

# Clinical Data to Inform Treatment Decisions for Virologically Suppressed Adults Switching Regimens

Head-to-head phase 3 trials comparing the efficacy, resistance, and safety profile of BIKTARVY® to other ART options

## SOLAR<sup>1</sup>

### BIKTARVY vs IM CAB + RPV Q8W

Studied through **Months 11 and 12\***

Sponsored by ViiV Healthcare

## STUDY 1844<sup>2,3</sup>

### BIKTARVY vs ABC/DTG/3TC

Studied through **Week 168**, including 120-week open-label extension phase from Week 48

Sponsored by Gilead Sciences

## STUDY 1878<sup>2,4</sup>

### BIKTARVY vs ATV- or DRV-based regimen<sup>†</sup>

Studied through **Week 96**, including 48-week extension phase

Sponsored by Gilead Sciences

## INDICATION

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing  $\geq 25$  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 bicitegravir or tenofovir.

## IMPORTANT SAFETY INFORMATION

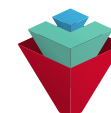
### BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting 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 coinfecting with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Please see full Important Safety Information on [page 15](#), and click to see full [Prescribing Information](#) for BIKTARVY, including **BOXED WARNING**.

3TC, lamivudine; ABC, abacavir; ART, antiretroviral therapy; ATV, atazanavir; CAB, cabotegravir; DRV, darunavir; DTG, dolutegravir; IM, intramuscular; Q8W, every 8 weeks; RPV, rilpivirine; SOLAR, switch onto long-acting regimen.

\*Month 11 for those who started with CAB + RPV injection and Month 12 for those who started with CAB + RPV oral lead-in or BIKTARVY.<sup>1</sup>  
<sup>†</sup>Regimen consisting of ABC/3TC or FTC/TDF plus boosted ATV or DRV (cobicistat or ritonavir).<sup>4</sup>



## BIKTARVY®

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## Consider the Impact of Resistance on the Individual and Community<sup>5</sup>

**IF RESISTANCE DEVELOPS, IT IS PERMANENT, IRREVERSIBLE, AND POTENTIALLY ELIMINATES FUTURE TREATMENT OPTIONS.<sup>5</sup>**

### INDIVIDUAL IMPACT

Treatment-emergent resistance can lead to suboptimal ART response, resulting in virologic failure.<sup>6</sup>



### COMMUNITY IMPACT

Individuals with treatment-emergent resistance may transmit the resistant virus to others in the community.<sup>6</sup>



### According to the DHHS Guidelines

**THE FUNDAMENTAL PRINCIPLE OF ARV REGIMEN OPTIMIZATION IS TO MAINTAIN VIRAL SUPPRESSION WITHOUT JEOPARDIZING FUTURE TREATMENT OPTIONS.<sup>5</sup>**

# SOLAR Study: BIKTARVY® vs IM CAB + RPV Q8W

## Virologically suppressed adults switching from BIKTARVY to IM CAB + RPV Q8W<sup>1</sup>

### PRIMARY ENDPOINT<sup>1</sup>

- Proportion of adults with HIV-1 RNA  $\geq 50$  copies/mL at Months 11 and 12\* using the FDA snapshot algorithm (mITT-E)
  - Month 11 for those starting with injections (SWI) CAB + RPV and Month 12 for those who started with oral lead-in (OLI) CAB + RPV or BIKTARVY

### STUDY DESIGN AND CRITERIA<sup>1,7,8</sup>

- Phase 3b, randomized, multicenter, parallel-group, open-label, noninferiority study
- Randomized in a 2:1 ratio to either IM CAB + RPV Q8W (n=454 [ITT-E]) or BIKTARVY (n=227 [ITT-E])
- Participants randomized to the IM CAB (600 mg) + RPV (900 mg) Q8W group had a choice to use an OLI (n=175) or SWI (n=279)<sup>†</sup>

Inclusion	Exclusion
<ul style="list-style-type: none"> <li>• Age <math>\geq 18</math> years</li> <li>• On uninterrupted BIKTARVY for <math>\geq 6</math> months with viral load <math>&lt; 50</math> copies/mL</li> <li>• BIKTARVY as initial or second regimen                             <ul style="list-style-type: none"> <li>- Any prior change in regimen, defined as a change of a single drug or multiple drugs simultaneously, must have occurred due to tolerability/safety, access to medications, or convenience/simplification, and must not have been done for treatment failure (HIV-1 RNA <math>\geq 400</math> copies/mL)</li> <li>- No history of non-INSTI-based regimen use</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Resistance to any of the components of BIKTARVY, CAB, or RPV</li> <li>• HBV coinfection</li> <li>• Conditions that may interfere with injections</li> <li>• Moderate to severe hepatic impairment</li> <li>• eGFR <math>&lt; 30</math> mL/min</li> </ul>

## 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.

Please see full Important Safety Information on [page 15](#), and click to see full [Prescribing Information](#) for BIKTARVY, including **BOXED WARNING**.

