Bictegravir 10-day Dose-Ranging Monotherapy
GS-141-1219
# Bictegravir 10-day Dose-Ranging Monotherapy

**GS-141-1219: Design**

<table>
<thead>
<tr>
<th>Study Design</th>
<th><strong>Bictegravir: 5 mg QD</strong> (n = 4)</th>
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</thead>
<tbody>
<tr>
<td><strong>Bictegravir: 25 mg QD</strong> (n = 4)</td>
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<tr>
<td><strong>Bictegravir: 50 mg QD</strong> (n = 4)</td>
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<td><strong>Bictegravir: 100 mg QD</strong> (n = 4)</td>
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<tr>
<td><strong>Placebo</strong> (n = 4)</td>
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## GS-141-1219: Study Design

- **Background**: Randomized, double-blind, dose-ranging, placebo-controlled, 10-day, phase 1b study to evaluate antiviral activity, safety, and pharmacokinetics of the INSTI bictegravir.

- **Inclusion Criteria (n = 20)**
  - Antiretroviral-naïve or
  - Antiretroviral-experienced but INSTI-naïve
  - Age: between 18 and 65
  - CD4 >200 cells/mm³
  - HIV RNA between 10,000 and 400,000 copies/mL

- **Treatment Arms**
  - Bictegravir: 5, 25, 50, or 100 mg daily
  - Placebo: daily

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GS-141-1219: Results

Baseline to Day 11: Change in Baseline HIV RNA Level

**Interpretation:** “Bictegravir is a novel, potent, unboosted integrase strand transfer inhibitor (INSTI) that demonstrated rapid, dose-dependent declines in HIV-1 RNA after 10 days of monotherapy. Bictegravir was well tolerated, and displayed rapid absorption and a half-life supportive of once-daily therapy in HIV-infected subjects.”

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