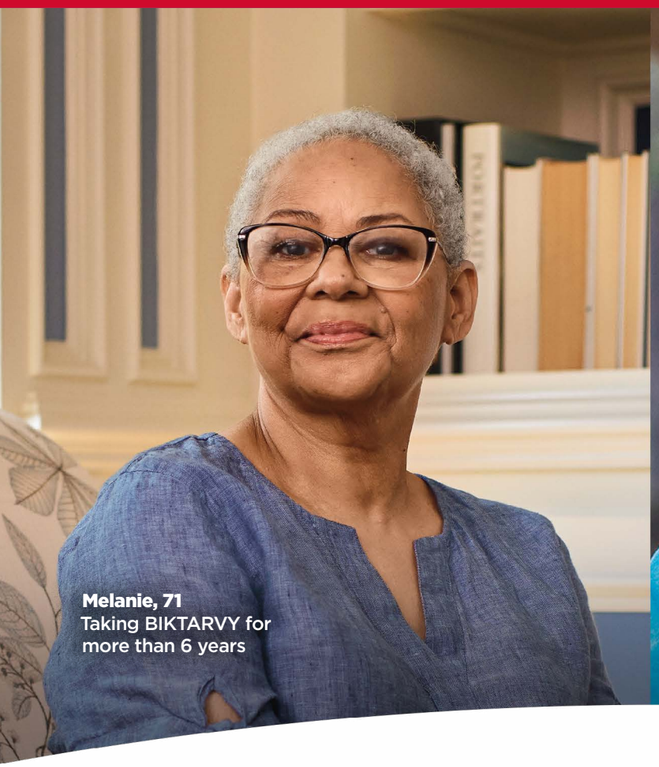
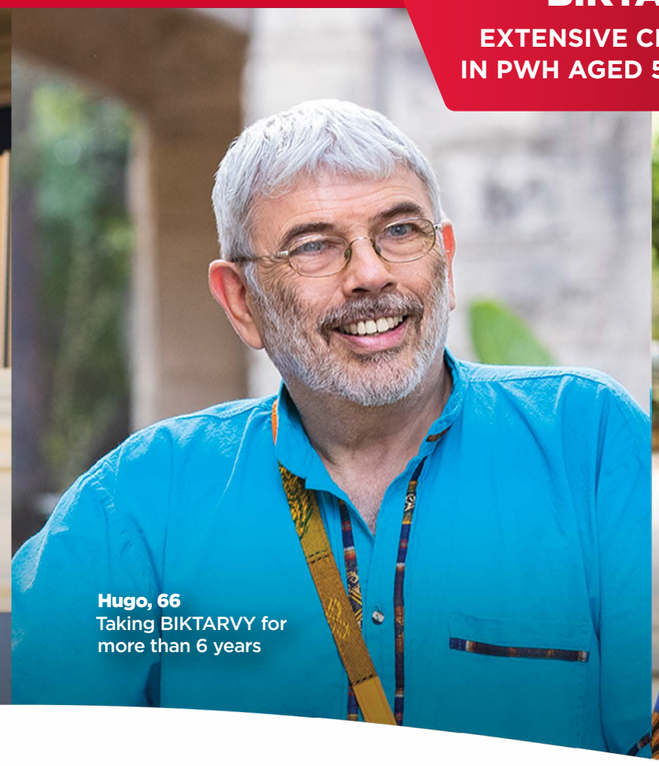
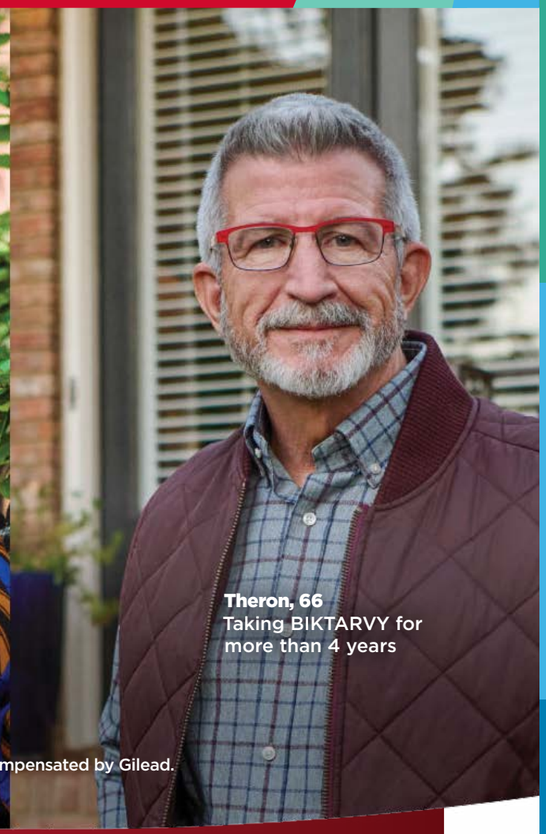
BIKTARVY®:
EXTENSIVE CLINICAL DATA IN PWH AGED 50 AND OLDER[1]







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INDICATION

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥25 kg who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

#1 prescribed regimen for PWH aged 50+ starting and switching HIV-1 treatment for over 6 years[1]

Source: *IQVIA LAAD*, February 2018 through September 2024*

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LAAD, Longitudinal Access and Adjudication Data; PWH, people with HIV.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

GILEAD

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OVER 50 WITH HIV

EXPLORE THE BREADTH OF BIKTARVY® CLINICAL DATA IN PWH AGED 50 AND OLDER[1]

#1 prescribed regimen for PWH aged 50+ starting and switching HIV-1 treatment for over 6 years[1]

Source: *IQVIA LAAD*, February 2018 through September 2024*

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LAAD, Longitudinal Access and Adjudication Data; PWH, people with HIV.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

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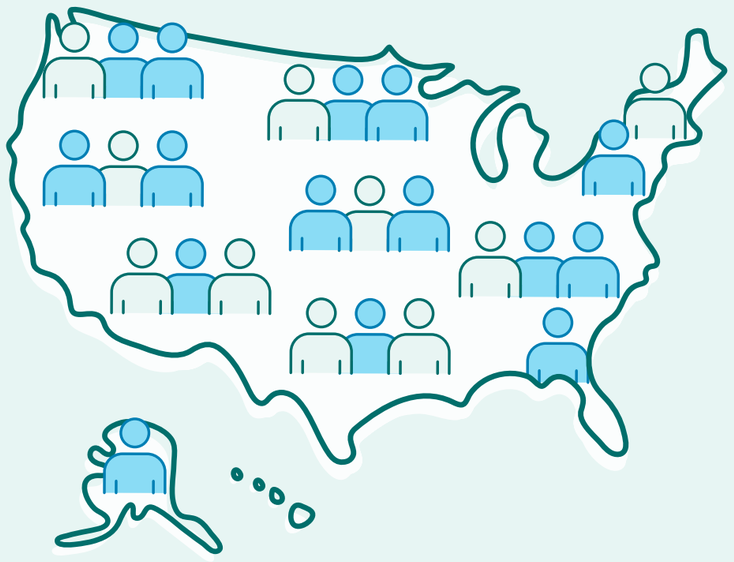
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

IN THE US

IN 2022,
approximately 54% of PWH were aged 50 or older[2]

BY 2030,
an estimated 70% of PWH are expected to be aged 50 or older[3]



For illustrative purposes only; not geographically accurate.

AGING WITH HIV

As PWH age, they may have unique needs and potential health complications[4]

Neurocognitive decline is a concern[4]

According to DHHS guidelines, age-related decline in neurocognitive function is faster in PWH compared to those without.

Cognitive impairment in PWH—with manifestations including problems with memory, attention, and executive function—is associated with reduced adherence to therapy and poorer health outcomes.

Comorbidities, polypharmacy, and other potential health complications[4]

For PWH aged 50 and older, DHHS guidelines recommend all drugs, supplements, and herbal treatments should be assessed regularly for appropriateness, potential for adverse effects, proper dosing, and drug interactions.

Risk of resistance[5,6]

Longer duration of ART is a risk factor associated with developing resistance. PWH aged 50 and older often have decades of ART experience, putting them at risk of developing resistance.

ART, antiretroviral therapy; DHHS, US Department of Health and Human Services; PWH, people with HIV.

Broad clinical trial experience in PWH aged 50 and older[1]

BIKTARVY® efficacy and safety profile established across eight phase 3 clinical trials[1,7-15]

including more than **790 adults aged 50+[1]**

and a trial **exclusively in adults aged 65+[7]**

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

BIKTARVY® has been studied in a **diverse range of PWH aged 50+[1,7]**

n=participants aged 50+ / N=total participants in clinical trial

Treatment-naïve adults

- Study 1489 (**n**/N=**40**/314)*
- Study 1490 (**n**/N=**56**/327)*

Virologically suppressed PWH

- Study 1844 (**n**/N=**124**/282)†
- Study 1878 (**n**/N=**126**/290)†
- Study 4030 (**n**/N=**157**/284)†

Virologically suppressed women

- Study 1961 (**n**/N=**43**/234)†

Virologically suppressed adults aged 65 and older

- Study 4449 (**n**/N=**86**/86)

Virologically suppressed Black American adults

- BRAAVE Study (**n**/N=**160**/330)

*In a post hoc pooled analysis for PWH who are treatment-naïve aged over and under 50, Studies 1489 and 1490 were included.[16]

†In a separate post hoc pooled analysis for PWH who are virologically suppressed aged over and under 50, Studies 1844, 1878, 4030, and 1961 were included.[17]

PWH, people with HIV.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Treatment-naïve clinical trial data

Long-term data through 5 years in treatment-naïve adults with BIKTARVY®

STUDY 1489

STUDY DESIGN AND POPULATION[8]

- Phase 3, randomized, double-blind, active-controlled, noninferiority study
- Treatment-naïve adults who received BIKTARVY (n=314) or ABC/DTG/3TC (n=315)

KEY INCLUSION CRITERIA[8]

- No documented resistance to FTC, TAF, ABC, or 3TC
- HIV-1 RNA ≥500 copies/mL
- eGFR$_{CG}$ ≥50 mL/min

PRIMARY ENDPOINT[8]

- Proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm

SECONDARY ENDPOINTS[18]

- Efficacy, safety, and tolerability were assessed through Weeks 96 and 144

OPEN-LABEL EXTENSION[19]

- After Week 144, all participants who completed Week 144 of the blinded treatment phase were given the option to receive open-label BIKTARVY for an additional 96 weeks
- Efficacy in the OLE from Week 144 through Week 240 was calculated using the FDA snapshot algorithm using missing=excluded (M=E) and missing=failure (M=F) analyses

In an M=E analysis, participants with missing data are excluded when calculating the proportion of participants with HIV-1 RNA <50 copies/mL. In an M=F analysis, all missing data are treated as treatment failures (HIV-1 RNA ≥50 copies/mL).

STUDY 1490

STUDY DESIGN AND POPULATION[9]

- Phase 3, randomized, double-blind, active-controlled, noninferiority study
- Treatment-naïve adults who received BIKTARVY® (n=320) or FTC/TAF+DTG (n=325)

KEY INCLUSION CRITERIA[9]

- No documented resistance to FTC or TAF
- HIV-1 RNA ≥500 copies/mL
- eGFR$_{CG}$ ≥30 mL/min

PRIMARY ENDPOINT[9]

- Proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm

SECONDARY ENDPOINTS[18]

- Efficacy, safety, and tolerability were assessed through Weeks 96 and 144

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In an M=E analysis, participants with missing data are excluded when calculating the proportion of participants with HIV-1 RNA <50 copies/mL. In an M=F analysis, all missing data are treated as treatment failures (HIV-1 RNA ≥50 copies/mL).

