Raltegravir 1200 mg Once Daily versus 400 mg Twice Daily

ONCEEMRK Trial (unpublished)
### Study Design: ONCEMRK STUDY

**Background:** Randomized, double-blind, phase 3 trial in antiretroviral-naïve subjects to compare the efficacy of reformulated raltegravir 1200 mg once-daily with raltegravir 400 mg twice-daily, both in combination with tenofovir DF-emtricitabine.

**Inclusion Criteria (n = 797 received treatment)**
- Antiretroviral-naïve
*Incomplete information at this time – unpublished study*

**Treatment Arms**
- *Raltegravir 1200 mg QD + TDF-FTC*
- Raltegravir 400 mg BID + TDF-FTC

*The 1200 mg dose of raltegravir given as two 600 mg tablets

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**Source:** Cahn P, et al. 21st International AIDS Conference; July 18-22, 2016; Durban, South Africa. Abstract FRAB0103LB.
Raltegravir 1200 mg Once Daily versus 400 mg Twice Daily
ONCEMRK: Result

Week 48: Virologic Response (non-completer = failure)

Conclusions: “In HIV-1-infected treatment-naïve subjects receiving tenofovir/emtricitabine, reformulated RAL 1200mg QD demonstrated potent and non-inferior efficacy compared to RAL 400 mg BID at Week 48. RAL 1200 mg QD was safe and well tolerated with a safety profile similar to RAL 400 mg BID.”

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