Dolutegravir + ABC-3TC and CSF HIV-1 RNA Levels

ING116070 Study
Dolutegravir + ABC-3TC and Impact on CSF HIV RNA Levels
ING116070 Study: Design

Study Design: ING116070

- **Background**: Single arm, phase 3b, open-label, multi-center trial to evaluate the distribution and antiviral activity of dolutegravir + abacavir-lamivudine in CSF

- **Inclusion Criteria (n = 13)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥5,000 copies/mL
  - CD4 count ≥200 cells/mm$^3$
  - No active CDC AIDS condition (except KS)

- **Treatment Arm (n = 12)**
  - Dolutegravir (QD) + Abacavir-lamivudine

## CSF Findings in Patients on Dolutegravir + Abacavir-Lamivudine

<table>
<thead>
<tr>
<th>Cerebrospinal Fluid (CSF) Parameter</th>
<th>Week 2</th>
<th>Week 16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean CSF DTG Concentration total, ng/mL</td>
<td>16.2</td>
<td>12.6</td>
</tr>
<tr>
<td>CSF/Total Plasma Ratio for DTG Concentration</td>
<td>0.47</td>
<td>0.55</td>
</tr>
<tr>
<td>CSF HIV-1 RNA &lt;50 copies/mL</td>
<td>11/12 (92%)</td>
<td>11/11 (100%)</td>
</tr>
<tr>
<td>CSF HIV-1 RNA &lt;2 copies/mL</td>
<td>ND</td>
<td>11/12 (92%)</td>
</tr>
</tbody>
</table>

Conclusions: “The dolutegravir concentrations in CSF were similar to unbound plasma concentrations and exceeded the in vitro 50% inhibitory concentration for wild-type HIV (0.2 ng/mL), suggesting that dolutegravir achieves therapeutic concentrations in the central nervous system. The HIV-1 RNA reductions were similar in CSF and plasma.”
Acknowledgment

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