Journal of the International AIDS Society

Poster presentation

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The Rainbow Cohort: saquinavir/r is effective and well tolerated in antiretroviral therapy (ART)-naïve patients – 48-week results from Germany

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from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):P13 doi:10.1186/1758-2652-11-S1-P13

This abstract is available from: http://www.jiasociety.org/content/11/S1/P13

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Purpose of the study

The aim of the Rainbow Cohort is to assess the tolerability and efficacy of initiating treatment with, or switching treatment to saquinavir (SQV) 500 mg film-coated tablet formulation. We present the final 48-week subgroup analysis of antiretroviral therapy (ART)-naïve patients.

Methods

Multicenter, prospective, open-label, observational cohort study. Tolerability assessments include changes in liver enzymes and lipid levels from baseline to week 48, efficacy assessments include changes in viral load (VL) and CD4 count.

Summary of results

48-week analysis of n = 275 ART-naïve patients. Baseline characteristics: 83% male, median age 39 years, median time since HIV diagnosis 1 year (IQR 0; 4), median baseline viral load (VL) 115,781 HIV-RNA cp/mL (IQR 35,375; 347,450), median CD4 count 200 cells/mm^3 (IQR 89; 297). Antiretroviral regimen included SQV/r plus tenofovir/emtricitabine, zidovudine/lamivudine or abacavir/lamivudine in 49%, 19% and 7% of patients, respectively.

In week 48, the proportion of patients achieving a VL <50 cp/mL was 75.3% (OT analysis) and 67.3% (ITT, LOCF analysis), respectively. Median increase in CD4 cell count was + 174 cells/mm^3 (IQR 86; 265). Median changes in triglycerides, total cholesterol, ALT, AST and γ-GT were +17 mg/dL (IQR -27; 71), +27 mg/dL (4; 55), -6 U/L (-26; 1), -1 U/L (-9; 6), -2 U/L (-25; 6), respectively. SQV treatment was stopped in 21% of the patients (3% due to side-effects, 1% due to virologic failure). See Figure 1.

Conclusion

These data confirm that SQV/r is effective and well tolerated in ART-naïve patients in the real-life clinical setting. The results of this observational cohort of treatment with the 500 mg tablet formulation of SQV are consistent with high efficacy and tolerability results seen in controlled studies with SQV/r.

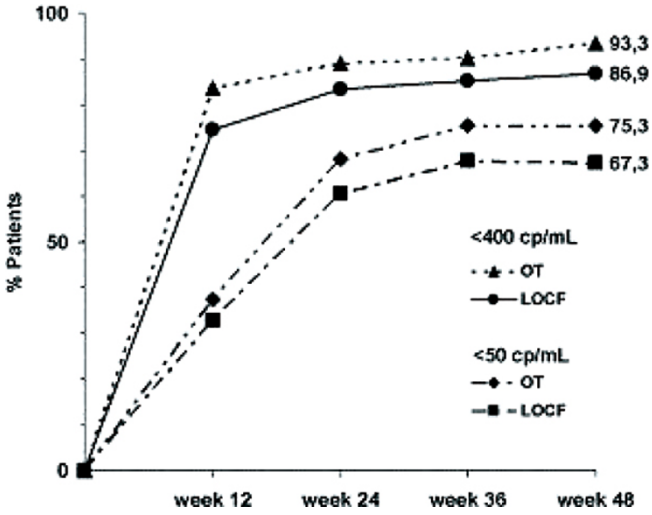

Figure 1
Proportion of patients below the detection limit during 48 weeks after start of a SQV/r containing antiretroviral therapy.

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