Bictegravir-Tenofovir alafenamide-Emtricitabine (Biktarvy)

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Bictegravir-Tenofovir alafenamide-Emtricitabine

Dose: 1 tablet once daily with or without food
Bictegravir-Tenofovir alafenamide-Emtricitabine

• **With Renal Impairment:** do not initiate if estimated CrCl <30 mL/min

• **Pregnancy:** insufficient data

• **Common Adverse Events (≥5%)**
  – Diarrhea (6%)
  – Nausea (5%)
  – Headache (5%)

• **Drug-Drug Interactions**
  – Avoid: rifamycins, dofetilide, carbamazepine, phenytoin, St. John’s wort
  – Consider: metformin, cation-containing compounds

Source: Bictegravir-Tenofovir alafenamide-Emtricitabine. Prescribing Information.
Bictegravir and Inhibition of Tubular Secretion of Creatinine

- **Bictegravir** decreases tubular secretion of creatinine via inhibition of MAET1 and OCT2.

**Illustration:** David H. Spach, MD
Bictegravir-Tenofovir alafenamide-Emtricitabine
Summary of Key Phase 3 Studies

• **Trials in Treatment-Naïve Adults**
  - GS-380-1489: BIC-TAF-FTC vs. DTG-ABC-3TC
  - GS-380-1490: BIC-TAF-FTC vs. DTG + TAF-FTC

• **Trials in Adults with Virologic Suppression**
  - GS-380-1844: Switch to BIC-TAF-FTC vs. continue DTG-ABC-3TC
  - GS-380-1878: Switch to BIC-TAF-FTC vs. continue boosted PI + NRTIs
  - GS-380-1961: Switch to BIC-TAF-FTC for women
  - GS-380-4030: Switch to BIC-TAF-FTC vs. DTG + TAF-FTC
  - BAAVE2020: Switch to BIC-TAF-FTC for Black Americans

**Abbreviations:** BIC-TAF-FTC = bictegravir-tenofovir alafenamide-emtricitabine; DTG-ABC-3TC = dolutegravir-abacavir-lamivudine; PI = protease inhibitor; NRTIs = nucleoside reverse transcriptase inhibitors
Bictegravir-Tenofovir alafenamide-Emtricitabine

Trials in Treatment Treatment-Naïve Adults
BIC-TAF-FTC vs. DTG-ABC-3TC as Initial Therapy

GS-380-1489: Week 48 Results
Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy
GS-380-1489: Design

• **Design**
  - Randomized, double-blind, active-controlled, phase 3 study evaluating the efficacy and safety of bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir-abacavir-lamivudine for treatment-naïve adults with HIV

• **Including Criteria**
  - Age ≥18 years
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - HIV RNA ≥500 copies/mL
  - eGFR ≥50 mL/min
  - HLA B*5701 negative
  - No chronic HBV infection

Week 48 Virologic Response (Intention-to-Treat Analysis)

HIV RNA <50 copies/mL (%)

- **Bictegravir-TAF-FTC**: 92.4 (290/314)
- **Dolutegravir-ABC-3TC**: 93.0 (293/315)

No treatment-emergent resistance to any study drug occurred

## Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy

**GS-380-1489: Adverse Effects**

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events (AE’s &gt;5%) Through Week 48</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse Effect</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Diarrhea, %</td>
</tr>
<tr>
<td>Headache, %</td>
</tr>
<tr>
<td>Nausea, %</td>
</tr>
<tr>
<td>Fatigue, %</td>
</tr>
<tr>
<td>Arthralgia, %</td>
</tr>
<tr>
<td>Insomnia, %</td>
</tr>
<tr>
<td>Change in eGFR (mL/min)</td>
</tr>
</tbody>
</table>

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy

GS-380-1489: Adverse Effects

Change in Markers of Proximal Tubulopathy at 48 Weeks

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy
GS-380-1489: Adverse Effects

Change in Bone Mineral Density at 48 Weeks

Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Results

Change in Lipids at 48 Weeks

**Interpretation**: “At 48 weeks, coformulated bictegravir, emtricitabine, and tenofovir alafenamide achieved virological suppression in 92% of previously untreated adults and was non-inferior to coformulated dolutegravir, abacavir, and lamivudine, with no treatment-emergent resistance. Bictegravir, emtricitabine, and tenofovir alafenamide was safe and well tolerated with better gastrointestinal tolerability than dolutegravir, abacavir, and lamivudine. Because coformulated bictegravir, emtricitabine, and tenofovir alafenamide does not require HLA B*5701 testing and provides guideline-recommended treatment for individuals co-infected with HIV and hepatitis B, this regimen might lend itself to rapid or same-day initiation of therapy in the clinical setting.”
BIC-TAF-FTC versus DTG + TAF-FTC as Initial Therapy