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; eGFR$_{CG}$, estimated glomerular filtration rate (Cockcroft-Gault); FDA, US Food and Drug Administration; FTC, emtricitabine; OLE, open-label extension; RNA, ribonucleic acid; TAF, tenofovir alafenamide.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Drug interactions

- **Prescribing information:** Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.
- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Drugs affecting renal function:** Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

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bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

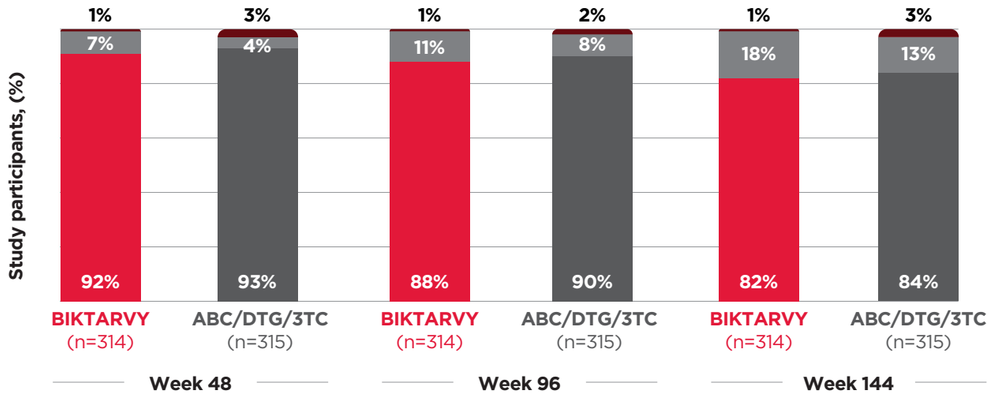
Visit BIKTARVYHCP.com REFERENCES

High rates of virologic suppression at 3 years in clinical trials

STUDIES 1489 & 1490 EFFICACY DATA

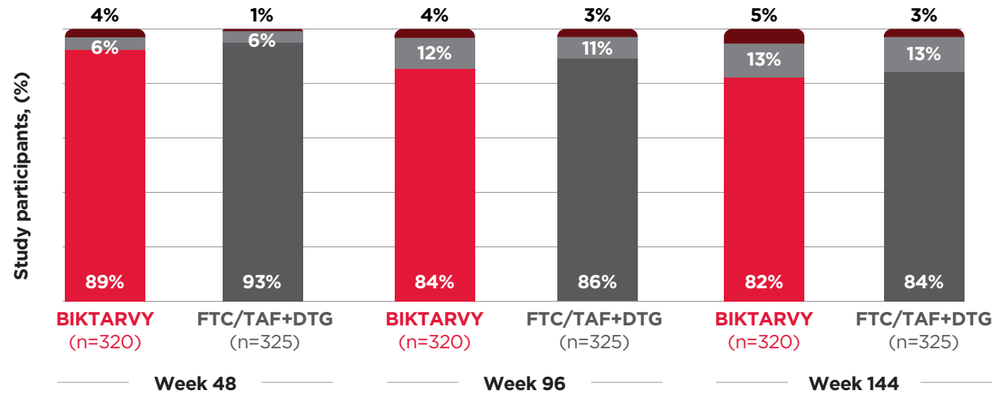
Treatment-Naïve Adults Who Received BIKTARVY® (n=314) or ABC/DTG/3TC (n=315)[8,18,20]

VIROLOGIC RESPONSE[8,18,20,*]



Treatment-Naïve Adults Who Received BIKTARVY® (n=320) or FTC/TAF+DTG (n=325)[9,18,21]

VIROLOGIC RESPONSE[9,18,21,*]



IN STUDIES 1489 AND 1490

BIKTARVY DEMONSTRATED LONG-TERM VIRAL SUPPRESSION AT WEEK 144 **WITH NONINFERIOR RESULTS VS COMPARATORS**[18]

Treatment outcomes were similar across subgroups regardless of age, sex, race, baseline viral load, and baseline CD4+ count at Week 144.[7]

*Percentages do not total 100% due to rounding.

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; RNA, ribonucleic acid; TAF, tenofovir alafenamide.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration

- **Dosage:** Patients weighing ≥25 kg: 1 tablet taken once daily with or without food.
- **Renal impairment:** Not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.
- **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Pregnancy and lactation

- **Pregnancy:** BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Individuals infected with HIV-1 should be informed of the potential risks of breastfeeding.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

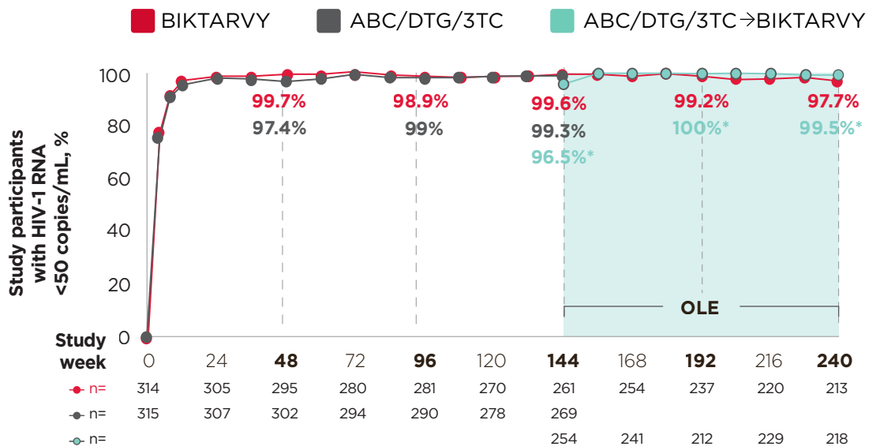
BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Treatment-naïve clinical trial data

Overall rapid and sustained reduction in viral load with BIKTARVY®

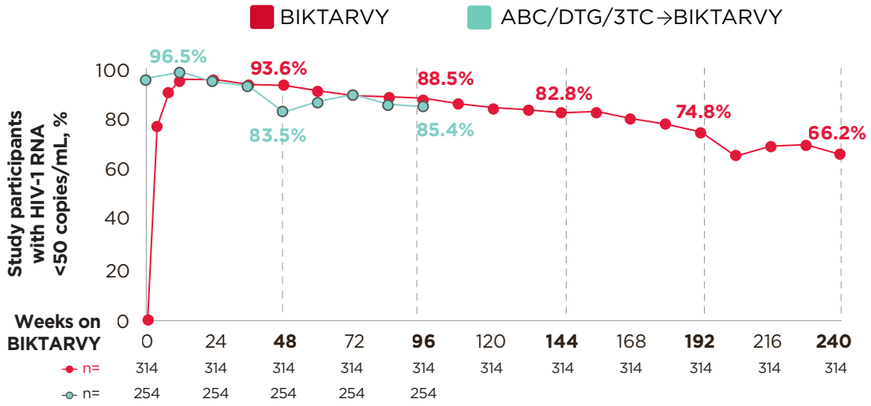
Study 1489: Treatment-naïve adults who received BIKTARVY (n=314) or ABC/DTG/3TC (n=315)[19]

Virologic Outcomes Through Week 240 Using M=E Analysis[19]



In an M=E analysis, participants with missing data are excluded when calculating the proportion of participants with HIV-1 RNA <50 copies/mL.

Virologic Outcomes Through Week 240 on BIKTARVY Using M=F Analysis[19]



In an M=F analysis, all missing data are treated as treatment failures (HIV-1 RNA ≥50 copies/mL).

Study week for participants initially randomized to BIKTARVY and OLE week for participants who switched from ABC/DTG/3TC to BIKTARVY[19]

*M=E data for participants who switched from ABC/DTG/3TC to BIKTARVY.[19]

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

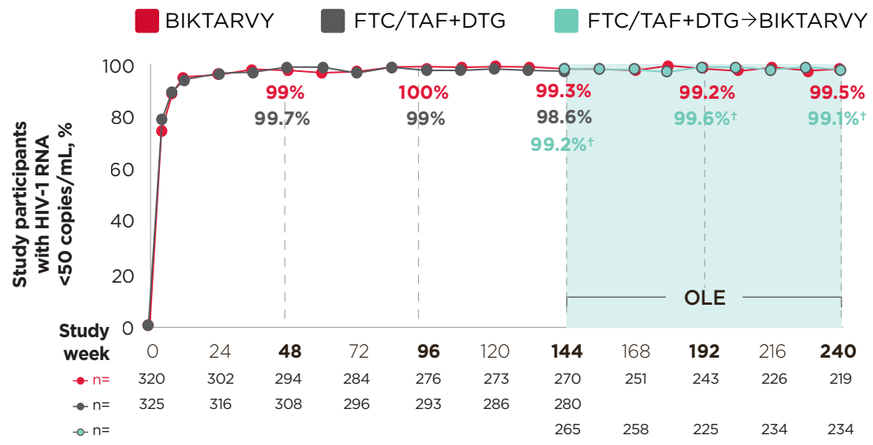
- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.

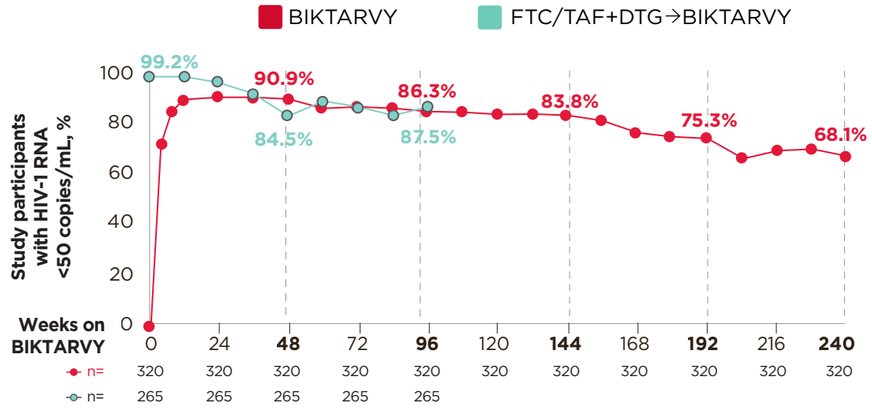
Study 1490: Treatment-naïve adults who received BIKTARVY® (n=320) or FTC/TAF+DTG (n=325)[19]

Virologic Outcomes Through Week 240 Using M=E Analysis[19]



In an M=E analysis, participants with missing data are excluded when calculating the proportion of participants with HIV-1 RNA <50 copies/mL.

Virologic Outcomes Through Week 240 on BIKTARVY Using M=F Analysis[19]



In an M=F analysis, all missing data are treated as treatment failures (HIV-1 RNA ≥50 copies/mL).

Study week for participants initially randomized to BIKTARVY and OLE week for participants who switched from FTC/TAF+DTG to BIKTARVY[19]

†M=E data for participants who switched from FTC/TAF+DTG to BIKTARVY.[19]

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; M=E, missing=excluded; M=F, missing=failure; OLE, open-label extension; RNA, ribonucleic acid; TAF, tenofovir alafenamide.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

BIKTARVY® demonstrated a high barrier to resistance through 5 years in treatment-naïve adults[19,22]

ZERO

cases of treatment-emergent resistance to BIKTARVY through 5 years[19,22,*]

STUDY 1489 & 1490

Resistance Outcomes in Treatment-Naïve Adults Through Week 240 in Studies 1489 and 1490*

Among the treatment-naïve adults who participated in Studies 1489 and 1490, 634 participants received BIKTARVY® through Week 144 of the double-blind phase, and 1025 participants received BIKTARVY through Week 96 of the extension phase. Of the 1025 treatment-naïve adults who participated in the OLE, 506 participants continued on BIKTARVY, 254 participants switched from ABC/DTG/3TC, and 265 participants switched from FTC/TAF+DTG at Week 144.[7,19,22]

In the final resistance analysis population, no amino acid substitutions associated with BIKTARVY resistance emerged in the 11 participants who experienced treatment failure and had evaluable genotypic resistance data.[7]

*Based on the final resistance analysis population.[19,22]

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; OLE, open-label extension; TAF, tenofovir alafenamide.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

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Treatment-naïve clinical trial data

BIKTARVY® has established long-term safety data through 5 years

Adverse Reactions (ARs) (All Grades) Reported in ≥2% of Treatment-Naïve Adults Who Received BIKTARVY Through Week 144[7,*]

	Study 1489		Study 1490	
	BIKTARVY (n=314)	ABC/DTG/3TC (n=315)	BIKTARVY (n=320)	FTC/TAF+DTG (n=325)
Nausea, %	6	18	3	5
Diarrhea, %	6	4	3	3
Headache, %	5	5	4	3
Fatigue, %	3	4	2	2
Abnormal dreams, %	3	3	<1	1
Dizziness, %	2	3	2	1
Insomnia, %	2	3	2	<1
Abdominal distension, %	2	2	1	2

THE MAJORITY (84%) OF ADVERSE EVENTS ASSOCIATED WITH BIKTARVY WERE GRADE 1[7]

*Frequencies of ARs are based on all adverse events attributed to trial drugs by the investigator. No ARs of Grade 2 or higher occurred in >1% of participants treated with BIKTARVY.[7]

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Drug interactions

- **Prescribing information:** Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.