CAB, cabotegravir; eGFR, estimated glomerular filtration rate; FDA, US Food and Drug Administration; HBV, hepatitis B virus; IM, intramuscular; INSTI, integrase strand transfer inhibitor; ITT-E, intention-to-treat exposed; mITT-E, modified intention-to-treat exposed; Q8W, every 8 weeks; RNA, ribonucleic acid; RPV, rilpivirine; SOLAR, switch onto long-acting regimen.

\*Month 11 for those who started with CAB + RPV injection and Month 12 for those who started with CAB + RPV oral lead-in or BIKTARVY.<sup>1</sup>

<sup>†</sup>The decision was determined by the participants following informed-consent discussions with the investigator.<sup>1</sup>



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## Baseline Participant Characteristics in the SOLAR Study<sup>1</sup>

	BIKTARVY® (n=223 [mITT-E*])	IM CAB + RPV Q8W (n=447 [mITT-E*])
<b>Median age, years (range)</b>	<b>37 (18-66)</b>	<b>37 (18-74)</b>
≥50 years, %	<b>19</b>	<b>19</b>
<b>Female sex at birth, %</b>	<b>18</b>	<b>17</b>
<b>Race</b>		
Black, %	<b>22</b>	<b>21</b>
White, %	<b>70</b>	<b>69</b>
Asian, %	<b>5</b>	<b>5</b>
Other races, <sup>†</sup> %	<b>3</b>	<b>5</b>
<b>Ethnicity</b>		
Hispanic or Latino/x, %	<b>17</b>	<b>21</b>
<b>CD4 count, cells/mm<sup>3</sup></b>	<b>640 (459-846)</b>	<b>649 (477-850)</b>
<b>BMI, kg/m<sup>2</sup>, median (IQR)</b>	<b>25.4 (23.4-29.6)</b>	<b>26.0 (23.2-29.4)</b>
<b>Prior duration of ART, median years</b>	<b>2.47</b>	<b>2.58</b>

### 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.

Please see full Important Safety Information on [page 15](#), and click to see full [Prescribing Information](#) for **BIKTARVY**, including **BOXED WARNING**.

ART, antiretroviral therapy; BMI, body mass index; CAB, cabotegravir; CD4, cluster of differentiation 4; IM, intramuscular; IQR, interquartile range; mITT-E, modified intention-to-treat exposed; NSAIDs, nonsteroidal anti-inflammatory drugs; Q8W, every 8 weeks; RPV, rilpivirine; SOLAR, switch onto long-acting regimen.

\*After consultation with a blinded expert, 11 participants (7 in the IM CAB + RPV Q8W group and 4 in the BIKTARVY group) were excluded from the ITT-E population (n=681) due to critical findings related to significant and persistent noncompliance to protocol entry criteria at 1 study site.<sup>1</sup>

<sup>†</sup>Other race participants: American Indian or Alaska Native, n=14 (IM CAB + RPV Q8W) and n=2 (BIKTARVY); Native Hawaiian or other Pacific Islander, n=1 (BIKTARVY); multiple, n=8 (IM CAB + RPV Q8W) and n=4 (BIKTARVY).<sup>1</sup>



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## Virologic Outcomes in the SOLAR Study

The efficacy of IM CAB + RPV Q8W was noninferior to BIKTARVY® at Months 11 and 12<sup>1,\*</sup>

VIROLOGIC OUTCOMES AT MONTHS 11 AND 12 (mITT-E POPULATION)<sup>1</sup>

	BIKTARVY® (n=223)	IM CAB + RPV Q8W (n=447)
HIV-1 RNA ≥50 copies/mL <sup>†</sup>	<1%	1%
HIV-1 RNA <50 copies/mL	93%	90%
No virologic data	7%	9%

<sup>†</sup>Adjusted treatment difference: 0.7% (95% CI: -0.7 to 2.0).<sup>1</sup>

- Virologic outcomes were based on the modified intention-to-treat exposed (mITT-E) population<sup>1</sup>
  - After consultation with a blinded expert, 11 participants (7 in the IM CAB + RPV Q8W group and 4 in the BIKTARVY group) were excluded from the ITT-E population (n=681) due to critical findings related to significant and persistent noncompliance to protocol entry criteria at 1 study site
- At Months 11 and 12, IM CAB + RPV Q8W demonstrated noninferior efficacy compared with BIKTARVY for the proportion of participants with HIV-1 RNA ≥50 copies/mL and <50 copies/mL in the mITT-E<sup>1,†</sup>

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Warnings and precautions (cont'd)

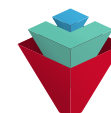
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and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

Please see full Important Safety Information on [page 15](#), and click to see full [Prescribing Information](#) for **BIKTARVY**, including **BOXED WARNING**.

CAB, cabotegravir; CI, confidence interval; CrCl, creatinine clearance; FTC, emtricitabine; IM, intramuscular; ITT-E, intention-to-treat exposed; mITT-E, modified intention-to-treat exposed; Q8W, every 8 weeks; RNA, ribonucleic acid; RPV, rilpivirine; SOLAR, switch onto long-acting regimen; TDF, tenofovir disoproxil fumarate.

