Health-related quality of life and tolerability in treatment-experienced HIV-1-infected patients on tipranavir versus comparator regimens

Supplementary material


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Health-related quality of life and tolerability of patients treated in RESIST

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Abstract

Purpose of the Study: To assess health-related quality of life (HRQOL) and tolerability in HIV patients on tipranavir boosted with ritonavir (TPV/r) vs. investigator-selected ritonavir-boosted comparator PI (CPI/r) regimens.

Methods: HRQOL data was assessed in 1,015 patients using combined data from two randomized, open-label, phase III trials (RESIST 1 and 2). Change in HRQOL was assessed at Week 48 in patients completing the MOS-HIV and analyzed using generalized estimating equations. The MOS-HIV includes Mental Health (MHS) and Physical Health Summary (PHS) and 10 subscale scores. At Week 48, 71% of TPV/r patients remained on treatment vs. 31% on CPI/r. Consequently, reported AEs were age-time-adjusted.

Summary of Results: Occurrence and severity of AEs were associated with lower MOS-HIV scores. Rates of AEs were higher in the CPI/r vs. TPV/r group (562.8 vs. 514.4 per 100 patient-exposure years [p<0.05]). Treatment-related AEs were more frequent in TPV/r vs. CPI/r patients (7.0 vs. 5.6% per 100 PFEY, respectively). TPV/r patients showed positive between group changes vs. CPI/r for the CPI/r vs. TPV/r group (562.8 vs. 514.4 per 100 patient-exposure years with lower MOS-HIV scores. Rates of AEs were higher in the CPI/r patients while rates of drug-related AEs were higher in TPV/r patients.

Conclusions: Despite a higher incidence of treatment-related AEs, HRQOL in TPV/r patients was stable or improved in comparison to treatment with CPI/r.

Background

• TPV/r (Apovirat®) is a novel non-peptidic protease inhibitor (PI) with potent in vitro activity against most HIV-1 strains resistant to currently available PIs. Results indicate that TPV/r is efficacious in PI-experienced patients.

• TPV/r was approved by the European Medicines Agency (EMEA) and US Food and Drug Administration (FDA) in 2005 for use in highly treatment experienced HIV-1-infected patients [1,2].

• Combined RESIST results showed that TPV/r has a safety profile similar to that of other ritonavir boosted PIs but it is more efficacious since patients on TPV/r were twice as likely to experience a treatment response (defined as confirmed 1 log10 copies/mL or better). Rates of any AE were higher in CPI/r patients while rates of drug-related AEs were higher in TPV/r patients.

• Between group differences for both summary and all subscale scores were significant in favor of CPI/r at Week 48 (Figure 2).

• Results were statistically significant for the MHS summary score (+1.4 points) and the energy/fatigue (+2.43 points), general health perceptions (+3.53 points), and mental health (+2.78 points) and overall QOL (+2.72 points) subscale scores (all p<0.005).

Conclusions

• Exposure adjusted AEs in patients included in the HRQOL analysis were similar in the TPV/r and CPI/r treatment arms. Rates of any AE were higher in CPI/r patients while rates of drug-related AEs were higher in TPV/r patients.

• As expected, when AEs were present, the patient’s HRQOL decreased. The impact on HRQOL was related to the severity of the AEs.

• Despite a higher incidence of treatment-related AEs, the overall HRQOL in TPV/r patients was stable or improved in comparison to the HRQOL of patients treated with CPI/r.

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References