**Tipranavir demonstrates superior and durable treatment response compared with comparator PI/r in highly treatment experienced patients: Week 96 RESIST 1 and 2 results**

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**Abstract**

**Background**: Tipranavir (TPV/r)-based regimens demonstrated substantial virological and immunological benefits among treatment-experienced patients in highly controlled, open-label, multicenter trials comparing tipranavir/ritonavir (TPV/r) with comparator regimens in treatment-experienced patients. In this study, we present Week 96 results for two placebo-controlled randomized studies (RESIST 1 and 2) of TPV/r versus comparator regimens in highly treatment-experienced patients.

**Methods**: TPV/r 500/200 mg BID was evaluated in a 2-arm randomized, placebo-controlled, double-blind, blinded endpoint study in HIV+ patients with 2 or more PI mutations. Patients were randomized 1:1 to receive TPV/r plus an optimized comparator regimen (CPI/r) or placebo plus an optimized comparator regimen (placebo plus CPI/r). At Week 24, patients in both arms could cross over to the active comparator arm. The primary endpoint was the percentage of patients achieving virological response by Week 48. Secondary endpoints included CD4 cell responses at Week 96 and safety. Week 96 data were analyzed using a last observation carried forward (LOCF) analysis.

**Results**: No statistically significant differences were observed between the arms in the primary endpoint. However, significantly more patients in the TPV/r arm achieved Week 96 virological response (90.9% vs. 70.0%, p=0.0002), median treatment-free time (115 vs. 0 days, p<0.0001), and median time to virologic failure (95 vs. 0 days, p<0.0001) compared to the CPI/r arm. Secondary endpoints showed a similar trend for Week 96 virological responses and durability of responses. In addition, median time to virologic response was superior in the TPV/r arm compared to the CPI/r arm (115 vs. 0 days, p<0.0001). There were no differences between the arms in the percentage of patients with CD4 cell count increases of at least 100 cells/mL at Week 96.

**Conclusions**: TPV/r demonstrated superior virological and immunological responses compared to CPI/r in highly treatment-experienced patients at Week 96. Median time to virologic failure was significantly longer in the TPV/r arm compared to the CPI/r arm. TPV/r plus CPI/r demonstrated a similar trend in secondary endpoints.