



## Nelfinavir-containing regimen in treatment-naïve HIV-1 patients (pts): comparison of efficacy in B versus non-B subtypes

S De Wit<sup>1</sup>, R Boulmé<sup>2</sup>, B Poll<sup>1</sup>, N Clumeck<sup>1</sup>, J C Schmit<sup>2</sup>, O Van Der Meeren<sup>3</sup>

1 Saint-Pierre University Hospital, Brussels, Belgium, 2 ABL, Advanced Biological Laboratories and CRP-Santé, Luxembourg, 3 Roche Belgium, Belgium

Studies have shown that mutation profile induced by nelfinavir (NFV) could be different in B vs non-B subtypes. We compared the response to NFV containing HAART in B vs non-B HIV-1 naïve pts as measured by the proportion of pts with viral load (VL) < 50 copies/mL and median change from baseline (BL) CD4 cell count at month (m) 12. RT and PR sequencing was done by ABI HIV ViroSeq<sup>®</sup> and viral subtype characterisation by ABL i-Subtyping and HIV-SEQ Stanford University and NCBI for control and validation. Chi-square, Wilcoxon and Fisher's exact tests were used for univariate analyses. All pts (n=104) who started first-line therapy between 3/98 and 7/01 with 2 NRTIs and NFV were retrieved from our database and divided in 2 groups: B (26pts) ; non-B (78pts), including sub-types A(10pts), C(18pts), D(2pts), G(4pts), H(1pt), J(1pt), recombinant forms (AE 5pts, AG 10pts) and mosaics of several types (27pts). Most B pts. were caucasians (96%) homosexual (81%) males (85%) whereas most non-B pts. were Africans (83%) heterosexual (96%) females (60%). BL VL and CD4 were respectively 5.0 vs 4.7 log<sub>10</sub>(p<.04) and 277 vs 240 cells/mm<sup>3</sup>(ns). Mean time on NFV was 293 and 309 days ; 8 (31%) vs 15 (15%) discontinued NFV during the follow-up period. No difference in the proportion of pts with VL< 50 c/mL was observed at m.12 in B vs non-B groups (58% vs 62% ITT-missing=failure; 56% vs 59% OT). A trend toward significance was observed at m.12 in median (md) change in CD4 from BL (+268 vs +165 cells/mm<sup>3</sup>, p<.07 Wilcoxon). From a multivariate regression analysis, sub-type B vs non-B was the only factor associated with the CD4 response. This trend was stronger when comparing B vs A (and AE + AG recombinants): at m.12, md change from BL VL was -2.80 vs -2.43 log<sub>10</sub> -(p<.06) and from BL CD4 +268 vs +116 cells/mm<sup>3</sup> - (p<.0525, Wilcoxon). The HIV population starting therapy in Belgium shows a high heterogeneity of HIV sub-types including a significant number of pts infected with mosaics of several sub-types. No difference in VL response at m.12 to a NFV-containing regimen was found between B and non-B HIV-1 sub-types. A trend to lower CD4 increase at m.12 was observed in non-B patients, particularly when comparing B vs A sub-types. Further analyses are underway to confirm these findings and to establish whether differences in resistance mutations pattern could be involved.

## Abstracts