Investigational

Bictegravir 10-day Dose-Ranging Monotherapy

GS-US-141-1219

National HIV Curriculum

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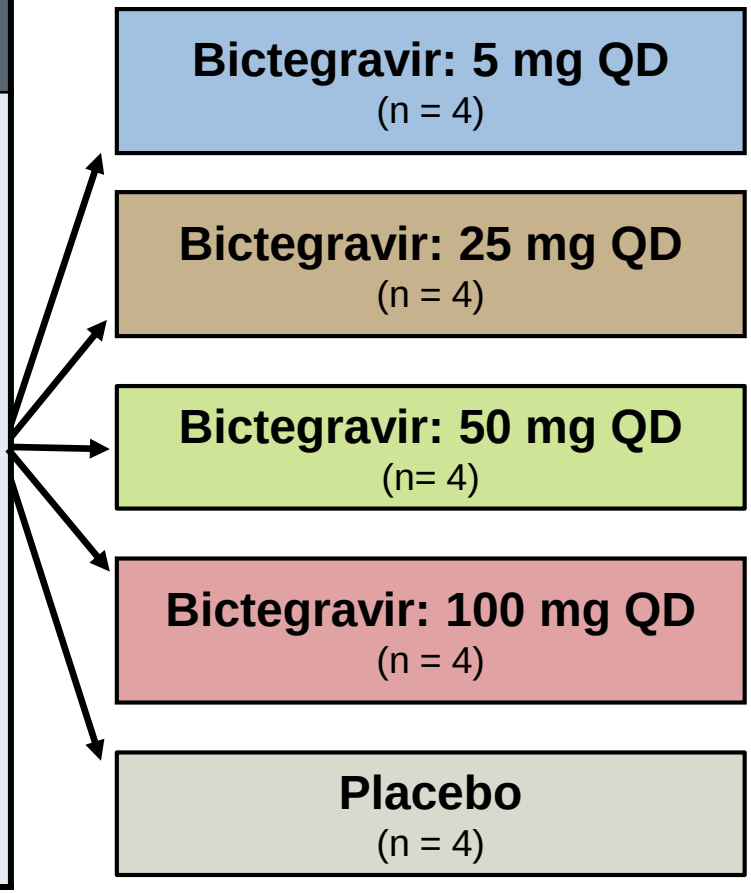
Bictegravir 10-day Dose-Ranging Monotherapy
GS-US-141-1219: Design

GS-US-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/mm^3
  - HIV RNA between 10,000 and 400,000 copies/mL
- **Treatment Arms**
  - Bictegravir: 5, 25, 50, or 100 mg daily
  - Placebo: daily



Source: Gallant JE, et al. J Acquir Immune Defic Syndr. 2017;75:61-6.

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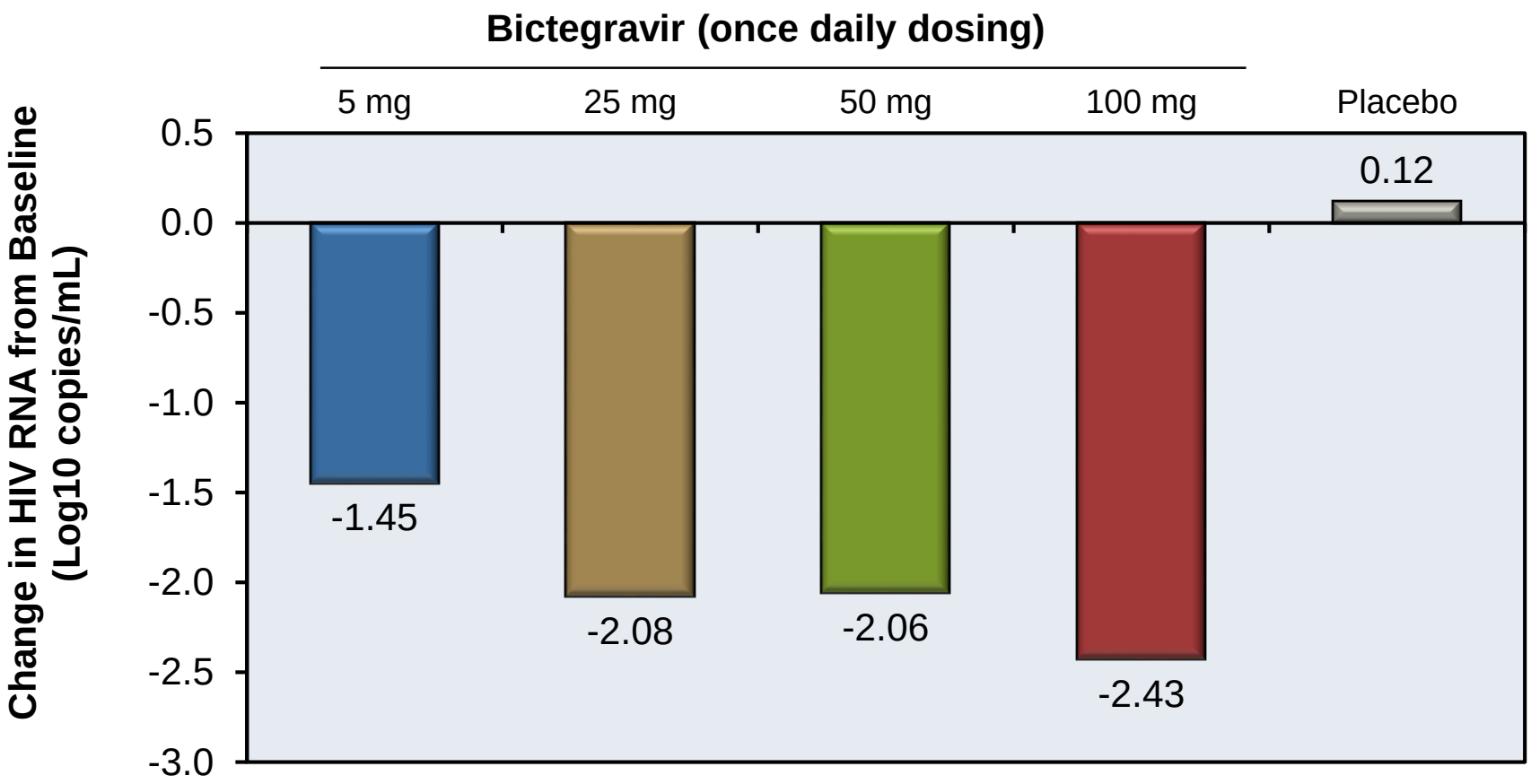
Bictegravir 10-day Dose-Ranging Monotherapy
GS-US-141-1219: Results

Baseline to Day 11: Change in Baseline HIV RNA Level



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Bictegravir 10-day Dose-Ranging Monotherapy
GS-US-141-1219: Conclusions

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.”

Source: Gallant JE, et al. J Acquir Immune Defic Syndr. 2017;75:61-6

Acknowledgment

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