\*Month 11 for those who started with CAB + RPV injection and Month 12 for those who started with CAB + RPV oral lead-in or BIKTARVY.<sup>1</sup>

<sup>1</sup>In the ITT-E population, 89% (n=406/454) and 93% (n=211/227) of participants receiving IM CAB + RPV Q8W and BIKTARVY demonstrated virologic success (HIV-1 RNA <50 copies/mL; adjusted treatment difference [95% CI], -3.5% [-7.9 to 0.9]); 1% (n=6/454) and <1% (n=1/227) of participants receiving IM CAB + RPV Q8W and BIKTARVY demonstrated nonresponse (HIV-1 RNA ≥50 copies/mL; adjusted treatment difference [95% CI], 0.9% [-0.5 to 2.2]); and 9% (n=39/447) and 7% (n=15/223) of participants receiving IM CAB + RPV Q8W and BIKTARVY had no virologic data, respectively. In the per-protocol population, 91% (n=394/433) and 93% (n=203/218) of participants receiving IM CAB + RPV Q8W and BIKTARVY demonstrated virologic success (HIV-1 RNA <50 copies/mL; adjusted treatment difference [95% CI], -2.1% [-6.4 to 2.2]), and <1% (n=4/433) and <1% (n=1/218) of participants receiving IM CAB + RPV Q8W and BIKTARVY demonstrated virologic nonresponse (HIV ≥50 copies/mL; adjusted treatment difference [95% CI], 0.5 [-0.8 to 1.7]).<sup>1</sup>



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### 3 Participants Experienced CVF\* With IM CAB + RPV Q8W Through Months 11 and 12<sup>†</sup> and 0 Participants Experienced CVF With BIKTARVY<sup>®1,8</sup>

	BIKTARVY mITT-E (n=223); ITT-E (n=227)	IM CAB + RPV Q8W mITT-E (n=447); ITT-E (n=454)
<b>Participants with confirmed virologic failure</b>	<b>0</b>	<b>3</b>
mITT-E	0	2
Additionally from ITT-E	0	1
<b>Participants with RAMs at virologic failure</b>	<b>0</b>	<b>3</b>
mITT-E	0	2
Additionally from ITT-E	0	1

**AMONG THE PARTICIPANTS ON IM CAB + RPV Q8W THROUGH MONTHS 11 AND 12, 3 PARTICIPANTS MET CRITERIA FOR CONFIRMED VIROLOGIC FAILURE WHILE RECEIVING ON-TIME INJECTIONS (DOSING WINDOW + 7 DAYS)**  
2 PARTICIPANTS HAD ON-TREATMENT NNRTI OR INSTI RAMs. GENOTYPING FOR THE 3RD PARTICIPANT FAILED AT BASELINE.

Sex, BMI (kg/m <sup>2</sup> ), country, HIV subtype	VL at SVF/CVF, (copies/mL)	SVF time point (month)	Baseline RAMs		RAMs at failure	
			NNRTI	INSTI	NNRTI	INSTI
<b>Participants with CVF in the mITT-E population</b>						
M, <30, Italy, B	1327/1409	6	None	None	<b>M230L</b>	<b>Q148R</b>
M, <30, Spain, AE	6348/419	11	None	G140G/R	<b>K101E</b>	<b>G118R</b>
<b>Participant with CVF in the ITT-E population</b>						
M, ≥30, US, C	3797/928	3	Assay failed	Assay failed	<b>E138E/K + Y181Y/C</b>	None

#### 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%).

Please see full Important Safety Information on [page 15](#), and click to see full Prescribing Information for **BIKTARVY**, including **BOXED WARNING**.

BMI, body mass index; CAB, cabotegravir; CVF, confirmed virologic failure; IM, intramuscular; INSTI, integrase strand transfer inhibitor; ITT-E, intention-to-treat exposed; M, male; mITT-E, modified intention-to-treat exposed; NNRTI, non-nucleoside reverse transcriptase inhibitor; Q8W, every 8 weeks; RAM, resistance-associated mutation; RNA, ribonucleic acid; RPV, rilpivirine; SOLAR, switch onto long-acting regimen; SVF, suspected virologic failure; VL, viral load.

\*Confirmed virologic failure defined as 2 consecutive HIV-1 RNA ≥200 copies/mL. After consultation with a blinded expert, 11 participants were excluded from the ITT-E population (n=681) due to critical findings related to significant and persistent noncompliance to protocol entry criteria at 1 study site.<sup>1</sup>

<sup>†</sup>Month 11 for those who started with CAB + RPV injection and Month 12 for those who started with CAB + RPV oral lead-in or BIKTARVY.