GS-380-1490: Week 48 Results
Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1490: Design

- **Design**
  - Randomized, double-blind, active-controlled, phase 3 study comparing bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir plus tenofovir alafenamide-emtricitabine as initial therapy

- **Inclusion Criteria**
  - Age ≥18 years
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - HIV RNA ≥500 copies/mL
  - eGFR ≥30 mL/min

Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1490: Week 48 Results

Week 48 Virologic Response (Intention-to-Treat Analysis)

No participant discontinued due to lack of efficacy in either arm
No treatment-emergent resistance to any study drug occurred

Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy
GS-380-1490: Adverse Events

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events (AE’s &gt;5%) Through Week 48</th>
<th>BIC-TAF-FTC (n = 320)</th>
<th>DTG + TAF-FTC (n = 325)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache, %</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Diarrhea, %</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Nausea, %</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Fatigue, %</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Arthralgia, %</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Insomnia, %</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Change in eGFR</td>
<td>-7.3 mL/min</td>
<td>-10.8 mL/min</td>
</tr>
</tbody>
</table>

Abbreviations: eGFR = estimated glomerular filtration

**Interpretation**: “These week 96 data support bictegravir, emtricitabine, and tenofovir alafenamide as a safe, well tolerated, and durable treatment for people living with chronic HIV.”
BIC-TAF-FTC versus DTG + 2 NRTIs as Initial Therapy

GS-380-1489 & 1490: Week 144 Results
Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy
GS-380-1489 & 1490: Week 144 Results

Week 144 Virologic Response (Intention-to-Treat Analysis)

No treatment-emergent resistance to any study drug occurred

Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1489 & 1490 (Week 144): Results

Week 144 Change in Weight from Baseline

![Bar chart showing median change in weight from baseline (kg) for Bictegravir-TAF-FTC and Dolutegravir + 2 NRTIs in Studies 14989 and 1490.]

- Study 14989: Bictegravir-TAF-FTC (4 kg), Dolutegravir + 2 NRTIs (3.5 kg)
- Study 1490: Bictegravir-TAF-FTC (4 kg), Dolutegravir + 2 NRTIs (5.0 kg)

**Interpretation:** “These long-term data support the use of bictegravir, emtricitabine, and tenofovir alafenamide as a safe, well tolerated, and durable treatment for people with HIV, with no emergent resistance.”

Bictegravir-Tenofovir alafenamide-Emtricitabine

Switch Studies in Adults with Virologic Suppression
Switch from DTG-ABC-3TC to BIC-TAF-FTC in Adults with Virologic Suppression

GS-380-1844
Switch from DTG-ABC-3TC to BIC-TAF-FTC
GS-380-1844: Design

• **Background**: Randomized, phase 3, multicenter, double-blind, active-controlled study evaluating the efficacy and safety of switching adults with HIV and viral suppression to BIC-TAF-FTC versus continuing DTG-ABC-3TC

• **Inclusion Criteria**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for at least 3 months
  - eGFR ≥50 mL/min for at least 3 months
  - No history of treatment failure
  - Taking DTG-ABC-3TC or DTG + ABC-3TC
  - No documented or suspected resistance to DTG, ABC, 3TC, FTC, or TAF
  - HCV infection allowed
  - HBV infection not allowed

Switch from DTG-ABC-3TC to BIC-TAF-FTC
GS-380-1844: Results

Week 48 Virologic Response (Intention-to-Treat Analysis)

At 48 weeks, proportion with HIV RNA ≥50 copies/mL not statistically different: 1% BIC vs <1% DTG
5 participants met criteria for virologic failure and resistance testing (3 BIC, 2 DTG); no resistance found

Switch from DTG-ABC-3TC to BIC-TAF-FTC GS-380-1844: Results

<table>
<thead>
<tr>
<th>Baseline Antiretroviral Medications</th>
<th>BIC-TAF-FTC (n = 282)</th>
<th>DTG-ABC-3TC (n = 281)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE’s leading to study drug discontinuation</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Headache, %</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Diarrhea, %</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Abnormal dreams, %</td>
<td>&lt;1</td>
<td>2</td>
</tr>
<tr>
<td>Fatigue, %</td>
<td>&lt;1</td>
<td>1</td>
</tr>
<tr>
<td>Nausea, %</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Insomnia, %</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

Interpretation: “The fixed-dose combination ofbictegravir, emtricitabine, and tenofovir alafenamide might provide a safe and efficacious option for ongoing treatment of HIV-1 infection.”