Adverse Reactions (ARs) (All Grades) Reported in ≥2% of Treatment-Naïve Adults Who Received BIKTARVY® Through Week 240[1,19]

	Study 1489		Study 1490	
	BIKTARVY (Baseline-W240) (n=314)	Switched From ABC/DTG/3TC to BIKTARVY (W144-240) (n=254)	BIKTARVY (Baseline-W240) (n=320)	Switched From FTC/TAF+DTG to BIKTARVY (W144-240) (n=265)
Headache, %	5	<1	5	<1
Diarrhea, %	6	1	3	0
Nausea, %	5	<1	3	0
Fatigue, %	3	0	3	<1
Abnormal dreams, %	3	<1	<1	0
Dizziness, %	2	0	3	0
Insomnia, %	2	0	2	0
Proteinuria, %	0	0	2	0

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.

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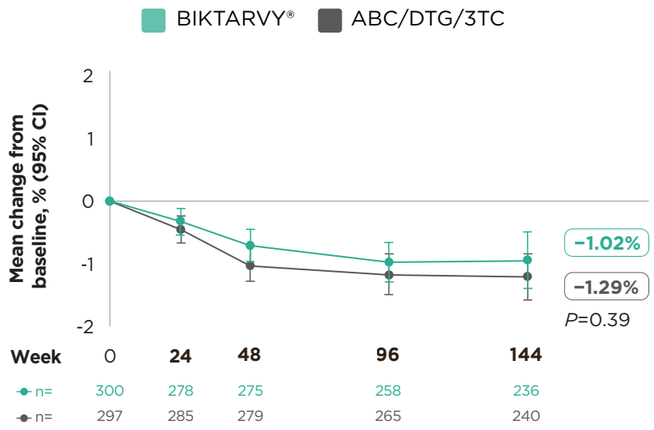
BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Treatment-naïve clinical trial data

Bone parameters through Week 144 and 240

Study 1489: Mean Change in Hip BMD Through Week 144[18]



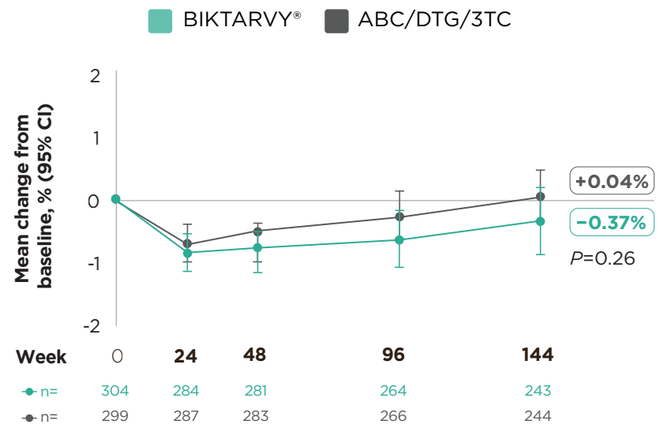
BMD declines of ≥7% at the total hip were experienced in:

- 1% of BIKTARVY arm and 2% of ABC/DTG/3TC arm at Week 48[1]
- 2% of BIKTARVY arm and 3% of ABC/DTG/3TC arm at Week 96[1]
- 5% of BIKTARVY arm and 4% of ABC/DTG/3TC arm at Week 144[1]
- Analysis was conducted in a subset of the study population (n=597)[1]

In the OLE:

- A mean change of −0.3% was observed from baseline at Week 240 (n=197)[19]
- BMD declines of ≥7% at the total hip were experienced in 8% of participants (n=15/197) at Week 240[1]
- Includes only participants initially randomized to BIKTARVY at Week 0, as these participants took BIKTARVY for 240 weeks[19]

Study 1489: Mean Change in Lumbar Spine BMD Through Week 144[18]



BMD declines of ≥5% at the lumbar spine were experienced in:

- 10% of BIKTARVY arm and 6% of ABC/DTG/3TC arm at Week 48[1]
- 12% of BIKTARVY arm and 6% of ABC/DTG/3TC arm at Week 96[1]
- 12% of BIKTARVY arm and 8% of ABC/DTG/3TC arm at Week 144[1]
- Analysis was conducted in a subset of the study population (n=603)[1]

In the OLE:

- A mean change of −0.2% was observed from baseline at Week 240 (n=201)[19]
- BMD declines of ≥5% at the lumbar spine were experienced in 20% of participants (n=41/201) at Week 240[1]
- Includes only participants initially randomized to BIKTARVY at Week 0, as these participants took BIKTARVY for 240 weeks[19]

The long-term clinical significance of changes in BMD is not known

- BMD was assessed at baseline, Week 24, Week 48, Week 96, Week 144, Week 192, and Week 240 by dual-energy X-ray absorptiometry (DXA) scans[1,18,19]
- BMD was only measured in Study 1489

3TC, lamivudine; ABC, abacavir; BMD, bone mineral density; CI, confidence interval; DTG, dolutegravir; OLE, open-label extension.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Drugs affecting renal function:** Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Dosage and administration

- **Dosage:** Patients weighing ≥25 kg: 1 tablet taken once daily with or without food.
- **Renal impairment:** Not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history.

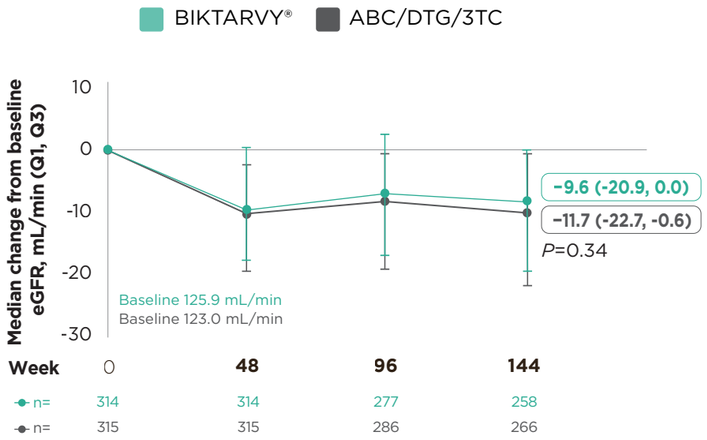
Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

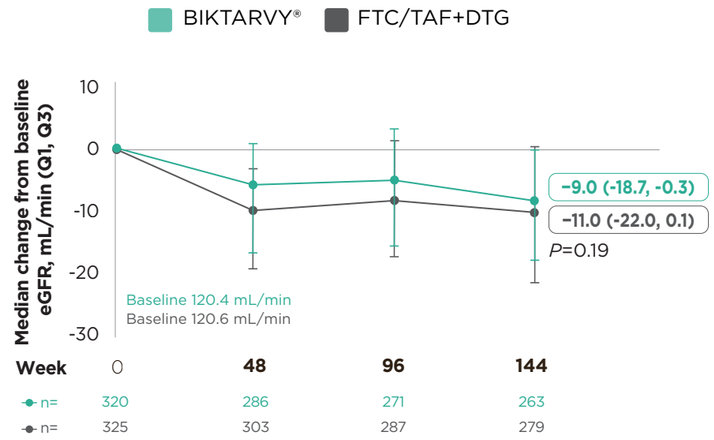
Treatment-naïve clinical trial data

Renal parameters through Week 144 and 240

Study 1489: Median Change in eGFR Through Week 144[8,20,23]



Study 1490: Median Change in eGFR Through Week 144[23-25]



Median serum creatinine increased from baseline to Week 144 by:

- 0.1 mg/dL in the BIKTARVY arm[23]
- 0.11 mg/dL in the ABC/DTG/3TC arm[23]

In the OLE for Study 1489 in participants who were initially randomized to BIKTARVY at Week 0 and continued through Week 240:

- A median eGFR change of **–8.2 mL/min** from baseline was observed at Week 240 (n=213)[1,19]
- Median serum creatinine increased by **0.11 mg/dL** in participants from baseline through Week 240[1]

In participants who switched from ABC/DTG/3TC to BIKTARVY at Week 144 through Week 240:

- A median eGFR change of **+2.0 mL/min** from Week 144 was observed at Week 240 (n=217)[22]

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; eGFR, estimated glomerular filtration rate; FTC, emtricitabine; OLE, open-label extension; TAF, tenofovir alafenamide; Q, quartile.

Median serum creatinine increased from baseline to Week 144 by:

- 0.11 mg/dL in the BIKTARVY arm[23]
- 0.12 mg/dL in the FTC/TAF+DTG arm[23]

In the OLE for Study 1490 in participants who were initially randomized to BIKTARVY at Week 0 and continued through Week 240:

- A median eGFR change of **–8.5 mL/min** from baseline was observed at Week 240 (n=217)[1,19]
- Median serum creatinine increased by **0.11 mg/dL** in participants from baseline through Week 240[1]

In participants who switched from FTC/TAF+DTG to BIKTARVY at Week 144 through Week 240:

- A median eGFR change of **+1.3 mL/min** from Week 144 was observed at Week 240 (n=233)[22]

The long-term clinical significance of changes in eGFR is not known

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.
- **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

Treatment-naïve clinical trial data

Metabolic parameters through Week 144 and 240

Median Cumulative Weight Change From Baseline Through Week 240[1,26]

	Study 1489		Study 1490	
	BIKTARVY® Baseline (n=314)	**ABC/DTG/3TC, switched to BIKTARVY for Week 144 through Week 240** Baseline (n=315)	**BIKTARVY** Baseline (n=320)	**FTC/TAF+DTG, switched to BIKTARVY for Week 144 through Week 240** Baseline (n=325)
Median cumulative weight change through Week 144, kg/y	**+4.0** (n=263)	**+3.5** (n=267)	**+4.3** (n=270)	**+5.0** (n=279)
Median cumulative weight change through Week 240, kg/y	**+6.1** (n=214)	**+6.8** (n=217)	**+6.1** (n=217)	**+5.4** (n=234)

Median cumulative weight change:

- In study participants who switched to BIKTARVY at Week 144, median cumulative weight gain from baseline to Week 240 was 6.8 kg in Study 1489 and 5.4 kg in Study 1490[26]
- Significantly lower median weight changes were observed at Week 144 for study participants treated with ABC/DTG/3TC vs FTC/TAF+DTG: 3.5 kg vs 5.0 kg (*P*=0.02)[26]
- Between Weeks 144 and 240 of the OLE, greater median weight changes were observed in study participants who switched from ABC/DTG/3TC to BIKTARVY vs those who switched from FTC/TAF+DTG to BIKTARVY: 2.4 kg vs 1.3 kg (*P*=0.01)[26]

In the OLE through Week 240:

- 3 study participants discontinued due to a weight-related adverse event attributed to study drug through Week 240[19,26]

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Individuals infected with HIV-1 should be informed of the potential risks of breastfeeding.

Median Change in Fasting Lipids From Baseline Through Week 144[23]

	Study 1489		Study 1490	
	BIKTARVY® Baseline (n=305) Week 144 (n=247)	**ABC/DTG/3TC** Baseline (n=305) Week 144 (n=256*)	**BIKTARVY** Baseline (n=314) Week 144 (n=256)	**FTC/TAF+DTG** Baseline (n=321) Week 144 (n=274)
Total-C (mg/dL)	**+14**	**+10**	**+12**	**+12**
LDL-C (mg/dL)	**+21**	**+14**	**+19**	**+19**
HDL-C (mg/dL)	**+5**	**+6**	**+3**	**+5**
Triglycerides (mg/dL)	**+6**	**+5**	**+2**	**+2**
Total-C:HDL-C ratio	**-0.1**	**-0.3**	**+0.0**	**-0.1**

In the OLE for Study 1489:

- In participants who were initially randomized to BIKTARVY at Week 0 and continued through Week 240, median changes in fasting lipids from baseline were as follows (n=202): Total-C: +20 mg/dL, LDL-C: +22 mg/dL, HDL-C: +5 mg/dL, triglycerides: +11 mg/dL, Total-C:HDL-C ratio: 0.0[1]
- In participants who switched from ABC/DTG/3TC to BIKTARVY at Week 144 through Week 240, median changes in fasting lipids from baseline were as follows (n=215)†: Total-C: +7 mg/dL, LDL-C: +2 mg/dL, HDL-C: 0.0 mg/dL, triglycerides: -3 mg/dL, Total-C:HDL-C ratio: +0.1[1]

In the OLE for Study 1490:

- In participants who were initially randomized to BIKTARVY at Week 0 and continued through Week 240, median changes in fasting lipids from baseline were as follows (n=208): Total-C: +22 mg/dL, LDL-C: +17 mg/dL, HDL-C: +4 mg/dL, triglycerides: +10 mg/dL, Total-C:HDL-C ratio: +0.1[1]
- In participants who switched from FTC/TAF+DTG to BIKTARVY at Week 144 through Week 240, median changes in fasting lipids from baseline were as follows (n=225): Total-C: +5 mg/dL, LDL-C: -2 mg/dL, HDL-C: +1 mg/dL, triglycerides: +2 mg/dL, Total-C:HDL-C ratio: -0.1[1]

