Background:

ELPIDA / Elsulfavirine (VM15009) is the produg of VM1500A, a novel potent non-nucleoside reverse transcriptase inhibitor with a favorable viral resistance profile and unique pharmacokinetic properties (T1/2 = 9 days). A 20 mg once daily dosing was chosen for further study based on 12-week efficacy, pharmacology and safety data; 48-week data comparing ELPIDA 20 mg to Emtricitabine/Tenofovir (FTC/TDF) has been reported effective and safe.

The objective of this study was to assess the efficacy and safety of an ART regimen including ELPIDA 20 mg plus two NRTIs during 96 weeks.

Methods:

In the parent randomized, double-blind, multicenter study, ART-naive HIV-1-infected patients, treated initially for 48 weeks with ELPIDA plus TDF/FTC, continued the study treatment for up to 96 weeks. During this period, they received ELPIDA 20 mg and various two NRTI regimens: TDF/FTC (35% of patients), ABC/3TC (21%), TDF+3TC (19%), ZDV+3TC (25%).

Results:

After initial 48 weeks of treatment, 81% of patients on ELPIDA® 20 mg and 73.7% patients on Emtricitabine had VL < 50 c/mL (MTI). A total of 81 out of 87 (93%) patients treated with ELPIDA® in the main study, continued in the follow-up study for additional 48 weeks.

A total of 73 out of 87 (84%) patients had VL < 50 c/mL and 79/87 (91%) had < 400 c/mL at week 96. Three patients receiving ELPIDA® had VL >1000 c/mL during the study, presumably due to poor compliance; none had NRTI resistance mutations.

No new significant AE, related to ELPIDA®, were registered during and after 48 weeks of treatment. New AE registered in the study were mainly related to changes of two NRTI regimen, including 2/89 (2.2%) patients with Grade 3 events (i.e. decreased appetite, irritability, dyspnea and rash). No drug-related SAE were reported.

Total exposure to ELPIDA® was 151.7 patient-years.

Conclusions:

This study demonstrated that ELPIDA® was safe and well tolerated up to 96 weeks, with continued virologic efficacy, immunologic improvement and favorable resistance profile. ELPIDA®-based therapy is a safe and effective long-term strategy offering multiple potential advantages over current therapies.