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 of bictegravir, emtricitabine, and tenofovir alafenamide might provide a safe and efficacious option for ongoing treatment of HIV-1 infection.”

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