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P024 - Safety and antiviral effect of Elpida (VM-1500), a novel NNRTI (+Truvada) in treatment-naïve HIV-1 infected patients at 24-48 weeks therapy

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Background: In treatment-naïve patients, Elpida 20 and 40 mg QD (with TDF/FTC) at week 12 demonstrated potent antiviral activity, comparable to EFV, and favorable safety/tolerability profile. Elpida 20 mg QD was selected for study.
Objective: To evaluate safety and antiviral effect for treatment regimens with Elpida+TDF/FTC in comparison with EFV+TDF/FTC in treatment-naïve HIV-1 infected patients.
Methodology: A randomized, placebo-controlled, double-blind study in patients with HIV infection who are antiretroviral therapy-naïve with median of HIV-1 RNA 4.7–4.8 log10 copies/mL and CD4-lymphocytes - 349–379 cells/mm^3. A total of 120 patients were randomized to Elpida (20 mg, group 1) or EFV (600 mg, group 2) with 1:1 ratio. All patients received TDF/FTC. Hundred percent of patients completed 24 weeks of treatment and 50% - 48 weeks.
Results: After 24 weeks of treatment, the fraction of patients with <50 HIV-1 RNA copies/mL in 1st gr. was 84.5% and 2nd gr. 66.7% (p=0.031, MTTI-analysis). At 48 weeks therapy - 93.3% and 83.5%, respectively. The median CD4-lymphocytes increased from 379 cells/mm^3 to 486 cells/mm^3 (gr.1), from 349 cells/mm^3 to 491 cells/mm^3 (gr.2) at 24 weeks treatment and to 549 cells/mm^3 (gr.1) and to 510 cells/mm^3 (gr.2) at 48 weeks. AEs (grade 1–4) were observed in 78.3% and 86.2% of patients from cohorts 1 and 2, respectively, including drug-related AEs (36.7% and 77.6%, respectively). For the CNS AEs, those numbers were 30% and 62.1% (p<0.001), including grade 3–4 AEs - 1.7% and 8.6%, respectively.
Conclusions: In treatment-naïve patients, Elpida 20 mg QD (with TDF/FTC) at 24–48 weeks demonstrated potent antiviral activity, comparable to EFV+TDF/FTC, and favorable safety/tolerability profile. Fewer drug-related AEs were observed for Elpida compared with EFV. The study will be completed at November 2016.

Abstract Category: Treatment Strategies: New Treatments and Targets