Rilpivirine Dose-Ranging versus Efavirenz, with 2NRTIs

C204

Rilpivirine (TMC-278) vs. Efavirenz, with 2NRTIs in ARV-Naive
C204: Study Design

Study Design: C204

- **Background**: Randomized, phase IIb, dose-ranging, international study of rilpivirine compared with efavirenz, all in combination with 2 NRTIs in treatment-naïve persons with chronic HIV.
- **Inclusion Criteria (n = 368)**
  - Age ≥18 years
  - Antiretroviral-naïve
  - HIV RNA ≥5,000 copies/mL
  - No baseline NNRTI mutations
- **Treatment Arms**
  - Rilpivirine 25, 75, or 150 mg daily + 2 NRTIs*
  - Efavirenz 600 mg daily + 2 NRTIs*

Rilpivirine: 25 mg + 2 NRTIs
(n = 93)

Rilpivirine: 75 mg + 2 NRTIs
(n = 95)

Rilpivirine: 150 mg + 2 NRTIs
(n = 91)

Efavirenz: 600 mg + 2 NRTIs
(n = 89)

*2 NRTIs: Zidovudine + Lamivudine (75%); Tenofovir DF + Emtricitabine (25%)

Source: Pozniak AL, et al. AIDS. 2010;24:55-65.

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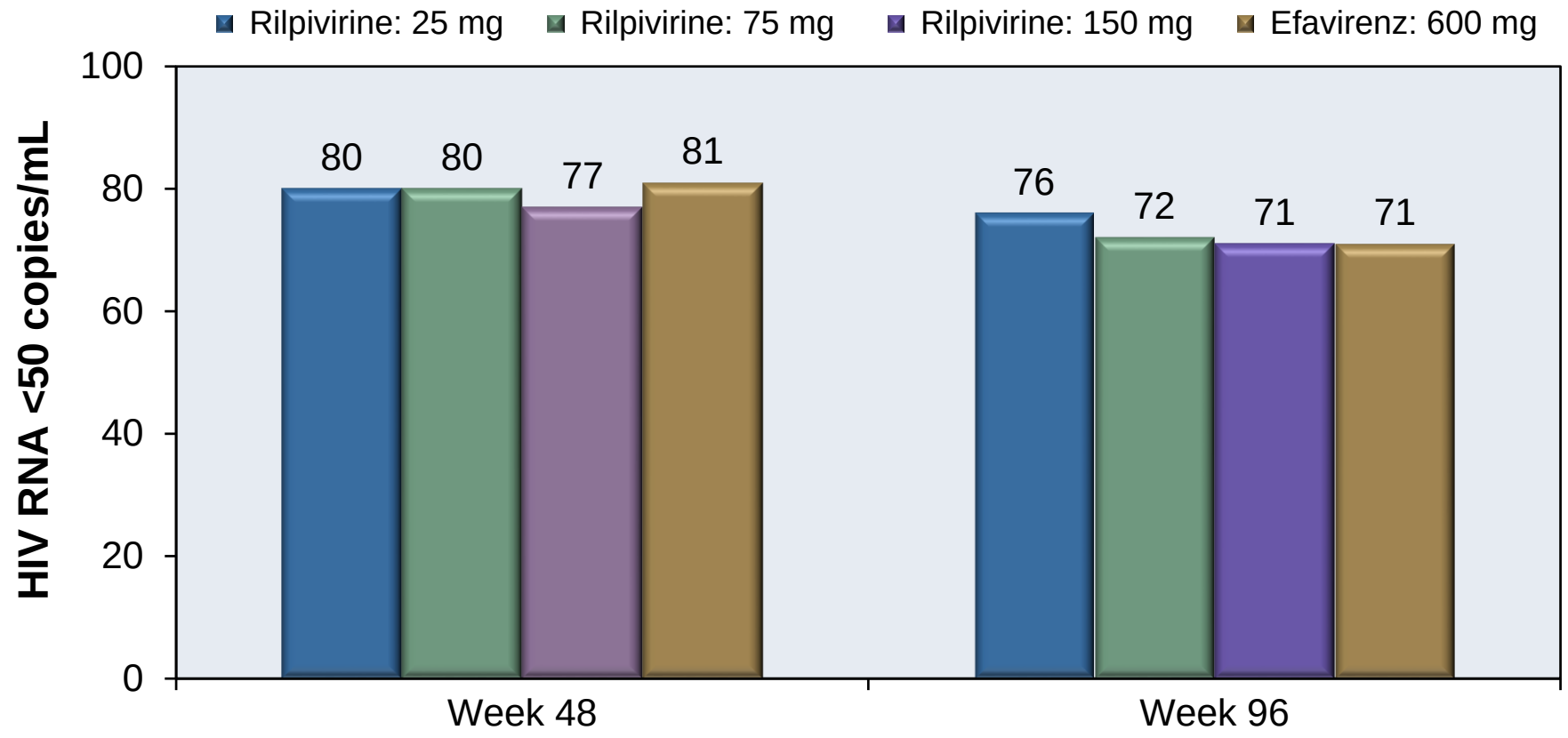
C204: Results

48 and 96 Week Data: Virologic Response (ITT)



All regimens included 2 NRTIs: Zidovudine + Lamivudine (75%); Tenofovir + Emtricitabine (25%)

Source: Pozniak AL, et al. AIDS. 2010;24:55-65.

Rilpivirine (TMC-278) vs. Efavirenz, with 2NRTIs in ARV-Naive
C204: Conclusions

- **Conclusion**: “All TMC278 doses demonstrated potent and sustained efficacy comparable with efavirenz in treatment-naive patients over 96 weeks. TMC278 was well tolerated with lower incidences of neurological and psychiatric adverse events, rash and lower lipid elevations than those with efavirenz. TMC278 25 mg once daily was selected for further clinical development.”

Source: Pozniak AL, et al. AIDS. 2010;24:55-65.

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