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## SOLAR Safety and Tolerability Data Through Months 11 and 12\*

### DRUG-RELATED ADVERSE EVENTS THROUGH MONTHS 11 AND 12 (EXCLUDING ISRs)<sup>1</sup>

	<b>BIKTARVY®</b> (n=227)	<b>IM CAB + RPV Q8W</b> (n=454)
<b>Any drug-related AE, %</b>	<b>1</b>	<b>20</b>
Drug-related Grade ≥3 AEs	<b>0</b>	<b>2</b>
Drug-related AEs leading to discontinuation	<b>0</b>	<b>2</b>
Drug-related serious AEs	<b>0</b>	<b>1</b>
<b>DRUG-RELATED AEs IN ≥2% OF PARTICIPANTS IN EITHER TREATMENT GROUP</b>		
<b>Pyrexia, %</b>	<b>0</b>	<b>3</b>
<b>Headache, %</b>	<b>0</b>	<b>2</b>
<b>Fatigue, %</b>	<b>0</b>	<b>2</b>
<b>Diarrhea, %</b>	<b>0</b>	<b>2</b>

### INJECTION SITE REACTIONS THROUGH MONTHS 11 AND 12<sup>8</sup>

	<b>Total IM CAB + RPV Q8W</b> (n=454)
<b>Number of injections, n</b>	<b>5952</b>
ISR events, n <sup>†</sup>	<b>1915</b>
<b>Pain, % of injections</b>	<b>23</b>
<b>Discomfort, % of injections</b>	<b>2</b>
<b>Nodule, % of injections</b>	<b>1</b>
<b>Grade 3, % of ISR events<sup>†</sup></b>	<b>2</b>
<b>Median duration (IQR), days</b>	<b>3 (2, 5)</b>
<b>Participant discontinued due to injection-related reasons, %<sup>§</sup></b>	<b>2</b>

**20% OF PARTICIPANTS ON IM CAB + RPV Q8W EXPERIENCED DRUG-RELATED AEs<sup>1</sup>**

**THE MOST COMMONLY REPORTED DRUG-RELATED AEs IN THE BIKTARVY GROUP WERE WEIGHT GAIN (n=1, <1%) AND ABNORMAL HEPATIC FUNCTION (n=1, <1%)<sup>1</sup>**

**Discontinuations due to any AEs:** 6% in the IM CAB + RPV Q8W group vs 1% in the BIKTARVY group through Months 11 and 12<sup>1</sup>

**Discontinuations due to drug-related AEs:** 4% in the IM CAB + RPV Q8W group vs 0% in the BIKTARVY group through Months 11 and 12<sup>1</sup>

### 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 15](#), and click to see full [Prescribing Information](#) for **BIKTARVY**, including **BOXED WARNING**.

AE, adverse event; CAB, cabotegravir; IM, intramuscular; IQR, interquartile range; ISR, injection site reaction; mITT-E, modified intention-to-treat exposed; Q8W, every 8 weeks; RPV, rilpivirine; SOLAR, switch onto long-acting regimen; SWI, starting with injections.

\*Month 11 for those who started with CAB + RPV injection and Month 12 for those who started with CAB + RPV oral lead-in or BIKTARVY.<sup>1</sup>

<sup>†</sup>A single injection could result in more than 1 ISR. Grading was missed for 1 ISR event in the IM CAB + RPV Q8W SWI group.<sup>8</sup>

<sup>‡</sup>There were no Grade 4 or Grade 5 ISRs.<sup>8</sup>

<sup>§</sup>Includes participants who discontinued due to ISR AEs and an additional participant who withdrew from the study citing injection intolerance. This also includes

1 participant who was excluded from the primary analysis (mITT-E) population.<sup>8</sup>



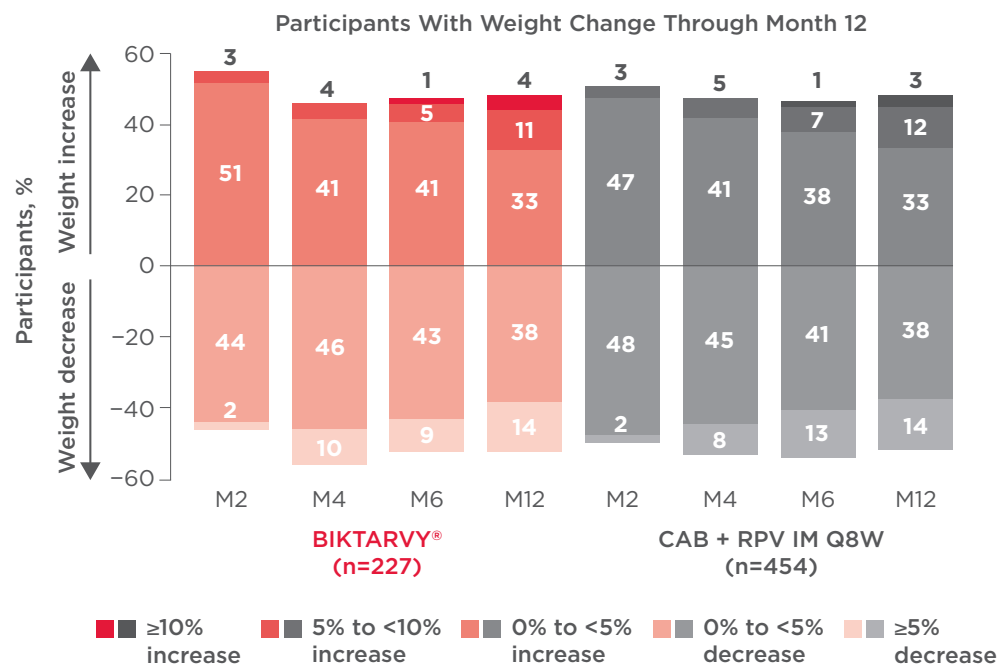
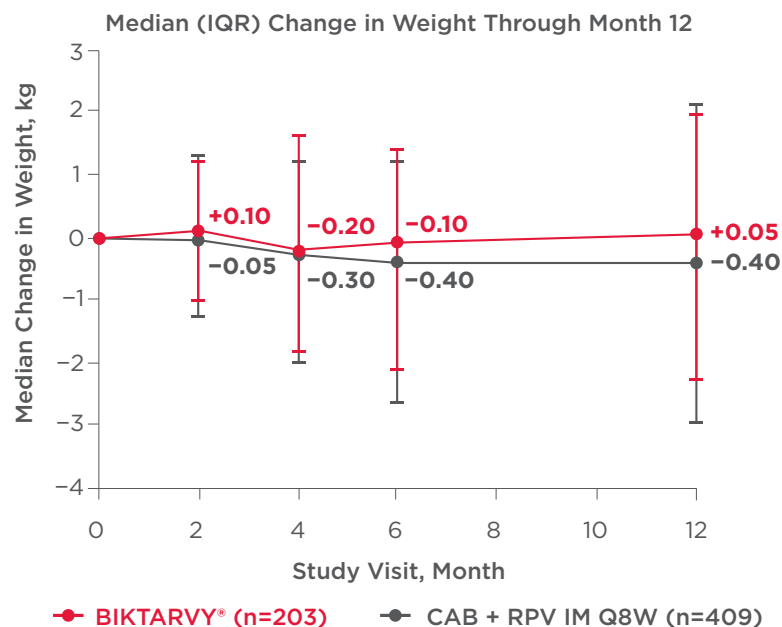
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# Median Weight Change Was Numerically Similar Between Study Groups Through Month 12<sup>9</sup>

