Journal of the International AIDS Society

Poster presentation

Open Access

Efficacy and safety of ritonavir-boosted fosamprenavir (FPV/r) in HIV-infected patients: 48-week results from an observational study

JF Hain*, S Eberle and RK Walli

Address: GlaxoSmithKline GmbH Co. KG, Munich, Germany
* Corresponding author

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):P86 doi:10.1186/1758-2652-11-S1-P86

This abstract is available from: http://www.jiasociety.org/content/11/S1/P86

Purpose of the study

To demonstrate the real-life efficacy and tolerability of FPV/r in HIV-infected patients without HAART or without prior virological treatment failure under a PI-containing ART regime.

Methods

Prospective single-arm observational study. Data were collected at enrolment visit and at approx. weeks 4, 12, 24, 36 and 48. Demographics, current laboratory findings, concomitant medication and conditions, and prior antiretroviral treatment were documented. Routine efficacy – viral load (VL) and CD4 cell count – and safety parameters were assessed.

Summary of results

In total 285 patients were included with a mean observation period of 312 days per patient. 74 patients (27%) were ART-naïve; 27% of the patients stopped the previous ART due to virologic failure, 46% of the patients due to drug intolerability. The majority of the patients were classified as well compliant (71.6% were graded 1 or 2 on a 6-point-scale at last visit). The median VL decreased in well-compliant patients from 5,900 copies/ml at entry to <50 copies/ml at week 12 with sustained suppression until last visit; in patients with poor compliance, the median VL decreased from 11,048 copies/ml at entry to <50 copies/ml at week 12. In parallel the CD4 T-cell count increased from a median of 297 cells/μl at entry to a median of 425 cells/μl at last visit (whole population). In 91.2% of the ART-naïve patients and in 70% of the patients without any virological failure in a previous ART the VL decreased <400 copies/ml at week 48.

Adverse drug reactions were reported in 100 patients (35.1%), predominantly diarrhoea (21.4%) and nausea (8.4%). Serious adverse drug reactions were observed in 11 patients. In 19% of the patients therapy with FPV/r was stopped, mostly due to drug intolerability.

Conclusion

Fosamprenavir/ritonavir demonstrated good efficacy and tolerability in ART-naïve patients as well as in HIV patients with any virological failure in a previous ART.