abbreviations

AE=adverse event
ART=antiretroviral therapy
BIC=bictegravir
BP=blood pressure
c/mL=copies per mL
CD4=cluster of differentiation-4
DM=diabetes mellitus
FTC=emtricitabine
HTN=hypertension
LEN=lenacapavir
OLE=open-label extension
Q=quartile
SAE=serious adverse event
STR=single-tablet regimen
TAF=tenofovir alafenamide
TEAE=treatment-emergent adverse event
TRAE=treatment-related adverse event
URTI=upper respiratory tract infection
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:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

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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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