Rilpivirine Dose-Ranging versus Efavirenz, with 2NRTIs

C204
### 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*

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

---

**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)

---

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

48 and 96 Week Data: Virologic Response (ITT)

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

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.”
Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.

The content in this presentation are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government.