Switch from Boosted PI + 2 NRTIs to BIC-TAF-FTC with Viral Suppression

GS-380-1878
Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC
GS-380-1878: Design

• Background
  - Randomized, phase 3, multicenter, open-label switch study evaluating the efficacy and safety of switching adults with viral suppression taking a boosted PI plus 2 NRTIs to BIC-TAF-FTC

• Inclusion Criteria
  - Age ≥18 years
  - HIV RNA <50 copies/mL for ≥6 months
  - Taking stable antiretroviral regimen for ≥6 months
  - No history of virologic failure
  - No prior treatment with an INSTI
  - eGFR ≥50 mL/min
  - HBV and HCV allowed
  - Taking atazanavir or darunavir (each boosted by ritonavir or cobicistat) + TDF-FTC or ABC-3TC

Switch Regimen
Bictegravir-TAF-FTC
(n = 290)

Maintain Regimen
Boosted PI + 2 NRTIs
(n = 287)

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC

GS-380-1878: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BIC-TAF-FTC (n = 290)</th>
<th>Boosted PI + 2 NRTIs (n = 287)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years (range)</td>
<td>48</td>
<td>47</td>
</tr>
<tr>
<td>Male, %</td>
<td>84</td>
<td>82</td>
</tr>
<tr>
<td>Black or African descent, %</td>
<td>27</td>
<td>25</td>
</tr>
<tr>
<td>Hispanic/Latino, %</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>Median CD4, cells/mL</td>
<td>617</td>
<td>626</td>
</tr>
<tr>
<td>HBV coinfection, %</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>HCV coinfection, %</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Median eGFR, mL/min</td>
<td>107</td>
<td>105</td>
</tr>
<tr>
<td>Baseline TDF-FTC, ABC-3TC, %</td>
<td>84, 16</td>
<td>85, 15</td>
</tr>
<tr>
<td>Baseline DRV, ATV, %</td>
<td>57, 43</td>
<td>54, 46</td>
</tr>
</tbody>
</table>

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC

GS-380-1878: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Antiretroviral Medications</th>
<th>BIC-TAF-FTC (n = 290)</th>
<th>Boosted PI + 2 NRTIs (n = 287)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NRTI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenofovir DF-emtricitabine, %</td>
<td>84</td>
<td>85</td>
</tr>
<tr>
<td>Abacavir-lamivudine, %</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td><strong>Protease Inhibitor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Darunavir, %</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>Atazanavir, %</td>
<td>43</td>
<td>46</td>
</tr>
</tbody>
</table>

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Results

Week 48 Virologic Response (Intention-to-Treat Analysis)

![Bar chart showing virologic response at Week 48](chart.png)

Primary outcome of HIV RNA ≥50 copies/mL at 48 weeks: 2% each arm

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Adverse Events

<table>
<thead>
<tr>
<th>Most Common Treatment-Related Adverse Events (AE’s) Through 48 Weeks</th>
<th>BIC-TAF-FTC (n = 290)</th>
<th>Boosted PI + 2 NRTI’s (n = 287)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache, %</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Diarrhea, %</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Nasopharyngitis, %</td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>URI, %</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Back pain, %</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Arthralgia, %</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Change in eGFR</td>
<td>-4.3 mL/min</td>
<td>0.2 mL/min</td>
</tr>
</tbody>
</table>

Abbreviations: eGFR = estimated glomerular filtration

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC
GS-380-1878: Results

Change in Lipids at 48 Weeks

<table>
<thead>
<tr>
<th></th>
<th>Bictegravir-TAF-FTC</th>
<th>Boosted PI + 2 NRTI's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>1 -1</td>
<td>5 5</td>
</tr>
<tr>
<td>LDL</td>
<td>0 0</td>
<td>3 3</td>
</tr>
<tr>
<td>HDL</td>
<td>3 3</td>
<td>1 1</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>-6 -6</td>
<td>4 4</td>
</tr>
</tbody>
</table>

Interpretation: “Fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide might be a safe and efficacious alternative to continued boosted protease inhibitor therapy in adults with HIV-1 infection.”
Switch to BIC-TAF-FTC in Women with Virologic Suppression

GS-380-1961
Switch to BIC-TAF-FTC in Women with Virologic Suppression GS-380-1961: Design

**Background:** Randomized, phase 3, multicenter, open label, active-controlled study evaluating the efficacy and safety of switching women with HIV and viral suppression to BIC-TAF-FTC versus continuing their baseline regimen.