Participants experienced weight gain and weight loss in both study groups<sup>9</sup>

## WEIGHT CHANGE THROUGH MONTH 12<sup>9</sup>

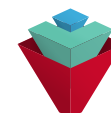


### IMPORTANT SAFETY INFORMATION (cont'd)

#### 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.

Please see full Important Safety Information on [page 15](#), and click to see full [Prescribing Information](#) for BIKTARVY, including **BOXED WARNING**.



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CAB, cabotegravir; IM, intramuscular; IQR, interquartile range; M, month; Q8W, every 8 weeks; RPV, rilpivirine; SOLAR, switch onto long-acting regimen.

# BIKTARVY® Has Been Extensively Studied

## Virologically suppressed adults switching to BIKTARVY from ABC/DTG/3TC and ATV- or DRV-based regimens

### PRIMARY ENDPOINT IN STUDIES 1844 & 1878<sup>10,11</sup>

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

### STUDY 1844<sup>2,3</sup>

- Phase 3, randomized, double-blind, active-controlled, noninferiority study
- Randomized in a 1:1 ratio to either switch to BIKTARVY (n=282) or continue on baseline regimen of ABC/DTG/3TC (n=281) through Week 48
- Open-label extension from Week 48 through Week 168 to evaluate the efficacy and safety of BIKTARVY after additional exposure

### STUDY CRITERIA<sup>2,10</sup>

Inclusion	Exclusion
<ul style="list-style-type: none"> <li>• Age <math>\geq</math>18 years</li> <li>• HIV-1 RNA &lt;50 copies/mL</li> <li>• eGFR<sub>Cr</sub> <math>\geq</math>50 mL/min</li> </ul>	<ul style="list-style-type: none"> <li>• Chronic HBV</li> <li>• Documented or suspected resistance to FTC, TFV, ABC, 3TC, DTG</li> </ul>

#### Additional inclusion criteria<sup>2</sup>

Study participants were on a stable baseline regimen for at least 3 months with no history of treatment failure.

### STUDY 1878<sup>2,4</sup>

- Phase 3, randomized, open-label, active-controlled, noninferiority study
- Randomized in a 1:1 ratio to either switch to BIKTARVY (n=290) or stay on baseline regimen of either ABC/3TC or FTC/TDF plus boosted ATV or DRV (cobicistat or ritonavir) (n=287) through Week 48
- Extension phase from Week 48 through Week 96 to evaluate the efficacy and safety of BIKTARVY after additional exposure

### STUDY CRITERIA<sup>11,12</sup>

Inclusion	Exclusion
<ul style="list-style-type: none"> <li>• Age <math>\geq</math>18 years</li> <li>• HIV-1 RNA &lt;50 copies/mL</li> <li>• eGFR<sub>Cr</sub> <math>\geq</math>50 mL/min</li> <li>• Chronic HBV or chronic HCV allowed*</li> </ul>	<ul style="list-style-type: none"> <li>• Documented or suspected resistance to FTC, TFV, ABC, or 3TC</li> </ul>

#### Additional inclusion criteria<sup>2</sup>

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.

## 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 15](#), and click to see full [Prescribing Information](#) for **BIKTARVY**, including **BOXED WARNING**.

