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

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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**

#### Treatment Emergent Adverse Events (AE’s >5%) Through Week 48

<table>
<thead>
<tr>
<th></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.”
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