**Inclusion Criteria**
- Women aged ≥18 years
- HIV RNA <50 copies/mL for at least 12 weeks
- *EVG/c/TAF/FTC, EVG/c/TDF/FTC, or ATV/r + TDF/FTC
- eGFR >50 mL/min
- No suspected resistance to study drugs
- Using contraception if child-bearing potential
- Chronic hepatitis B or C allowed

*Regimens: 53% EVG/c/TAF/FTC and 42% EVG/c/TDF/FTC

Switch to BIC-TAF-FTC in Women with Virologic Suppression GS-380-1961: Results by U.S. FDA Snapshot Algorithm

Interpretation: “Fixed-dose combination bicitravir-emtricitabine-tenofovir alafenamide provides a safe and efficacious option for ongoing treatment of HIV in women. This study contributes important data on safety, tolerability, and outcomes of antiretroviral therapy among women living with HIV.”
Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression

GS-380-4030
Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression
GS-380-4030: Design

• **Background**
  - Randomized, double-blind, switch study comparing the efficacy of switching adults with viral suppression (with or without documented or suspected NRTI resistance) taking DTG plus TAF-FTC or TDF-FTC to BIC-TAF-FTC versus DTG plus TAF-FTC

• **Inclusion Criteria**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for 3 months if no resistance
  - HIV RNA <50 copies/mL for 6 months if NRTI resistance
  - Taking stable regimen of DTG plus TDF-FTC or TAF-FTC
  - eGFR ≥30 mL/min
  - Chronic HBV and HCV infection permitted
  - Documented or suspected NRTI resistance permitted
  - Excluded if integrase resistance or virologic failure on INSTI

Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression GS-380-4030: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>BIC-TAF-FTC (n = 284)</th>
<th>DTG + TAF-FTC (n = 281)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median (range)</td>
<td>51 (22-79)</td>
<td>50 (20-79)</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>39 (14%)</td>
<td>41 (15%)</td>
</tr>
<tr>
<td>Black, n (%)</td>
<td>68 (24%)</td>
<td>61 (22%)</td>
</tr>
<tr>
<td>Hispanic or Latino, n (%)</td>
<td>61 (22%)</td>
<td>49 (18%)</td>
</tr>
<tr>
<td>CD4 cell count, cells/µL, median (IQR)</td>
<td>659 (486-885)</td>
<td>642 (462-791)</td>
</tr>
<tr>
<td>TAF-FTC NRTI backbone, n (%)</td>
<td>194 (68%)</td>
<td>195 (69%)</td>
</tr>
<tr>
<td>K65R/E/N or ≥3 TAMs mutation(s), n (%)</td>
<td>16 (6%)</td>
<td>14 (5%)</td>
</tr>
<tr>
<td>Any other pattern of NRTI mutation(s), n (%)</td>
<td>55 (19%)</td>
<td>53 (19%)</td>
</tr>
<tr>
<td>No NRTI mutation, n (%)</td>
<td>213 (75%)</td>
<td>214 (76%)</td>
</tr>
</tbody>
</table>

Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression GS-380-4030: Results

Virologic Outcome at Week 48

Interpretation: “The single-tablet regimen B/F/TAF is a safe, effective option for people virologically suppressed on DTG plus either F/TDF or F/TAF, including in individuals with preexisting resistance to NRTIs.”
Switch to Bictegravir-Tenofovir alafenamide-Emtricitabine for Black Americans

BRAAVE2020
Switch to Bictegravir-TAF-FTC for Black Americans
BRAAVE2020: Design

- **Background**
  - Randomized, phase 3, multicenter, open-label switch study evaluating the efficacy and safety of switching Black American adults with viral suppression to BIC-TAF-FTC, including individuals with a history of NRTI, NNRTI, and/or PI resistance

- **Inclusion Criteria**
  - Age ≥18 years
  - Self-described as Black, African American, or mixed race that includes Black
  - HIV RNA <50 copies/mL for ≥12 months
  - Taking stable antiretroviral regimen that includes 2 NRTIs plus 3<sup>rd</sup> agent for ≥6 months
  - eGFR ≥50 mL/min
  - No INSTI resistance; no K65R, T69ins, or ≥3TAMs

