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Final Analysis of T1249-102: T-1249 Retains Potent Short Term Antiviral Activity in Patients who Have Failed a Regimen Containing Enfuvirtide (ENF)

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Background: T-1249 is active against most HIV isolates resistant to ENF in vitro. This study evaluated the safety and antiretroviral activity of T-1249 in patients (pts) failing a regimen containing ENF. Interim analysis of the first 25 patients has been previously presented. **Methods**: Pts were HIV-1 infected adults who, while participating in an ENF study, demonstrated plasma HIV RNA between 5,000 and 500,000 copies/ml (cpm). Pts replaced ENF with T-1249 at a dose of 192 mg/day SC for 10 days while continuing the background regimen. **Results**: Fifty-three pts received at least one dose of T-1249; median baseline (BL) HIV RNA was 4.97 $\log_{10}$ cpm. Median time on ENF since virological failure (viral load >5,000 cpm) prior to enrollment in T1249-102 was 66 wks (range 28-165). Fifty-two (98%) pts whose plasma virus could be amplified at BL demonstrated ENF-resistance mutations and/or decreased susceptibility to ENF; these pts constituted the ITT population. The median (95% CI) $\log_{10}$ HIV RNA change from BL at Day 11 was –1.26 (–1.40, –1.09). Thirty-eight (73%) pts had $\geq$ 1.0 $\log_{10}$ drop in HIV RNA at Day 11. There were no serious adverse events (AEs) judged possibly related to T-1249. Reactions at the injection site in most patients were mild and not treatment limiting. Most frequent AEs occurring at frequency of >2% included arthralgia (4%), diarrhea (4%), fatigue (4%), myalgia (4%), and pyrexia (4%). **Conclusions**: T-1249 demonstrates potent short-term suppression of plasma HIV RNA in most pts who harbor ENF resistant viruses. These results suggest that Fusion Inhibitors constitute a new class of antiretroviral agents with the potential to be sequenced.

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