*Except for triglycerides, which are (n=255) at Week 144.[23]
†Except for triglycerides, which are (n=213) at Week 240.[1]

3TC, lamivudine; ABC, abacavir; BIC, bictegravir; DTG, dolutegravir; FTC, emtricitabine; HDL, high-density lipoprotein; LDL, low-density lipoprotein; OLE, open-label extension; TAF, tenofovir alafenamide.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

Treatment-naïve post hoc pooled analysis clinical trial data

BIKTARVY® clinical trials included treatment-naïve PWH aged 50 and older

TREATMENT-NAÏVE 50+ SUBGROUP ANALYSIS STUDY DESIGN

Post Hoc Pooled Analysis of 144-Week Randomized Phase and 96-Week Open-Label Extension

OBJECTIVE[16]

- To assess the efficacy and safety of BIKTARVY through 5 years (Week 240) in treatment-naïve PWH aged 50 years and older in two phase 3 studies

METHODS[16]

- A post hoc pooled analysis of participants who received BIKTARVY in the 144-week randomized phase and the 96-week open-label extension of the following two phase 3 randomized, double-blind, multicenter studies:
  - Study 1489
  - Study 1490

ADDITIONAL STUDY DETAILS[16]

- Participants were required to be HLA-B*5701 negative for inclusion in the study

Study 1489[16]:

- Negative for chronic HBV infection
- No known resistance to FTC, TFV, ABC, or 3TC

Study 1490[16]:

- Chronic HBV or HCV infection allowed
- No known resistance to FTC or TFV

STUDY LIMITATIONS

- This analysis was not prespecified, and statistical testing for comparison was not conducted. Data should be considered descriptive only

3TC, lamivudine; ABC, abacavir; c, copies; CD4, cluster of differentiation 4; FTC, emtricitabine; HBV, hepatitis B virus; HCV, hepatitis C virus; HLA, human leukocyte antigen; PWH, people with HIV; Q, quartile; TFV, tenofovir.

IMPORTANT SAFETY INFORMATION (cont'd)

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Contraindications

- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

Baseline Demographics and Clinical Characteristics, By Age Group[16]

		BIKTARVY® in PWH Aged ≥50 Years (n=96)	BIKTARVY in PWH Aged <50 Years (n=538)
Age, years, median (Q1, Q3)		55 (52, 60)	30 (25, 37)
Male sex at birth, n (%)		81 (84)	484 (90)
Region, n (%)	US	56 (58)	365 (68)
	Ex-US	40 (42)	173 (32)
Race, n (%)	White	59 (62)	304 (57)
	Black	30 (32)	181 (34)
	Other*	6 (6)†	52 (10)†
Hispanic or Latine ethnicity, n (%)		11 (11)	144 (27)‡
HIV-1 RNA, log_{10} c/mL, median (Q1, Q3)		4.48 (4.00, 4.93)	4.41 (4.00, 4.86)
HIV-1 RNA >100,000 c/mL, n (%)		23 (24)	96 (18)
CD4 cell count, cells/µL, median (Q1, Q3)		436 (235, 601)	442 (299, 590)
Medical history, n (%)	Diabetes mellitus	16 (17)	22 (4)
	Hyperlipidemia	39 (41)	48 (9)
	Hypertension	46 (48)	52 (10)

*Includes American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, and Other.[16]
†Race data not available for 1 participant.[16]
‡Ethnicity data not available for 2 participants.[16]

Baseline diabetes, hyperlipidemia, and hypertension were observed to be more frequent among participants aged 50 years and older.[16]

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

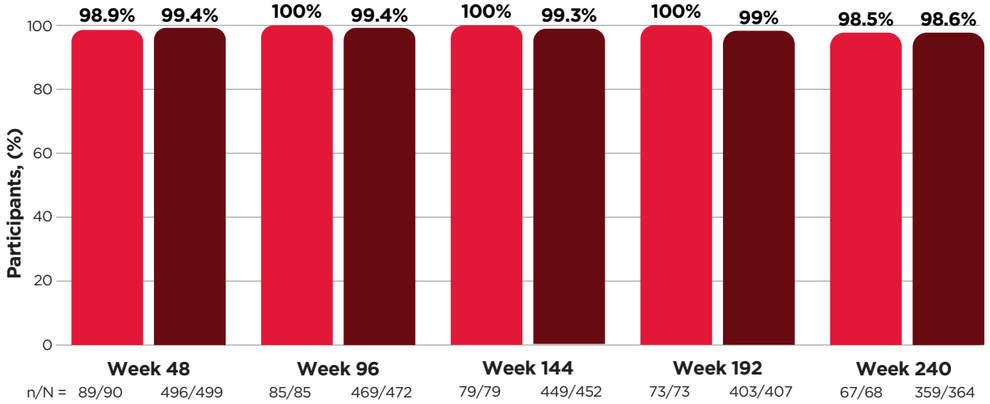
BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Treatment-naïve post hoc pooled analysis clinical trial data

High rates of virologic suppression at 5 years in treatment-naïve PWH aged 50 and older

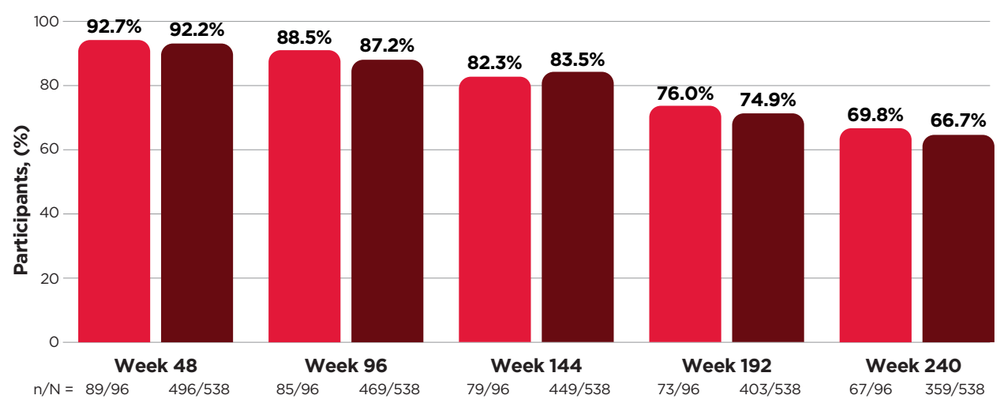
High rates of virologic suppression with BIKTARVY® at 5 years in both age groups[16]

HIV-1 RNA <50 c/mL Using M=E Analysis at Week 240



In an M=E analysis, study participants with missing data are excluded when calculating the proportion of study participants with HIV-RNA <50 copies/mL.

HIV-1 RNA <50 c/mL Using M=F Analysis at Week 240[27]



In an M=F analysis, all missing data are treated as treatment failures (HIV-1 RNA ≥50 copies/mL).

NUMERICALLY SIMILAR RATES OF VIROLOGIC SUPPRESSION WITH BIKTARVY WERE OBSERVED BETWEEN BOTH AGE GROUPS[16,27]

c, copies; M=E, missing=excluded; M=F, missing=failure; PWH, people with HIV; RNA, ribonucleic acid.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

Treatment-naïve post hoc pooled analysis clinical trial data

Demonstrated long-term safety and tolerability profile through Week 240 in PWH aged 50 and older

Adverse Reactions Through Week 240[16]

n (%)	BIKTARVY® in PWH Aged ≥50 Years (n=96)	BIKTARVY in PWH Aged <50 Years (n=538)
Adverse reactions	25 (26)	153 (28)
Grade 3 or 4 adverse reactions	4 (4)	5 (<1)
Serious adverse reactions	2 (2)	3 (<1)
Discontinuations due to adverse event	4 (4)	6 (1)

RATES OF STUDY DRUG DISCONTINUATIONS DUE TO AEs WERE LOW IN BOTH AGE GROUPS[16]

Adverse Reactions Reported in ≥2% of Study Participants in Either Subgroup Through Week 240[1]

n (%)	BIKTARVY® in PWH Aged ≥50 Years (n=96)	BIKTARVY in PWH Aged <50 Years (n=538)
Nausea	5 (5)	23 (4)
Creatinine clearance decreased	2 (2)	3 (1)
Diarrhea	4 (4)	26 (5)
Dizziness	4 (4)	11 (2)
Headache	4 (4)	27 (5)
Abdominal pain	2 (2)	2 (<1)
Dyspepsia	2 (2)	3 (1)
Fatigue	2 (2)	15 (3)
Flatulence	2 (2)	6 (1)
Hypercholesterolemia	2 (2)	4 (1)
Somnolence	2 (2)	2 (<1)
Insomnia	0 (0)	13 (2)

AE, adverse event; PWH, people with HIV.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Drug interactions

- **Prescribing information:** Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.
- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Drugs affecting renal function:** Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Dosage and administration

- **Dosage:** Patients weighing ≥25 kg: 1 tablet taken once daily with or without food.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Treatment-naïve post hoc pooled analysis clinical trial data

Renal, bone, and metabolic parameters for PWH aged over and under 50

Change From Baseline in Renal and Metabolic Parameters at Week 240[16]

		BIKTARVY® in PWH Aged ≥50 Years (n=96)		BIKTARVY in PWH Aged <50 Years (n=538)	
		Median (Q1, Q3)	n	Median (Q1, Q3)	n
eGFR,* mL/min	Baseline	**99.2 (83.6, 114.0)**	**96**	**126.3 (108.5, 146.8)**	**538**
	Change at Week 240	**-10.5 (-19.6, 2.4)**	**67**	**-7.7 (-19.4, 3.0)**	**363**
Body weight, kg	Baseline	**79.3 (70.7, 89.9)**	**96**	**75.9 (67.3, 87.1)**	**538**
	Change at Week 240	**4.8 (0.7, 10.2)**	**68**	**6.4 (2.4, 12.0)**	**363**
TC: HDL ratio†	Baseline	**4.1 (3.2, 5.0)**	**93**	**3.7 (3.0, 4.5)**	**526**
	Change at Week 240	**-0.3 (-0.9, 0.4)**	**65**	**0.1 (-0.4, 0.6)**	**345**

Baseline value was defined as the last non-missing value obtained at or prior to the first dose of BIKTARVY.

THROUGH WEEK 240, **CHANGE FROM BASELINE IN eGFR WAS NUMERICALLY SIMILAR** BETWEEN BOTH AGE GROUPS[16]

The long-term clinical significance of changes in eGFR is not known

Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus[1]

*By Cockcroft-Gault equation.[16]
†Only laboratory measurements under fasting status are summarized.[16]

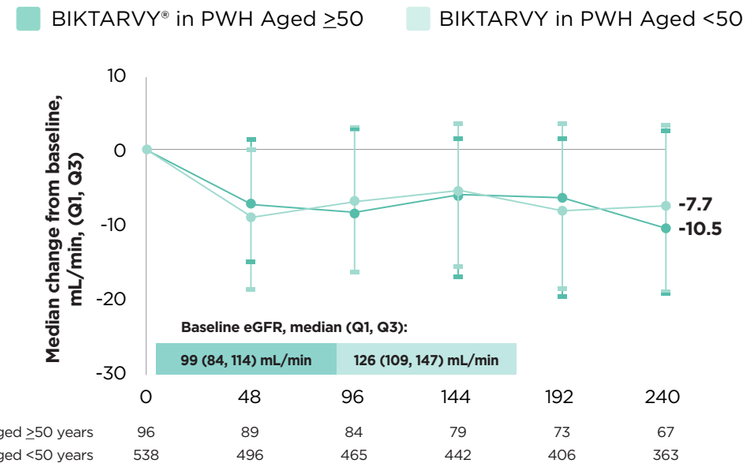
CI, confidence interval; CrCl, creatinine clearance; eGFR, estimated glomerular filtration rate; HDL, high-density lipoprotein; PWH, people with HIV; Q, quartile; TC, total cholesterol.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

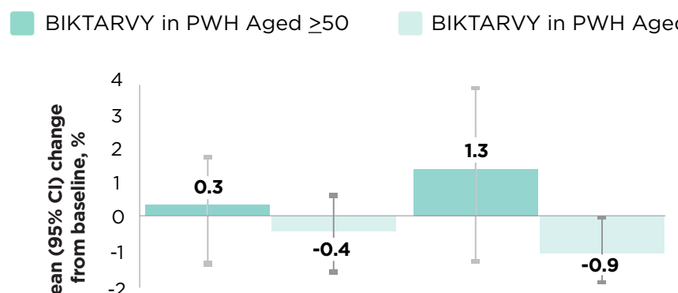
- **Renal impairment:** Not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.
- **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Change From Baseline in eGFR Through Week 240[27]



Change From Baseline in Bone Mineral Density (BMD) at Week 240[16]

From Study 1489



	Hip BMD		Spine BMD	
	Aged ≥50 years	Aged <50 years	Aged ≥50 years	Aged <50 years
n at baseline and Week 240	21	126	21	130
BMD at baseline, g/m², mean (95% CI)	1.0 (0.94-1.07)	1.1 (1.03-1.08)	1.1 (1.06-1.21)	1.2 (1.13-1.19)

Baseline value was defined as the last non-missing value obtained at or prior to the first dose of BIKTARVY.

