**Efficacy evaluations**

- The primary endpoint was virologic response (RNA < 50 copies/mL) at Week 48.
- The primary outcome was to compare sex-based differences in response rates.
  - Secondary endpoints included:
    - CD4+ cell count change from baseline to Week 48.
    - Time to virologic failure.
    - Time in treatment.

**Safety evaluations**

- Although DRV/r-based therapy is generally well tolerated, serious adverse events (SAEs) and discontinuations due to AEs were recorded throughout the study.
- Clinical laboratory abnormalities were determined according to the US strategic 
  advancement of HIV/AIDS grading system.
- A woman’s eligibility to continue treatment could be determined by several factors, including:
  - Maternal or infant safety.
  - Insight into health care provider and patient relationship.
  - Quality of life.

**Population patient and statistical analysis**

- The primary analysis population was defined as all enrolled patients who received at least one dose of study medication.
- The intent-to-treat analysis was defined as all enrolled patients who received at least one dose of study medication until the onset of the primary endpoint.
- The observed analysis was performed on the last observation carried forward (LOCF) principle.

**Results**

- A total of 429 patients were enrolled in GRAICE and received at least one dose of study medication (206, 48.5% were women).
- Women were younger than men (mean age, 37.9 vs. 41.7 years).
- Women were less likely to be non-Hispanic white (52.6% vs. 80.3%) and more likely to be African American (37.2% vs. 10.9%).
- Women were more likely to be treatment-experienced than men (16.9% vs. 8.6%).

**Discussion**

- **The ITT–TLOVR analysis**, which treats all study discontinuations as failures, indicated a similar virologic response rate between men and women (91.3% vs. 90.7%, P = .95).
- **The ITT–LOCF analysis** showed a similar virologic response rate between men and women (91.8% vs. 91.6%, P = .82).
- **The LOCF analysis** showed a similar virologic response rate between men and women (91.8% vs. 91.6%, P = .82).
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**Conclusions**

- **The GRACE study successfully enrolled a high proportion of women and is, to**
  - date, the largest in North America to assess sex-based differences in the efficacy and safety of DRV/r-based therapy.
- **The primary endpoint was virologic response (RNA < 50 copies/mL) at Week 48.**
- **The primary outcome was to compare sex-based differences in response rates.**
- **Secondary endpoints included:**
  - CD4+ cell count change from baseline to Week 48.
  - Time to virologic failure.
  - Time in treatment.

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