

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Fätkenheuer G, Nelson M, Lazzarin A, et al. Subgroup analyses of maraviroc in previously treated R5 HIV-1 infection. *N Engl J Med* 2008;359:1442-55.

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MOTIVATE 1

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All causality treatment-emergent adverse events in HIV/HBV and HIV/HCV co-infected patients in the MOTIVATE 1 and 2 clinical trials

Among patients co-infected with HBV or HCV in the MOTIVATE 1 and 2 studies the incidence of treatment-emergent adverse events (all causality) was similar across treatment groups and was not significantly different from those patients who were not co-infected.

- Adverse event profile in HIV/HCV co-infected patients
 - Taking in to account the small numbers and differences in group size (15 patients in the maraviroc once daily group, 29 in the maraviroc twice daily group and 20 in the placebo group), the total numbers of adverse events reported (80, 126 and 104 for the maraviroc once daily, maraviroc twice daily and placebo groups, respectively) were similar across treatment groups (data not corrected for exposure). There were 8 Grade 3 or 4 adverse events reported in the maraviroc once daily group, 26 in the maraviroc twice daily group and 12 in the placebo group. Given the small number of patients, no conclusion can be made regarding the incidence of particular adverse event terms.
 - Hepatobiliary disorders of any grade were rare and only reported in the maraviroc twice daily group in 4/29 patients. Severity ranged from Grade 1 (hepatosplenomegaly) to Grade 4 (hepatic failure).
- Adverse event profile in HIV/HBV co-infected patients
 - Taking in to account the small numbers and differences in group size (22 patients in the maraviroc once daily group, 28 in the maraviroc twice daily group and 17 in the placebo group) the total numbers of adverse events reported (92, 173 and 86 for the maraviroc once daily, maraviroc twice daily and placebo groups, respectively) were similar across treatment groups (data not corrected for duration of exposure). There were 11 Grade 3 or 4 adverse events reported in the maraviroc once daily group, 25 in the maraviroc twice daily group and 11 in the placebo group. Given the small number of patients, no conclusion can be made regarding the incidence of particular adverse event terms.
 - Hepatobiliary disorders of any grade were rare. Cytolytic hepatitis was recorded for one HBV/HIV co-infected patient in the placebo group. No hepatobiliary adverse events were recorded for HBV/HIV co-infected patients in the maraviroc groups.