The long-term clinical significance of changes in BMD is not known

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

Virologically suppressed clinical trial data

Select BIKTARVY® clinical trials in virologically suppressed patients

STUDIES 1844, 1878, 4030, & 1961 STUDY DESIGN

STUDY 1844

STUDY DESIGN AND POPULATION[10,28]

- Randomized (1:1), double-blind, active controlled, noninferiority study
- Virologically suppressed adults who switched to BIKTARVY (n=282) or continued on baseline regimen ABC/DTG/3TC or ABC/3TC+DTG (n=281) through Week 48. Open-label extension through Week 168 to continue BIKTARVY (n=259) or switch to BIKTARVY (n=265)

PRIMARY ENDPOINT[10]

- Proportion of adults with HIV-1 RNA ≥50 copies/mL at Week 48 (NI margin, 4%) using the FDA snapshot algorithm

SECONDARY ENDPOINT[10]

- Proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm

OPEN-LABEL EXTENSION[28]

- The objective of OLE from Week 48 through Week 168 was to evaluate the efficacy and safety of BIKTARVY after additional exposure
  - Efficacy in the extension phase from Week 48 through Week 168 was calculated using M=E analysis

KEY INCLUSION CRITERIA[7,10]

- No documented/suspected resistance to FTC, TFV, ABC, 3TC, or DTG
- Study participants were on a stable baseline regimen for at least 3 months with no history of treatment failure[5]

STUDY 1878

STUDY DESIGN AND POPULATION[11]

- Randomized (1:1), open-label, active controlled, noninferiority study
- Virologically suppressed adults who switched to BIKTARVY (n=290) or continued on baseline regimen ABC/3TC or FTC/TDF + boosted DRV or ATV (n=287) through Week 48. Extension through Week 96 to continue BIKTARVY (n=272) or switch to BIKTARVY (n=244)

PRIMARY ENDPOINT[11]

- Proportion of adults with HIV-1 RNA ≥50 copies/mL at Week 48 (NI margin, 4%) using the FDA snapshot algorithm

SECONDARY ENDPOINT[11]

- Proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm

EXTENSION PHASE[29]

- The objective of the extension phase from Week 48 through Week 96 was to evaluate the efficacy and safety of BIKTARVY after additional exposure
  - Efficacy in the extension phase from Week 48 through Week 96 was calculated using M=E analysis

KEY INCLUSION CRITERIA[7,11]

- No documented/suspected resistance to FTC, TFV, ABC, or 3TC
- Study participants were on a stable baseline regimen for at least 6 months, were not previously treated with any INSTI, and had no history of treatment failure

STUDY 4030

STUDY DESIGN AND POPULATION[12]

- Phase 3, randomized (1:1), double-blind, active-controlled, noninferiority study
- Virologically suppressed adults on a baseline regimen of FTC/TDF+DTG or FTC/TAF+DTG who switched to BIKTARVY® (n=284) or continued on FTC/TAF+DTG (n=281) through Week 48

PRIMARY ENDPOINT[12]

- Proportion of adults with HIV-1 RNA ≥50 copies/mL at Week 48 (NI margin, 4%) using the FDA snapshot algorithm

SECONDARY ENDPOINT[12]

- Proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 (NI margin, 10%) using the FDA snapshot algorithm

KEY INCLUSION CRITERIA[12]

- No documented INSTI resistance or confirmed virologic failure on an INSTI-containing regimen
- Documented or suspected NRTI, NNRTI, and PI resistance permitted
- HIV-1 RNA <50 copies/mL
  - For ≥6 months if NRTI resistance was documented or suspected
  - For ≥3 months if no NRTI resistance was documented or suspected

STUDY 1961

STUDY DESIGN AND POPULATION[13,30]

- Phase 3, randomized (1:1), open-label, active-controlled study
- Virologically suppressed adult women who switched to BIKTARVY (n=234) or continued on a baseline regimen of E/C/F/TAF or E/C/F/TDF or ATV+RTV+FTC/TDF (n=236) through Week 48. Extension through Week 96 to continue BIKTARVY (n=231) or switch to BIKTARVY (n=228)

EXTENSION PHASE[30]

- At Week 48, the women receiving an INSTI- or PI-based regimen at baseline were switched to BIKTARVY, and an additional analysis was performed at Week 96
  - Efficacy in the extension phase from Week 48 through Week 96 was calculated using M=E analysis

KEY INCLUSION CRITERIA[13]

- No documented/suspected resistance to FTC, TFV, ATV, or EVG
- Study participants were on a stable baseline regimen for at least 3 months

PRIMARY ENDPOINT[13]

- Proportion of adults with HIV-1 RNA ≥50 copies/mL at Week 48 (NI margin, 4%) using the FDA snapshot algorithm

In an M=E analysis, participants with missing data are excluded when calculating the proportion of participants with HIV-1 RNA <50 copies/mL.

3TC, lamivudine; ABC, abacavir; ATV, atazanavir; C, cobicistat; DTG, dolutegravir; E, elvitegravir; EVG, elvitegravir; F, emtricitabine; FDA, US Food and Drug Administration; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; M=E, missing=excluded; NI, non-inferiority; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; OLE, open-label extension; PI, protease inhibitor; RTV, ritonavir; RNA, ribonucleic acid; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; TFV, tenofovir.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

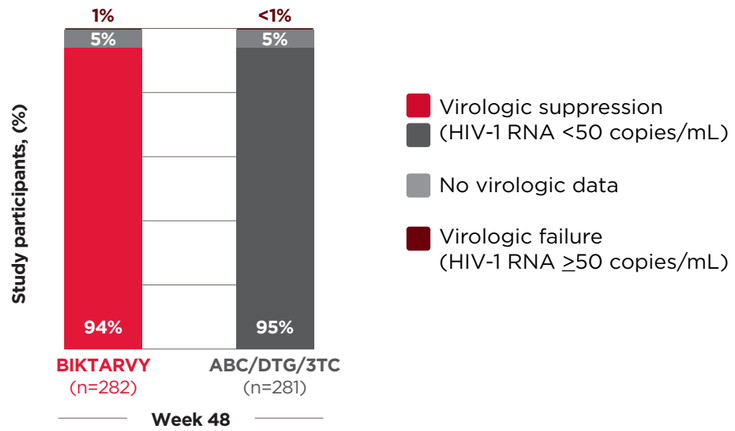
BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Virologically suppressed clinical trial data

Durable efficacy in virologically suppressed adults at 3 years

Study 1844: Virologically Suppressed Adults Who Received BIKTARVY® (n=282) or ABC/DTG/3TC (n=281)[7]

VIROLOGIC RESPONSE[7,*]



0.7% treatment difference in HIV-1 RNA ≥50 copies/mL (-1.0% to 2.8%; *P*=0.62)[†]

POWERFUL EFFICACY[7]

94% of adults who switched to BIKTARVY maintained virologic suppression at Week 48

- Treatment outcomes between treatment groups were similar across subgroups by age, sex assigned at birth, race, and region at Week 48

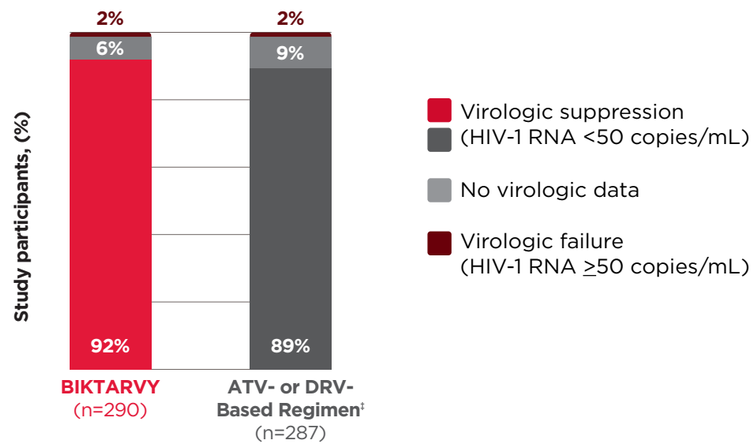
DURABLE VIRAL SUPPRESSION AT WEEK 168[28]

In a 120-week open-label extension from Week 48, using an M=E analysis, virologic suppression was maintained in 100% of study participants on BIKTARVY (n=14) at Week 168 from BIKTARVY switch

In an M=E analysis, participants with missing data are excluded when calculating the proportion of participants with HIV-1 RNA<50 copies/mL.

Study 1878: Virologically Suppressed Adults Who Received BIKTARVY® (n=290) or ATV- or DRV-Based Regimen[‡] (n=287)[7]

VIROLOGIC RESPONSE[7]



0.0% treatment difference in HIV-1 RNA ≥50 copies/mL (-2.5% to 2.5%; *P*=1.00)[†]

POWERFUL EFFICACY[7]

92% of adults who switched to BIKTARVY maintained virologic suppression at Week 48

- Treatment outcomes between treatment groups were similar across subgroups by age, sex assigned at birth, race, and region at Week 48

DURABLE VIRAL SUPPRESSION AT WEEK 96[29]

In the extension from Week 48, using an M=E analysis, virologic suppression was maintained in 100% of study participants on BIKTARVY (n=318) at Week 96 from BIKTARVY switch

In an M=E analysis, study participants with missing data are excluded when calculating the proportion of study participants with HIV-1 RNA <50 copies/mL.

*Percentages do not total 100% due to rounding.
[†]95% confidence interval.[7]
[‡]ABC/3TC or FTC/TDF + boosted ATV or DRV (cobicistat or ritonavir) regimen.[7]

3TC, lamivudine; ABC, abacavir; ATV, atazanavir; DRV, darunavir; DTG, dolutegravir; FTC, emtricitabine; M=E, missing=excluded; RNA, ribonucleic acid; TDF, tenofovir disoproxil fumarate.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation (cont'd)

- **Lactation:** Individuals infected with HIV-1 should be informed of the potential risks of breastfeeding.

Contraindications

- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

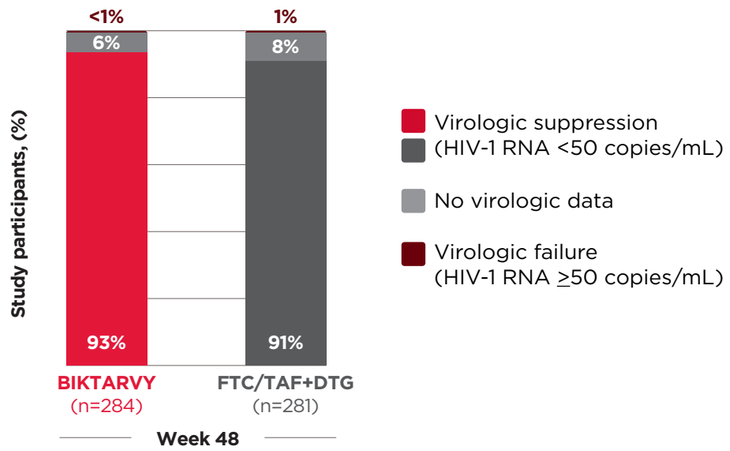
BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

BIKTARVY® provided powerful efficacy

Powerful efficacy in virologically suppressed adults at Week 48, including those with known or suspected preexisting M184V/I resistance mutation[12]

Study 4030: Virologically Suppressed Adults Who Received BIKTARVY (n=284) or FTC/TAF+DTG (n=281)

VIROLOGIC RESPONSE[12]



Week 48

-0.7% treatment difference in HIV-1 RNA ≥50 copies/mL (-2.8% to 1.0%)

POWERFUL EFFICACY

- BIKTARVY was noninferior to FTC/TAF+DTG at Week 48, with 0.4% of adults who switched to BIKTARVY having HIV-1 RNA ≥50 copies/mL using the FDA snapshot algorithm[12]
- 93% of adults who switched to BIKTARVY maintained viral suppression at Week 48 compared to 91% of adults who switched or stayed on FTC/TAF+DTG, using the FDA snapshot algorithm[12]
- Treatment outcomes were similar across subgroups regardless of known or suspected preexisting M184V/I resistance, age, sex, race, and geographic region at Week 48[12]

IMPORTANT SAFETY INFORMATION (cont'd)

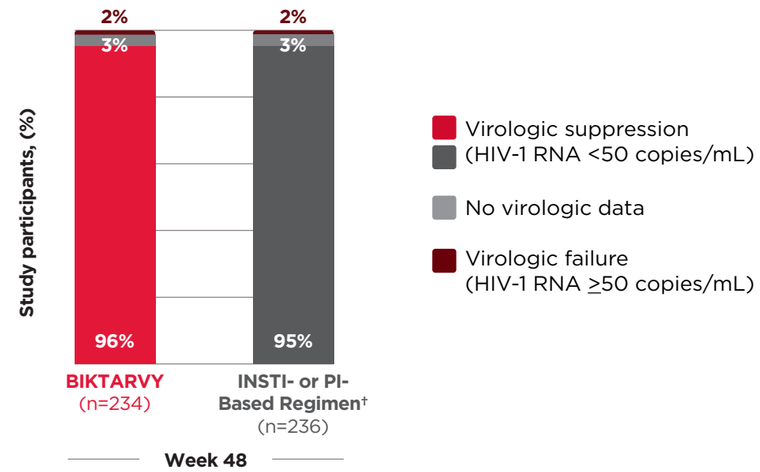
Warnings and precautions (cont'd)

- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.