3TC, lamivudine; ABC, abacavir; ART, antiretroviral therapy; ATV, atazanavir; DRV, darunavir; DTG, dolutegravir; eGFR<sub>Cr</sub>, estimated glomerular filtration rate (Cockcroft-Gault); FDA, US Food and Drug Administration; FTC, emtricitabine; HBV, hepatitis B virus; HCV, hepatitis C virus; INSTI, integrase strand transfer inhibitor; NI, noninferiority; RNA, ribonucleic acid; TFV, tenofovir disoproxil.

\*HBV infection was not allowed if the participant was on a regimen that did not contain TDF.<sup>11</sup>



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## Participant Characteristics of Studies 1844 and 1878

		STUDY 1844 <sup>10</sup>		STUDY 1878 <sup>11</sup>	
		BIKTARVY® (n=282)	ABC/DTG/3TC (n=281)	BIKTARVY® (n=290)	ATV- or DRV- Based Regimen* (n=287)
<b>Median age, years (range)</b>		<b>47</b> (21-71)	<b>45</b> (20-70)	<b>48</b> (20-74)	<b>47</b> (21-79)
<b>Sex</b>	Male, %	<b>88</b>	<b>90</b>	<b>84</b>	<b>82</b>
	Female, %	<b>12</b>	<b>10</b>	<b>16</b>	<b>18</b>
<b>Race</b>	White, %	<b>73</b>	<b>73</b>	<b>65</b>	<b>66</b>
	Black, %	<b>21</b>	<b>22</b>	<b>27</b>	<b>25</b>
	Asian, %	<b>3</b>	<b>3</b>	<b>2</b>	<b>3</b>
<b>Hispanic/Latino, %</b>		<b>16</b>	<b>19</b>	<b>21</b>	<b>16</b>
<b>Median eGFR<sub>CG</sub>, mL/min (IQR)</b>		<b>101</b> (85-119)	<b>101</b> (85-122)	<b>107</b> (87.0-124.2)	<b>105</b> (87.1-125.3)
<b>Baseline ARV regimen<sup>†</sup></b>					
FTC/TDF, ABC/3TC, %		-	-	<b>84, 16</b>	<b>85, 15</b>
DRV, ATV, %		-	-	<b>57, 43</b>	<b>54, 46</b>

<sup>10</sup>ABC/3TC or FTC/TDF + boosted ATV or DRV (cobicistat or ritonavir) regimen.<sup>2</sup>  
<sup>†</sup>A dash (-) indicated that a characteristic was not reported.

### RETROSPECTIVE ANALYSIS OF PREEXISTING RESISTANCE AT BASELINE<sup>2,13,i,5</sup> BIKTARVY ARMS FROM STUDIES 1844 & 1878 N<sup>II</sup>=519 (IN) N<sup>II</sup>=543 (RT/PR)

<b>INSTI, %</b>	<b>2.5</b>	<b>NNRTI, %</b>	<b>22.8</b>
T97A, %	<b>1.7</b>	K103N/S, %	<b>11.8</b>
Q148H, %	<b>0.2</b>	E138A/K/Q, %	<b>4.6</b>
<b>NRTI, %</b>	<b>16.4</b>	<b>PI, %</b>	<b>10.1</b>
1 or 2 TAMs, %	<b>6.4</b>		
M184V/I, %	<b>9.9</b>		
K65R/N, %	<b>1.3</b>		

Historical genotype records were assessed at screening, and documented resistance to study drugs or evidence of previous virologic failure led to exclusion. Retrospective deep sequencing analysis was later attempted on baseline samples from all BIKTARVY-treated participants.<sup>13</sup>

<sup>i</sup>This list is not inclusive of all RAMs observed in this analysis.<sup>13</sup>

<sup>5</sup>BIKTARVY is not indicated for patients with known or suspected substitutions associated with resistance to bictegravir or tenofovir.<sup>2</sup>

<sup>11</sup>Retrospective deep sequencing data were combined with the historical genotype data from screening.<sup>13</sup>

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Dosage and administration

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

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3TC, lamivudine; ABC, abacavir; ARV, antiretroviral; ART, antiretroviral therapy; ATV, atazanavir; DRV, darunavir; DTG, dolutegravir; eGFR<sub>CG</sub>, estimated glomerular filtration rate (Cockcroft-Gault); FTC, emtricitabine; IN, integrase; INSTI, integrase strand transfer inhibitor; IQR, interquartile range; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; PR, protease; RAM, resistance-associated mutation; RT, reverse transcriptase; TAM, thymidine analog mutation; TDF, tenofovir disoproxil fumarate.



