Early Virological and Immunological Response is Comparable between Nevirapine and ATV-boosted Atazanavir: An ARTEN Sub-analysis

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Introduction
In the Phase IIIb ARTEN trial, nevirapine (NVP) was compared with atazanavir (ATV) in combination with tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) in 569 antiretroviral-naive adults with HIV-1 infection. The Phase IIIb ARTEN study included one arm with patients treated with a combination of NVP and ritonavir-boosted atazanavir (ATV) in combination with TDF and FTC. The primary objective was to evaluate the virologic efficacy and safety of NVP versus ATZ/r in a total of 569 ARV-naïve patients with HIV-1 infection. The ARTEN study included one arm with patients treated with NVP plus ritonavir-boosted atazanavir (ATV) compared to ATZ/r. The secondary objectives were to evaluate the immunologic and safety outcomes of NVP compared to ATZ/r.

Methods
- The Phase IIIb ARTEN study compared the efficacy and safety of NVP plus ritonavir-boosted atazanavir (ATV) with ATZ/r. The study was a randomized, double-blind, multicenter trial conducted in 85 centers in 29 countries. The study population included HIV-infected patients aged 18-65 years with HIV-1 RNA ≥10,000 copies/mL and CD4+ cell counts ≥200 cells/µL. The primary endpoint was the proportion of patients with HIV-1 RNA <50 copies/mL at 48 weeks of follow-up.
- The study was powered to detect a 15% difference in the proportion of patients with HIV-1 RNA <50 copies/mL at 48 weeks of follow-up between the NVP and ATZ/r arms. The study was designed with a non-inferiority margin of 10%.
- Follow-up visits were scheduled at 4, 8, 12, 24, 48 weeks, and every 24 weeks thereafter. Patients were required to have HIV-1 RNA ≤100 copies/mL or a ≥2-log decrease from baseline at weeks 48 or 96.

Results
- The primary analysis was the test of non-inferiority of the combined NVP arms compared to ATZ/r. The primary endpoint was the proportion of patients with HIV-1 RNA <50 copies/mL at 48 weeks of follow-up.
- The non-inferiority margin was set at 10%.
- The study was powered to detect a 15% difference in the proportion of patients with HIV-1 RNA <50 copies/mL at 48 weeks of follow-up between the NVP and ATZ/r arms.
- The study was designed with a non-inferiority margin of 10%.
- Follow-up visits were scheduled at 4, 8, 12, 24, 48 weeks, and every 24 weeks thereafter. Patients were required to have HIV-1 RNA ≤100 copies/mL or a ≥2-log decrease from baseline at weeks 48 or 96.

Conclusions
The primary endpoint was met with non-inferiority demonstrated by the ARTEN trial. The study results support the use of NVP plus ritonavir-boosted atazanavir (ATV) in combination with TDF and FTC as an alternative treatment option for antiretroviral-naive HIV-1 infected patients.

References