Switch Regimen
Bictegravir-TAF-FTC
(n = 328)

Maintain Regimen
Continue baseline ART
(n = 165)

10% of all participants with M184V at baseline

Switch to Bictegravir-TAF-FTC for Black Americans
BRAAVE2020: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>BIC-TAF-FTC (n = 328)</th>
<th>Continue Baseline ART (n = 165)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median (range)</td>
<td>49 (18-79)</td>
<td>49 (19-70)</td>
</tr>
<tr>
<td>Female sex at birth, n (%)</td>
<td>101 (31)</td>
<td>55 (33)</td>
</tr>
<tr>
<td>Cisgender, n (%)</td>
<td>317 (96)</td>
<td>159 (96)</td>
</tr>
<tr>
<td>Hispanic or Latino, n (%)</td>
<td>61 (22%)</td>
<td>49 (18%)</td>
</tr>
<tr>
<td>CD4 cell count, cells/µL, median (IQR)</td>
<td>747 (570-922)</td>
<td>758 (494-969)</td>
</tr>
<tr>
<td>TAF-FTC NRTI backbone, n (%)</td>
<td>224 (68)</td>
<td>107 (65)</td>
</tr>
<tr>
<td>TDF-FTC NRTI backbone, n (%)</td>
<td>56 (17)</td>
<td>34 (21)</td>
</tr>
<tr>
<td>ABC-3TC NRTI backbone, n (%)</td>
<td>44 (13)</td>
<td>24 (15)</td>
</tr>
<tr>
<td>Other NRTI backbone, n (%)</td>
<td>4 (1)</td>
<td>0</td>
</tr>
</tbody>
</table>

# Switch to Bictegravir-TAF-FTC for Black Americans

## BRAAVE2020: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>BIC-TAF-FTC (n = 328)</th>
<th>Continue Baseline ART (n = 165)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline 3\textsuperscript{rd} agent, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INSTI</td>
<td>202 (61)</td>
<td>99 (60)</td>
</tr>
<tr>
<td>NNRTI</td>
<td>100 (30)</td>
<td>51 (31)</td>
</tr>
<tr>
<td>PI</td>
<td>30 (9)</td>
<td>14 (9)</td>
</tr>
<tr>
<td>CCR5 antagonist</td>
<td>0</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Baseline ARV resistance, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRTI resistance</td>
<td>44 (13)</td>
<td>26 (16)</td>
</tr>
<tr>
<td>M184V/I</td>
<td>31 (9)</td>
<td>20 (12)</td>
</tr>
<tr>
<td>NNRTI resistance</td>
<td>70 (21)</td>
<td>32 (19)</td>
</tr>
<tr>
<td>PI resistance</td>
<td>36 (11)</td>
<td>26 (16)</td>
</tr>
<tr>
<td>INSTI resistance</td>
<td>8 (2)</td>
<td>3 (2)</td>
</tr>
</tbody>
</table>

Switch to Bictegravir-TAF-FTC for Black Americans
BRAAVE2020: Results

Week 24 Virologic Response (Intention-to-Treat Analysis)

Primary outcome of HIV RNA ≥50 copies/mL at 24 weeks: 0.8% BIC-TAF-FTC arm; 1.6% continue baseline ART arm

Week 24 Virologic Response by Baseline Resistance (Intention-to-Treat Analysis)

Bictegravir-TAF-FTC vs Continue baseline ART

<table>
<thead>
<tr>
<th>Baseline Resistance</th>
<th>Bictegravir-TAF-FTC</th>
<th>Continue baseline ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any NRTI RAM</td>
<td>98/43/44</td>
<td>96/25/26</td>
</tr>
<tr>
<td>No NRTI RAM</td>
<td>96/258/269</td>
<td>95/125/132</td>
</tr>
<tr>
<td>M184V/I</td>
<td>97/30/31</td>
<td>96/19/20</td>
</tr>
<tr>
<td>No M184V/I</td>
<td>95/271/282</td>
<td>95/131/138</td>
</tr>
</tbody>
</table>

HIV RNA <50 copies/mL (%)

RAM = resistance associated mutation

Conclusions: “For Black Americans with HIV, switching to B/F/TAF was noninferior to continuing a variety of regimens, including those with pre-existing NRTI mutations.”

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