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# Powerful Efficacy in Virologically Suppressed Adults Who Switched to BIKTARVY®

BIKTARVY was noninferior to ABC/DTG/3TC and ATV- or DRV-based regimens at Week 48<sup>2,10,11</sup>

## VIROLOGIC OUTCOMES AT WEEK 48

	STUDY 1844		STUDY 1878	
	BIKTARVY® (n=282)	ABC/DTG/3TC (n=281)	BIKTARVY® (n=290)	ATV- or DRV- Based Regimen* (n=287)
HIV-1 RNA ≥50 copies/mL <sup>†</sup>	1%	<1%	2%	2%
HIV-1 RNA <50 copies/mL	94%	95%	92%	89%
No virologic data	5%	5%	6%	9%

<sup>†</sup>Study 1844 treatment difference: 0.7% (95% CI: -1.0% to 2.8%; P=0.62). Study 1878: treatment difference: 0.0% (95% CI: -2.5% to 2.5%; P=1.0).<sup>2</sup>

## TREATMENT OUTCOMES WERE SIMILAR ACROSS SUBGROUPS

REGARDLESS OF AGE, SEX ASSIGNED AT BIRTH, RACE, AND REGION.<sup>2</sup>

### STUDY 1844 WEEK 168 RESULTS<sup>3</sup>

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

### STUDY 1878 WEEK 96 RESULTS<sup>4</sup>

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

## 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.

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3TC, lamivudine; ABC, abacavir; ART, antiretroviral therapy; ATV, atazanavir; CI, confidence interval; CrCl, creatinine clearance; DRV, darunavir; DTG, dolutegravir; FTC, emtricitabine; M=E, missing=excluded; RNA, ribonucleic acid; TDF, tenofovir disoproxil fumarate.

\*ABC/3TC or FTC/TDF + boosted ATV or DRV (cobicistat or ritonavir) regimen.<sup>2</sup>



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# Zero Cases of Treatment-Emergent Resistance to BIKTARVY® for up to 3 Years in Virologically Suppressed PWH Switching to BIKTARVY<sup>10,11,14,15,\*</sup>

## RESISTANCE OUTCOMES THROUGH RANDOMIZED PHASE

	STUDY 1844 THROUGH WEEK 48 <sup>10,*</sup>		STUDY 1878 THROUGH WEEK 48 <sup>11,15,*</sup>	
	<b>BIKTARVY®</b> (n=282)	<b>ABC/DTG/3TC</b> (n=281)	<b>BIKTARVY®</b> (n=290)	<b>ATV- or DRV- Based Regimen†</b> (n=287)
Met criteria for resistance analysis	3	3	2	6
<b>Confirmed treatment-emergent resistance</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1†</b>

\*Based on the resistance analysis population.

In the BIKTARVY arms, 2 study 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.<sup>2,16</sup>

## RESISTANCE OUTCOMES THROUGH EXTENSION

	STUDY 1844 THROUGH WEEK 168 (OPEN-LABEL EXTENSION) <sup>3,14,*</sup>		STUDY 1878 THROUGH WEEK 96 (EXTENSION PHASE) <sup>4,15,*</sup>	
	<b>Continued on BIKTARVY®</b> (n=259)	<b>Switched From ABC/DTG/3TC to BIKTARVY®</b> (n=265)	<b>Continued on BIKTARVY®</b> (n=272)	<b>Switched From ATV- or DRV- Based Regimen† to BIKTARVY®</b> (n=244)
Met criteria for resistance analysis	0	1	0	3
<b>Confirmed treatment-emergent resistance</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

\*Based on the resistance analysis population.

## 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.

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3TC, lamivudine; ABC, abacavir; ART, antiretroviral therapy; ATV, atazanavir; CrCl, creatinine clearance; DRV, darunavir; DTG, dolutegravir; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; RT, reverse transcriptase; TDF, tenofovir disoproxil fumarate.

<sup>2</sup>ABC/3TC or FTC/TDF + boosted ATV or DRV (cobicistat or ritonavir) regimen.

<sup>15</sup>One study participant developed virologic failure with treatment-emergent L74V in RT through Week 48.



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## Safety and Tolerability Profile After Switching to BIKTARVY®

Adverse reactions (all grades) reported in ≥2% of virologically suppressed adults who switched to BIKTARVY<sup>10,11,\*</sup>

### SAFETY OUTCOMES THROUGH WEEK 48

	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

The majority of adverse reactions associated with BIKTARVY were Grade 1 in Study 1844 (58%) and in Study 1878 (76%).<sup>15</sup>

### SAFETY RESULTS AT WEEK 168 AND WEEK 96<sup>15</sup>

- The safety profile of BIKTARVY in the extension phase for Study 1844 through Week 168 and for Study 1878 through Week 96 was similar to that in the randomized phase of each study

### LOW RATES OF DISCONTINUATION DUE TO ADVERSE EVENTS IN VIROLOGICALLY SUPPRESSED ADULTS

IN THE BIKTARVY ARMS THROUGH WEEK 168 (INCLUDING OLE) IN STUDY 1844 (1.3%, n=547) AND WEEK 96 (INCLUDING EXTENSION) IN STUDY 1878 (1.1%, n=534).<sup>3,4</sup>

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Dosage and administration (cont'd)

- 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.

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3TC, lamivudine; ABC, abacavir; ART, antiretroviral therapy; ATV, atazanavir; CrCl, creatinine clearance; DRV, darunavir; DTG, dolutegravir; FTC, emtricitabine; OLE, open-label extension; TDF, tenofovir disoproxil fumarate.