Powerful efficacy in virologically suppressed adult women at Week 96[13]

Study 1961: Virologically Suppressed Adult Women Who Received BIKTARVY® (n=234) vs an INSTI- or PI-Based Regimen† (n=236)[13]

VIROLOGIC RESPONSE[13,*]



Week 48

0.0% treatment difference in HIV-1 RNA ≥50 copies/mL (-2.9% to 2.9%‡; *P*=1.00)‡

POWERFUL EFFICACY

96% of adult women who switched to BIKTARVY maintained virologic suppression at Week 48[13]

- Treatment outcomes between treatment groups were similar across subgroups by age, race, and geographic region at Week 48[31]

DURABLE VIRAL SUPPRESSION AT WEEK 96

In a 48-week extension from Week 48, using an M=E analysis, virologic suppression was maintained at Week 96 in 99.5% of study participants who stayed on BIKTARVY (n=208) and in 98.5% of study participants who switched to BIKTARVY (n=194) at Week 48[30]

In an M=E analysis, participants with missing data are excluded when calculating the proportion of participants with HIV-1 RNA <50 copies/mL.

*Percentages do not total 100% due to rounding.
†E/C/F/TAF or E/C/F/TDF or ATV+RTV+FTC/TDF.[13]
‡95% confidence interval.[13]

ATV, atazanavir; C, cobicistat; DTG, dolutegravir; E, elvitegravir; F, emtricitabine; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; M=E, missing=excluded; PI, protease inhibitor; RNA, ribonucleic acid; RTV, ritonavir; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY® demonstrated a high barrier to resistance in virologically suppressed adults

ZERO cases of treatment-emergent resistance to BIKTARVY in Studies 1844, 1878, 4030, and 1961[10-13,*]

Study 1844 & Study 1878

Resistance Outcomes in Virologically Suppressed Adults Through Week 168 in Study 1844 and Through Week 96 in Study 1878*

- Among 572 virologically suppressed adults randomized to BIKTARVY in Studies 1844 and 1878 through Week 48, 2 participants with virologic rebound had genotypic and phenotypic data (1 for RT, 1 for IN and RT), and no treatment-emergent resistance to BIKTARVY was detected through Week 48[7,32,*]
  - 524 virologically suppressed adults participated in an open-label extension (OLE) of Study 1844; 259 were continuing BIKTARVY, and 265 switched to BIKTARVY at Week 48. **No treatment-emergent resistance to BIKTARVY was detected through Week 168**, including in the 1 participant who switched to BIKTARVY and met the criteria for resistance analysis[28,33,*]
  - 516 virologically suppressed adults participated in an extension phase of Study 1878; 272 were continuing BIKTARVY, and 244 switched to BIKTARVY at Week 48. **No treatment-emergent resistance to BIKTARVY was detected through Week 96**, including in the 3 participants who switched to BIKTARVY and met the criteria for resistance analysis[29,*]

STUDY 4030

Resistance Outcomes in Virologically Suppressed Adults Through Week 48 in Study 4030*

- Among the 284 virologically suppressed adults randomized to BIKTARVY® in Study 4030 through Week 48, 0 participants met the criteria for resistance analysis, and **no treatment-emergent resistance to BIKTARVY was detected through Week 48**[12]

STUDY 1961

Resistance Outcomes in Virologically Suppressed Adult Women Through Week 96 in Study 1961*

- Among 234 virologically suppressed adult women randomized to BIKTARVY in Study 1961 through Week 48, 1 participant met the criteria for resistance analysis. No treatment-emergent resistance to BIKTARVY was detected through Week 48[13,*]
  - 459 virologically suppressed adult women participated in an extension phase of Study 1961. 231 were continuing BIKTARVY and 228 switched to BIKTARVY at Week 48. Three participants who switched met the criteria for resistance analysis, and **no treatment-emergent resistance to BIKTARVY was detected through Week 96**[30,*]

*Based on the resistance analysis population or final resistance analysis population, as applicable.[13,30]

IN, integrase; OLE, open-label extension; RT, reverse transcriptase.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions

- **Prescribing information:** Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

BIKTARVY® has established safety data in phase 3 clinical trials of virologically suppressed PWH

Adverse Reactions (ARs) (All Grades) Reported in ≥2% of Virologically Suppressed Adults Who Received BIKTARVY Through Week 48[10,11,*]

	Study 1844		Study 1878	
	BIKTARVY (n=282)	ABC/DTG/3TC (n=281)	BIKTARVY (n=290)	ATV- or DRV-Based Regimen (n=287)
Headache, %	2	3	5	0
Flatulence, %	0	2	2	0
Nausea, %	0	2	2	0
Diarrhea, %	1	1	2	0

Studies 1844 and 1878: Adverse Reactions Reported in ≥1% of Virologically Suppressed Adults on BIKTARVY® Through the Extension Phase[1]

	Study 1844	Study 1878
	BIKTARVY (n=547)	BIKTARVY (n=534)
Headache, %	1.6	2.4
Diarrhea, %	0.9	1.5
Nausea, %	0.5	1.7
Flatulence, %	0.2	1.5
Constipation, %	0.2	1.3

- **The majority of ARs associated with BIKTARVY were Grade 1 in Study 1844 (58%) and in Study 1878 (76%)[1,10,11]**
- The safety profile of BIKTARVY in the extension phases through Week 96 and Week 168 was similar to that in the randomized phases of Studies 1878 and 1844, respectively[1,10,11]
- Overall, the safety profile of BIKTARVY in virologically suppressed adults was similar to that in treatment-naïve adults[7]

*Frequencies of ARs are based on all adverse events attributed to trial drugs by the investigator. No ARs of Grade 2 or higher occurred in >1% of study participants treated with BIKTARVY.[1]

3TC, lamivudine; ABC, abacavir; ATV, atazanavir; DTG, dolutegravir; DRV, darunavir; PWH, people with HIV.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.
- **Drugs affecting renal function:** Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Dosage and administration

- **Dosage:** Patients weighing ≥25 kg: 1 tablet taken once daily with or without food.
- **Renal impairment:** Not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history.

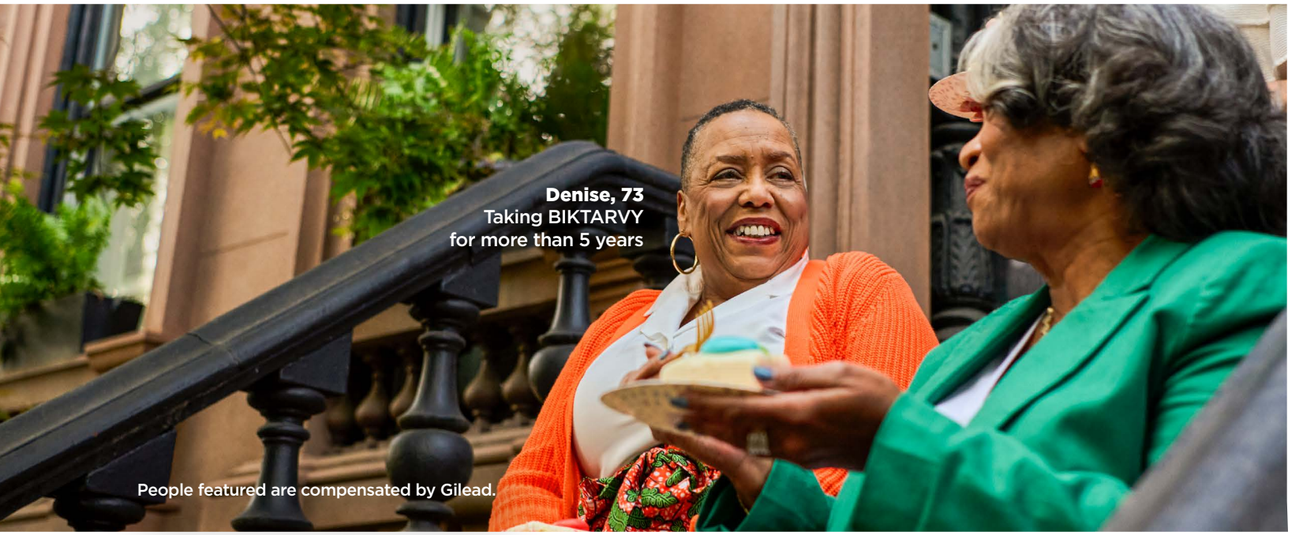
Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

BIKTARVY® has established safety data in phase 3 clinical trials of virologically suppressed PWH

Study 4030 Through Week 48:
Adverse Reactions Reported in ≥2% of Virologically Suppressed Adults[1]

	BIKTARVY (n=284)	FTC/TAF+DTG (n=281)
Abnormal dreams, %	2	1
Weight increased, %	2	1
Diarrhea, %	1	2
Headache, %	1	2



Study 1961 Through Week 48:
Adverse Reactions (All Grades) Reported in >1 Virologically Suppressed Adult Woman Who Received BIKTARVY®[13]

	BIKTARVY (n=234)	INSTI- or PI-Based Regimen* (n=236)
Iron deficiency anemia, %	0.9	0
Nausea, %	0.9	0
Vomiting, %	0.9	0

Study 1961 Through Week 96:
Adverse Reactions (All Grades) Reported in >1 Virologically Suppressed Adult Woman Who Continued on or Switched to BIKTARVY in the Extension Phase[30]

	BIKTARVY From Baseline Through Week 96 (n=234)	SBR* to BIKTARVY Week 48 to Week 96 (n=228)
Headache, %	1	<1
Dyslipidemia, %	1	0
Insomnia, %	<1	<1
Iron deficiency anemia, %	1	0
Nausea, %	1	0
Vomiting, %	1	0

*E/C/F/TAF or E/C/F/TDF or ATV+RTV+FTC/TDF.[13]

ATV, atazanavir; C, cobicistat; DTG, dolutegravir; E, elvitegravir; F, emtricitabine; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; PI, protease inhibitor; PWH, people with HIV; RTV, ritonavir; SBR, stayed on baseline regimen; TAF, tenofovir alafenamide TDF, tenofovir disoproxil fumarate.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.
- **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

BIKTARVY® was studied in virologically suppressed adults, including PWH aged 50 and older

Post Hoc Pooled Analysis of Four Phase 3 Randomized, Multicenter Trials of Participants Who Switched to BIKTARVY

OBJECTIVE[17]

- To assess the efficacy and safety of switching to BIKTARVY in virologically suppressed PWH aged ≥50 and <50 years in four phase 3 studies

METHODS[17]

- A post hoc pooled analysis of participants who switched to BIKTARVY in the 48-week randomized phase of the following four phase 3 randomized, multicenter studies:
  - Study 1844
  - Study 1878
  - Study 4030
  - Study 1961

ADDITIONAL STUDY DETAILS[17]

- Adults (≥18 years of age)*
- No documented or suspected resistance to FTC or TFV†
- eGFR$_{CG}$ ≥30 mL/min or ≥50 mL/min, depending on study‡
- HIV-1 RNA <50 c/mL for ≥3 months prior to screening§
- Receiving a stable ARV regimen for ≥3 months prior to screening

STUDY LIMITATIONS

- This analysis was not prespecified, and statistical testing for comparison was not conducted. Data should be considered descriptive only

