ETV+ DRV/r + RAL in Treatment-Experienced Patients TRIO Trial



Etravirine + Darunavir/r + Raltegravir TRIO: Study Design

Study Design: TRIO

- Background: Phase 2, non-comparative trial assessing safety and efficacy of an antiretroviral regimen containing etravirine, darunavir boosted with ritonavir, and raltegravir in adults with HIV and multidrug-resistant virus
- Inclusion Criteria (n = 103)
 - Age ≥18 years
 - On stable ARV regimen for ≥8 weeks
 - HIV RNA >1000 copies/ml
 - Mutations allowed: ≥3 PI, ≥3 NRTI, ≤ 3NNRTI
 - Naïve to etravirine, darunavir, and raltegravir
- Treatment Arms
 - Etravirine 200 mg bid + Darunavir 600 mg BID +
 Ritonavir 100mg bid + Raltegravir 400 mg bid +
 optimized background regimen (OBR)

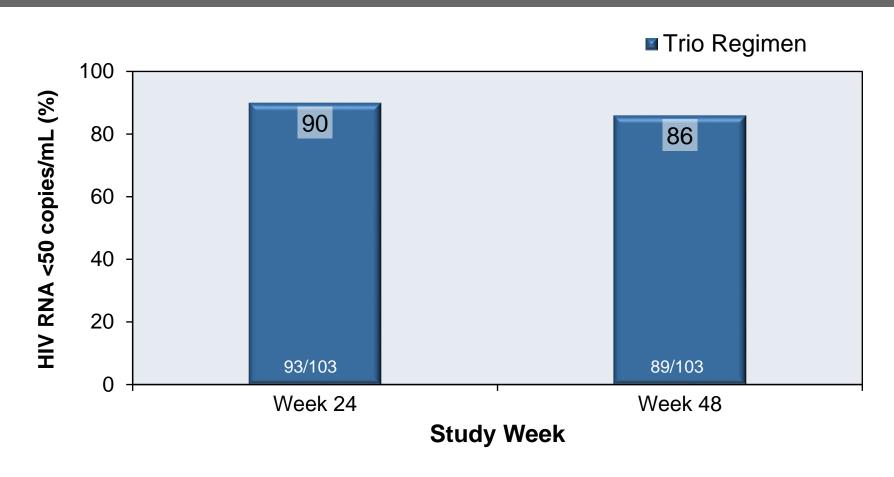
*OBT = NRTIs +/- Enfuvirtide

Trio Regimen
Etravirine +
Darunavir + Ritonavir +
Raltegravir
+ OBT
(n = 103)



Etravirine + Darunavir/r + Raltegravir TRIO: Result

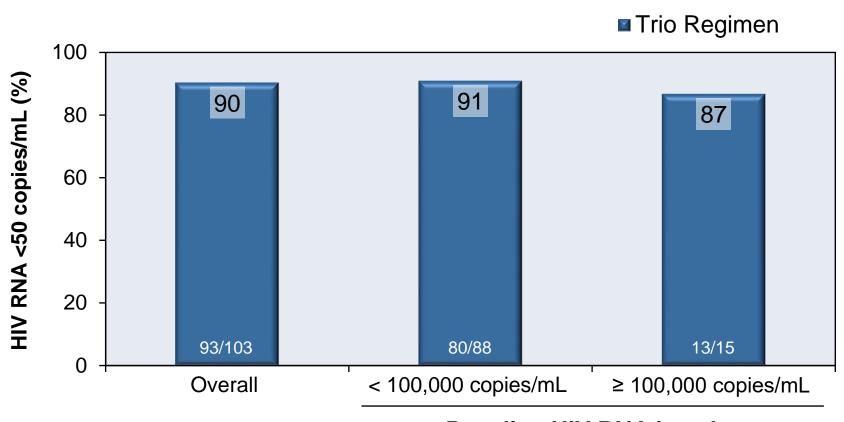
Week 24 and 48: Virologic Response (Intention-to-treat Analysis)





Etravirine + Darunavir/r + Raltegravir TRIO: Result

Week 24: Virologic Response (ITT Analysis), by Baseline HIV RNA



Baseline HIV RNA Level



Etravirine + Darunavir/r + Raltegravir TRIO: Conclusions

Conclusion: "In patients infected with multidrug-resistant virus who have few remaining treatment options, the combination of raltegravir, etravirine, and darunavir/ritonavir is well tolerated and is associated with a rate of virologic suppression similar to that expected in treatment-naive patients."



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