\*Frequencies of adverse reactions are based on all adverse events attributed to trial drugs by the investigator. These adverse reactions were reported in at least 2% of participants receiving BIKTARVY in either Study 1844 or Study 1878. No adverse reactions of Grade 2 or higher occurred in >1% of participants treated with BIKTARVY through Week 48.

†ABC/3TC or FTC/TDF + boosted ATV or DRV (cobicistat or ritonavir) regimen.<sup>2</sup>

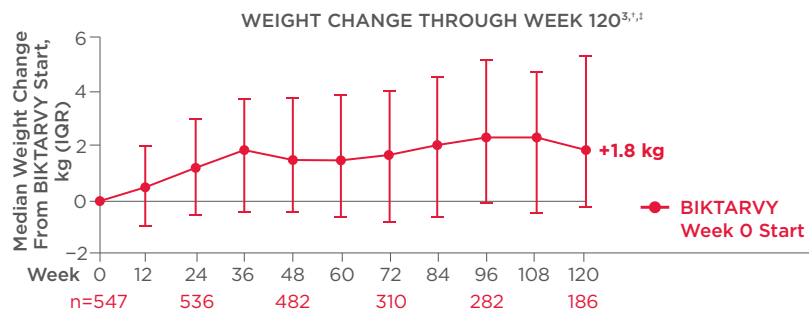
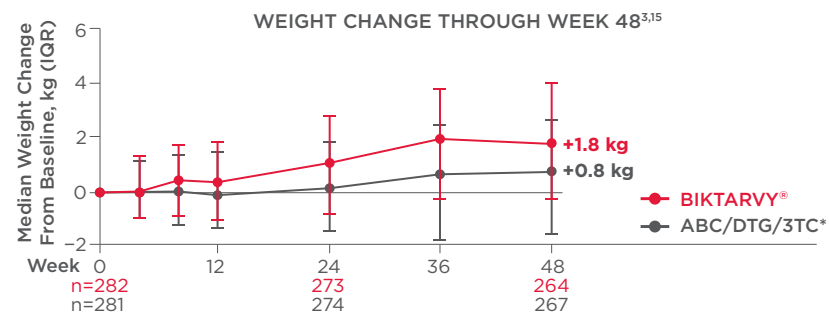


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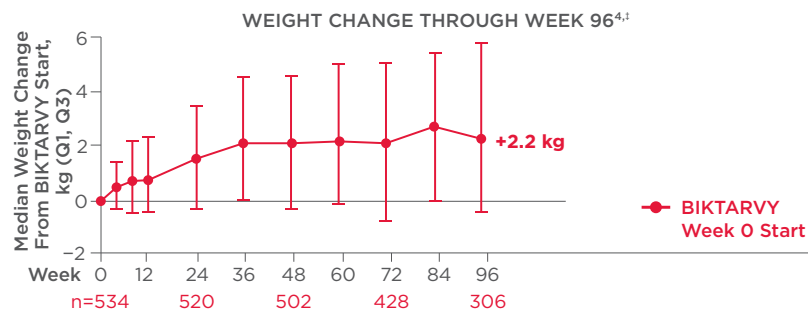
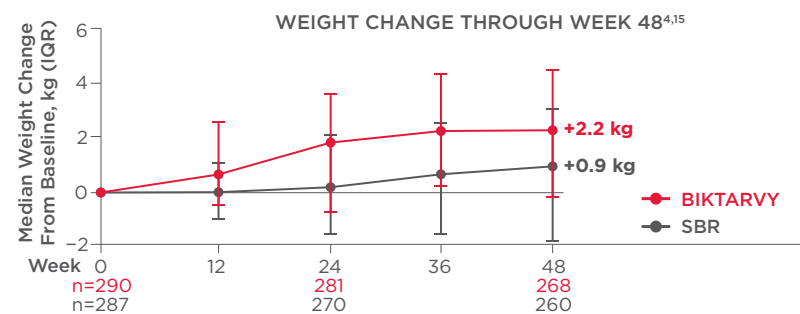
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## Weight Change From Baseline in Studies 1844 and 1878

### STUDY 1844



### STUDY 1878



**NO ADULTS DISCONTINUED BIKTARVY DUE TO WEIGHT-RELATED ADVERSE EVENTS IN STUDY 1844 (THROUGH WEEK 168) AND STUDY 1878 (THROUGH WEEK 96)<sup>3,4,10,11</sup>**

### 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.

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3TC, lamivudine; ABC, abacavir; ARV, antiretroviral therapy; BIC, bicitgravir; DTG, dolutegravir; FTC, emtricitabine; IQR, interquartile range; Q, quartile; SBR, stayed on baseline regimen TAF, tenofovir alafenamide.

\*Shown for reference.<sup>3</sup>

<sup>1</sup>Low participant numbers out to Week 168 (n=12); median change at Week 168: +2.1 kg.<sup>3</sup>

<sup>1</sup>This analysis includes participants initially randomized to BIKTARVY and participants who switched to BIKTARVY during the extension phase.<sup>3</sup>



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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  $\geq 25$  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 bicitegravir 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 coinfecting 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 coinfecting 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  $\geq 5\%$ ; 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  $\geq 25$  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.

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