*Women for Study 1961.[17]
†Except NRTI resistance was permitted in Study 4030.[17]
‡≥30 mL/min for Study 4030; ≥50 mL/min for Studies 1844, 1878, and 1961.[17]
§≥6 months for Studies 1878 and 4030 (if there was documented or suspected NRTI resistance prior to screening).[17]

ARV, antiretroviral; c, copies; CD4, cluster of differentiation 4; eGFR$_{CG}$, estimated glomerular filtration rate (Cockcroft-Gault); FTC, emtricitabine; NRTI, nucleoside reverse transcriptase inhibitor; PWH, people with HIV; Q, quartile; RNA, ribonucleic acid; TFV, tenofovir.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Individuals infected with HIV-1 should be informed of the potential risks of breastfeeding.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

Baseline Demographics and Clinical Characteristics[17]

		BIKTARVY® in PWH Aged ≥50 Years (n=450)	BIKTARVY in PWH Aged <50 Years (n=640)
Age, years, median (Q1, Q3)		**56 (52, 60)**	**39 (33, 45)**
Male sex at birth, n (%)		**342 (76)**	**393 (61)**
Region, n (%)	US	**327 (73)**	**294 (46)**
	Ex-US	**123 (27)**	**346 (54)**
Race, n (%)	White	**291 (65)**	**369 (58)**
	Black	**131 (29)**	**166 (26)**
	Other‖	**27 (6)¶**	**104 (16)¶**
Hispanic or Latine ethnicity, n (%)		**72 (16)#**	**131 (21)****
HIV-1 RNA, <50 c/mL, n (%)		**441 (98)**	**632 (99)**
HIV-1 RNA, >1,000 c/mL, n (%)		**0**	**2 (0.3)**
CD4 cell count, cells/µL, median, (Q1, Q3)		**640 (486, 852)**	**691 (523, 887)**
CD4 cell count >500 c/mL, n (%)		**328 (73)**	**494 (77)**
Medical history, n (%)	Diabetes mellitus	**38 (8)**	**30 (5)**
	Hyperlipidemia	**149 (33)**	**96 (15)**
	Hypertension	**114 (25)**	**83 (13)**

COMORBIDITIES OF DIABETES, HYPERLIPIDEMIA, AND HYPERTENSION WERE OBSERVED TO BE MORE FREQUENT AMONG PARTICIPANTS AGED 50 YEARS AND OLDER[17]

‖Includes American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, and other.[17]
¶Race data not available for 1 participant.[17]
#Ethnicity data not available for 1 participant.[17]
**Ethnicity data not available for 2 participants.[17]

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg tablets

Comedications, by age group

Select Concomitant Non-ARV Medications in PWH Aged ≥50 and <50 Years[17,*]

n (%)	BIKTARVY® in PWH Aged ≥50 Years (n=450)	BIKTARVY in PWH Aged <50 Years (n=640)
≥1 non-ARV medication	**431 (96)**	**590 (92)**
Specific non-ARV medications†		
Lipid modifying agents	**184 (41)**	**75 (12)**
Renin-angiotensin system	**124 (28)**	**78 (12)**
Antithrombotic agents	**90 (20)**	**29 (5)**
Beta-blocking agents	**68 (15)**	**29 (5)**
Calcium channel blockers	**52 (12)**	**26 (4)**
Diuretics	**47 (10)**	**25 (4)**
Antihypertensives	**45 (10)**	**19 (3)**

WARNING: Do not use BIKTARVY with dofetilide or rifampin.
Please see the Prescribing Information for a full list of drug interactions

*Concomitant non-ARV medications during study were non-ARV medications used between the first dose and the last dose dates of study drug (inclusive).[17]
†Used in ≥10% of PWH aged ≥50 years.[17]

ARV, antiretroviral; PWH, people with HIV.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

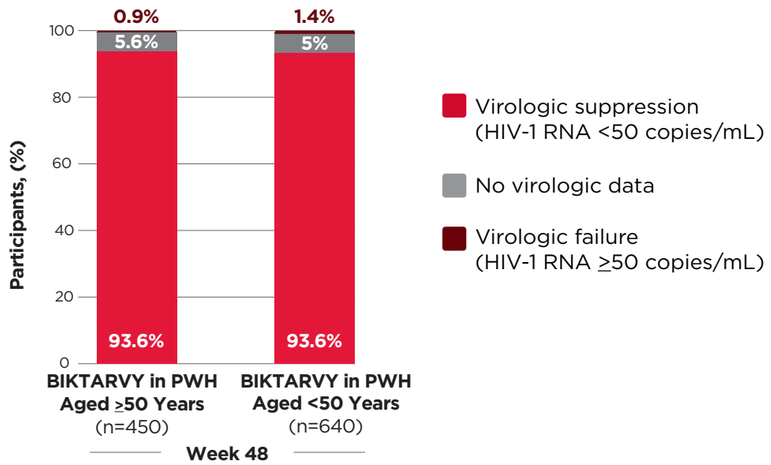
Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

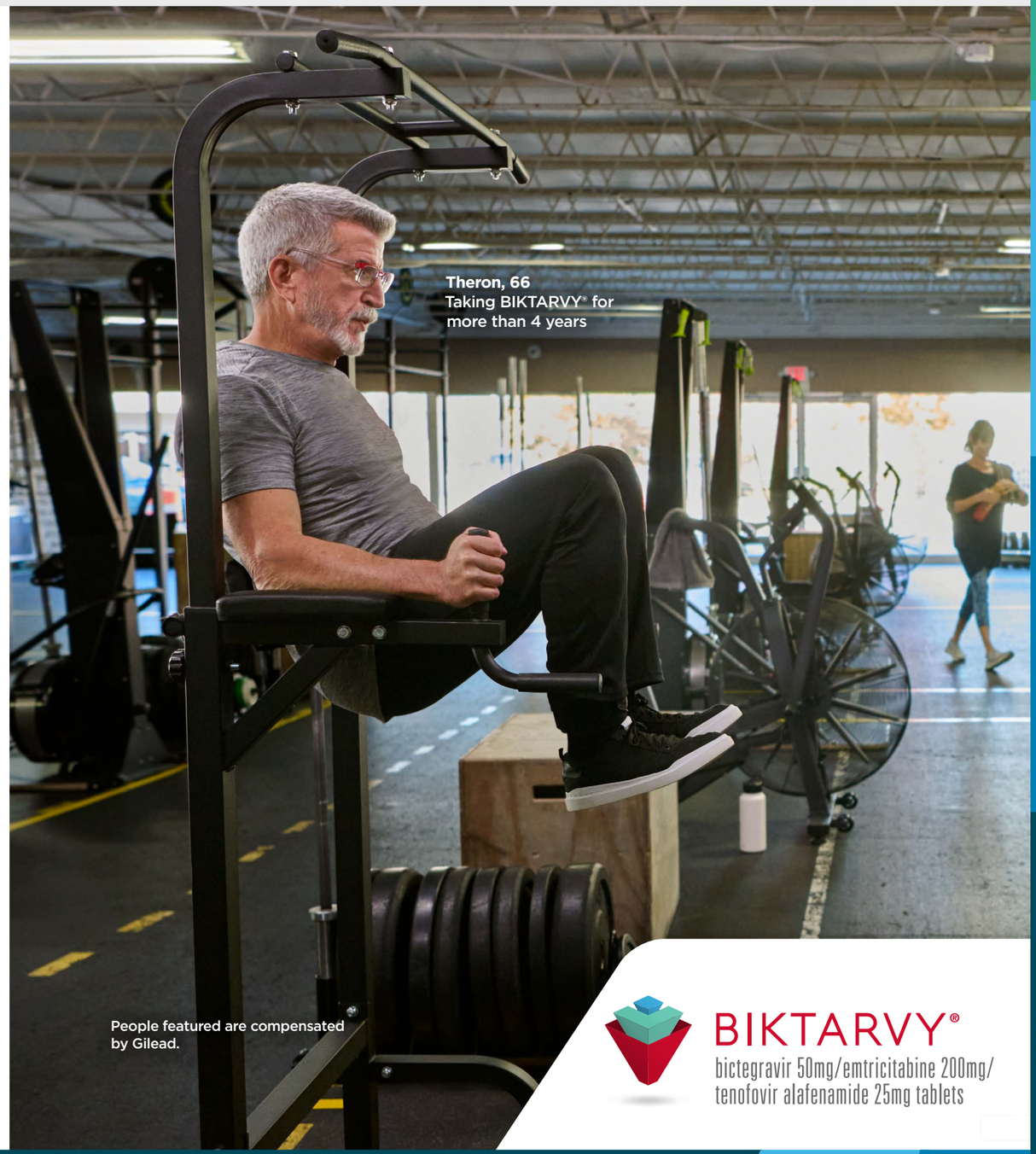
High rates of virologic suppression with BIKTARVY® in PWH aged over and under 50 at Week 48

Virologic Response at Week 48 (FDA Snapshot Algorithm)[17,*]



*Percentages do not total 100% due to rounding.

FDA, US Food and Drug Administration; PWH, people with HIV; RNA, ribonucleic acid.



IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

Virologically suppressed post hoc pooled analysis clinical trial data

Demonstrated safety profile for PWH aged over and under 50 through Week 48

Adverse Reactions Through Week 48[17]

n (%)	BIKTARVY® in PWH Aged ≥50 Years (n=450)	BIKTARVY in PWH Aged <50 Years (n=640)
Adverse reactions	58 (13)	80 (13)
Grade 3 or 4 adverse reactions	3 (1)	4 (1)
Serious adverse reactions	1 (<1)	1 (<1)
Discontinuation due to adverse event	8 (2)	6 (1)

Adverse Reactions Reported in ≥2% of Study Participants in Either Subgroup Through Week 48[1]

n (%)	BIKTARVY in PWH Aged ≥50 Years (n=450)	BIKTARVY in PWH Aged <50 Years (n=640)
Headache	12 (3)	14 (2)
Diarrhea	8 (2)	5 (1)
Constipation	7 (2)	3 (<1)

PWH, people with HIV.

IMPORTANT SAFETY INFORMATION (cont'd)

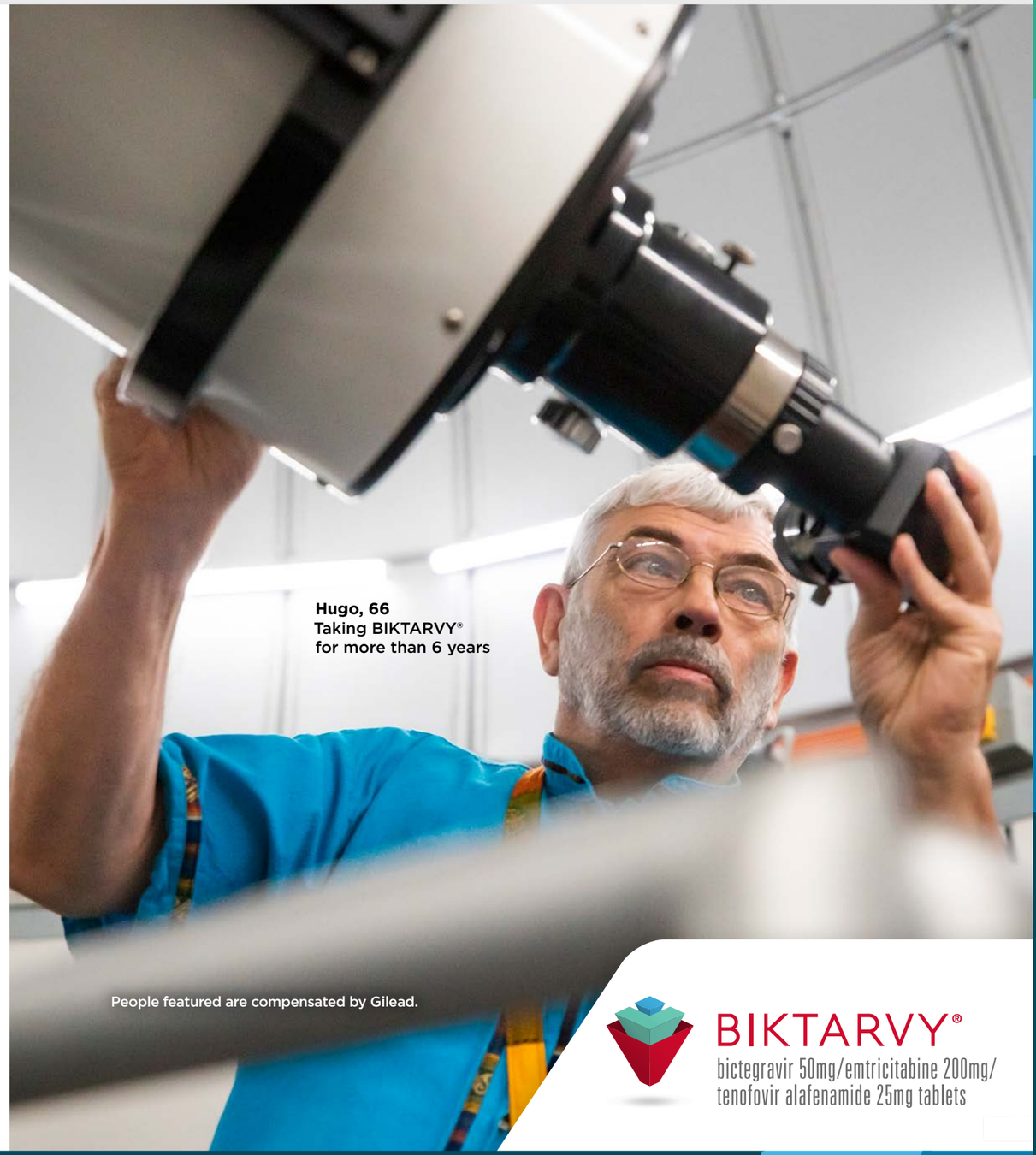
Warnings and precautions (cont'd)

- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Please see full Important Safety Information on page 27, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.



INDICATION

BIKTARVY® is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥25 kg who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Contraindications

- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Drug interactions

- **Prescribing information:** Consult the full prescribing information for BIKTARVY® for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.
- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.
- **Drugs affecting renal function:** Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Dosage and administration

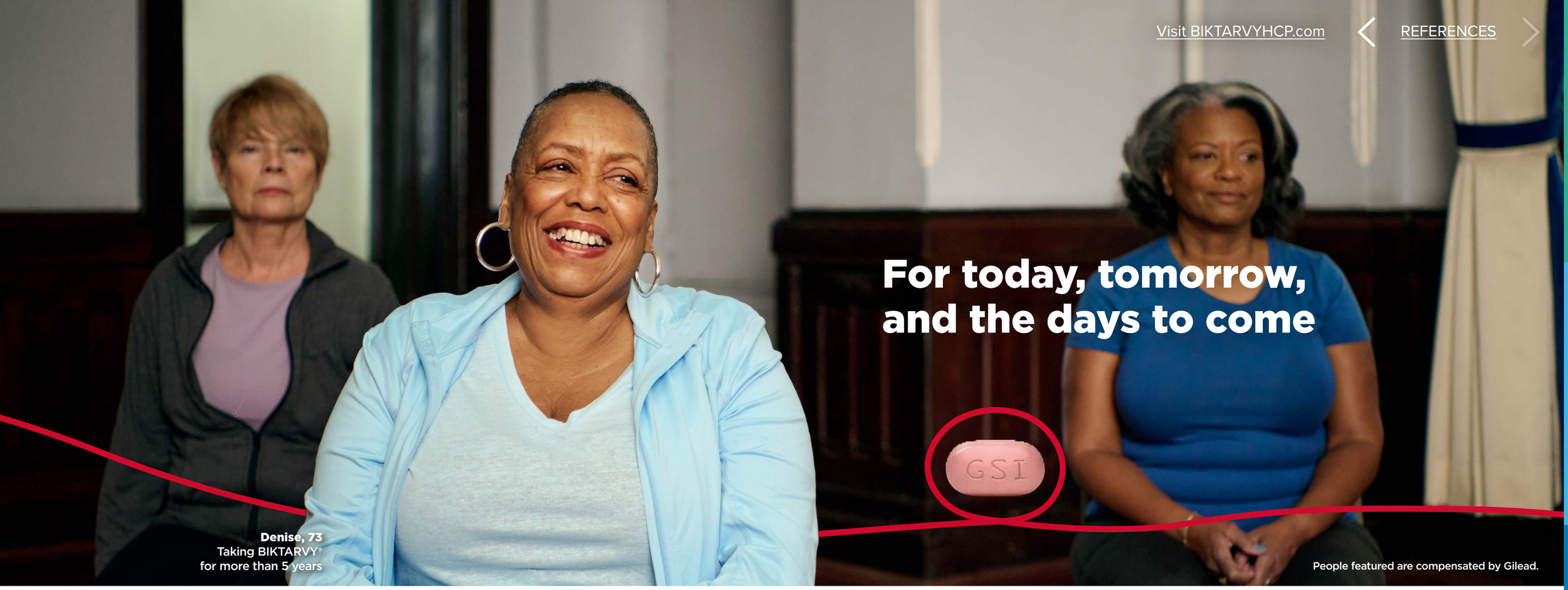
- **Dosage:** Patients weighing ≥25 kg: 1 tablet taken once daily with or without food.
- **Renal impairment:** Not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.
- **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Pregnancy and lactation

- **Pregnancy:** BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Individuals infected with HIV-1 should be informed of the potential risks of breastfeeding.

Please see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets



References: 1. Data on file. Gilead Sciences, Inc. **2.** Aging with HIV. HIV.gov. Updated June 4, 2024. Accessed November 26, 2024. https://www.hiv.gov/hiv-basics/living-well-with-hiv/taking-care-of-yourself/aging-with-hiv **3.** Smit M, Cassidy R, Cozzi-Lepri A, et al. Projections of non-communicable disease and health care costs among HIV-positive persons in Italy and the U.S.A.: a modelling study. *PLoS* One. 2017;12(10):1-12. **4.** Panel on antiretroviral guidelines for adults and adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Updated September 12, 2024. Accessed September 14, 2024. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf **5.** Pennings PS. HIV drug resistance: problems and perspectives. *Infect Dis Rep*. 2013;5(Suppl 1):e5. **6.** HealthHIV State of Aging with HIV. Third Annual National Survey. Health HIV. Updated 2024. Accessed January 3, 2025. https://healthhiv.org/stateof/agingwithhiv/ **7.** BIKTARVY. Prescribing information. Gilead Sciences, Inc.; 2024. **8.** Gallant J, Lazzarin A, Mills A, et al. Bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection (GS-US-380-1489): a double-blind, multicentre, phase 3, randomised controlled non-inferiority trial. *Lancet*. 2017;390(10107): 2063-2072. **9.** Sax PE, Pozniak A, Montes ML, et al. Coformulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide, for initial treatment of HIV-1 infection (GS-US-380-1490): a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet*. 2017;390(10107):2073-2082. **10.** Molina JM, Ward D, Brar I, et al. Switching to fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide from dolutegravir plus abacavir and lamivudine in virologically suppressed adults with HIV-1: 48 week results of a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. *Lancet HIV*. 2018;5(7):e357-e365. **11.** Daar ES, DeJesus E, Ruane P, et al. Efficacy and safety of switching to fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide from boosted protease inhibitor-based regimens in virologically suppressed adults with HIV-1: 48 week results of a randomised, open-label, multicentre, phase 3, non-inferiority trial. *Lancet HIV*. 2018;5(7):e347-e356. **12.** Sax PE, Rockstroh JK, Luetkemeyer AF, et al. Switching to bictegravir, emtricitabine, and tenofovir alafenamide in virologically suppressed adults with human immunodeficiency virus. *Clin Infect Dis*. 2021;73(2):e485-e493. **13.** Kityo C, Hagins D, Koenig E, et al. Switching to fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide (B/F/TAF) in virologically suppressed HIV-1 infected women: a randomized, open-label, multicenter, active-controlled, phase 3, noninferiority trial. *J Acquir Immune Defic Syndr*. 2019;82(3): 321-328. **14**. Maggiolo F, Rizzardini G, Molina JM, et al. Bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed people with HIV aged ≥65 years: week 48 results of a phase 3b, open-label trial. *Infect Dis Ther*. 2021;10(2):775-788. **15.** Hagins D, Kumar P, Saag M, et al. Switching to bictegravir/emtricitabine/tenofovir alafenamide in Black Americans with HIV-1: a randomized phase 3b, multicenter, open-label study. *J Acquir Immune Defic Syndr.* 2021;88(1):86-95. **16.** Kityo CM, Gupta SK, Kumar PN, et al. Efficacy and safety of B/F/TAF in treatment-naïve people with HIV aged ≥ 50 years: 5-year follow-up from two phase 3 studies. Poster presented at IDWeek; October 16-19, 2024; Los Angeles, CA, USA. Poster P-547. **17.** Kityo CM, Gupta SK, Kumar PN, et al. Efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed people with HIV aged ≥50 years: 48-week follow-up from four phase 3 studies. Poster presented at: International Workshop on HIV and Aging 2024; October 24-25, 2024; Washington, DC. Poster 52. **18.** Orkin C, DeJesus E, Sax PE, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir-containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials. *Lancet HIV.* 2020;7(6):e389-e400. **19.** Wohl DA, Pozniak A, Workowski K, et al. B/F/TAF five-year outcomes in treatment-naïve adults. Poster presented at: Conference on Retroviruses and Opportunistic Infections; February 12-16, 2022; Virtual. Poster 494. **20.** Wohl DA, Yazdanpanah Y, Baumgarten A, et al. Bictegravir combined with emtricitabine and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet HIV*. 2019;6(6):e355-e363. **21.** Stellbrink HJ, Arribas JR, Stephens JL, et al. Co-formulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet HIV*. 2019;6(6):e364-e372. **22.** Orkin C, Antinori A, Rockstroh J, et al. Outcomes after switching from 144 weeks of blinded DTG/ABC/3TC or DTG+F/TAF to 96 weeks of open-label B/F/TAF. Poster presented at: HIV Glasgow 2022; October 23-26, 2022; Glasgow, UK. Poster P088. **23.** Orkin C, DeJesus E, Sax PE, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir-containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials – Appendix. *Lancet HIV.* 2020;7(6):e389-e400. **24.** Sax PE, Pozniak A, Montes ML, et al. Coformulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide, for initial treatment of HIV-1 infection (GS-US-380-1490): a randomised, double-blind, multicentre, phase 3, non-inferiority trial – Appendix. *Lancet.* 2017;390(10107):2073-2082. **25.** Stellbrink HJ, Arribas JR, Stephens JL, et al. Co-formulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial – Appendix. *Lancet HIV.* 2019;6(6):e364-e372. **26.** Orkin C, Antinori A, Rockstroh JK, et al. Switch to bictegravir/emtricitabine/tenofovir alafenamide from dolutegravir-based therapy. *AIDS*. 2024;38(7):983-991. **27.** Kityo CM, Gupta SK, Kumar PN, et al. Efficacy and safety of B/F/TAF in treatment-naïve people with HIV aged ≥ 50 years: 5-year follow-up from two phase 3 studies. Supplement. Poster presented at IDWeek; October 16-19, 2024; Los Angeles, CA, USA. Poster P-547. **28.** Brar I, Ruane P, Ward D, et al. Long-term follow-up after a switch to bictegravir, emtricitabine, and tenofovir alafenamide from dolutegravir, abacavir, and lamivudine. Poster presented at: IDWeek; October 21-25, 2020; Virtual. Poster 1028. **29.** Rockstroh J, Molina J-M, Post F, et al. Long-term follow-up after a switch to bictegravir, emtricitabine, tenofovir alafenamide (B/F/TAF) from a boosted protease inhibitor-based regimen. Poster presented at: HIV Drug Therapy Glasgow 2020; October 5-8, 2020; Virtual. Poster P036. **30.** Kityo C, Hagins D, Koenig E, et al. Longer-term (96-week) efficacy and safety of switching to bictegravir, emtricitabine and tenofovir alafenamide (B/F/TAF) in women. Oral abstract presentation at: International AIDS Society Conference on HIV Science 2019; July 21-24, 2019; Mexico City, Mexico. Abstract MOAB0106. **31.** Kityo C, Hagins D, Koenig E, et al. Switching to fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide (B/F/TAF) in virologically suppressed HIV-1 infected women: a randomized, open-label, multicenter, active-controlled, phase 3, noninferiority trial – Appendix. *J Acquir Immune Defic Syndr*. 2019;82(3):321-328. **32.** Andreatta K, Willkom M, Martin R, et al. Resistance analyses of bictegravir/emtricitabine/tenofovir alafenamide switch studies. Presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA. Poster 506. **33.** Andreatta K, Chang S, Delaney M, et al. Long-term efficacy among participants switched to bictegravir/emtricitabine/tenofovir alafenamide from dolutegravir/abacavir/lamivudine with preexisting resistance and viral blips. Presented at: International AIDS Society Conference on HIV Science 2021; July 18-21, 2021; Virtual. Poster PEB172.

Click to learn more about the BIKTARVY® phase 3 clinical trial program →

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