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Efficacy and Safety of Switching HIV-1 Infected Subjects from a Protease Inhibitor to an Efavirenz-Based Regimen: VEST-QD Week 24 Interim Results

C. COHEN[1], S. SCHNEIDER [2], R. DRETLER [3], S. GREEN [4], D. WRIGHT [5], N. BELLOS [6], M. MCMANUS [7], G. THAL [7], J. MAA [7], K. PORTER [7];

[1]Community Research Initiative, Boston, MA, [2]St. Mary's Med. CARE Clin., Long Beach, CA, [3]ID Specialists of Atlanta, Decatur, GA, [4]Hampton Roads Med. Specialists, Hampton, VA, [5]Central Texas Clin. Res., Austin, TX, [6]Southwest ID Associates, Dallas, TX, [7]Bristol-Myers Squibb, Plainsboro, NJ.

Background: Previous studies have demonstrated that switching from a PI to an NNRTI maintains viral suppression and may increase adherence and quality of life. **Methods:** 48-Week, open-label, randomized, ongoing, multicenter study in 300 HIV-1 infected subjects who are virologically suppressed on an initial PI-based regimen. All subjects are switched off their PI to an EFV-based regimen. Arm A switched their NRTIs to 3TC+ddI EC (QD regimen) and Arm B continued their current NRTIs (any dosing frequency). A planned interim analysis in the first ~150 subjects at Week 24 includes evaluations of efficacy and safety. **Results:** 186 subjects (92 Arm A, 94 Arm B, 87% men, mean CD4 602 cells/mm^3) are included in this analysis. The NRTIs used in Arm B were: AZT+3TC (51%), d4T + 3TC (30%), ABC +3TC (4%), other (15%). Efficacy (ITT:NC=F) and patient disposition are shown below:
[Table1]
Grade 2-4 treatment related adverse events that occurred in ≥ 2% of subjects were dizziness (4.3%) and abnormal dreams (2.2%). A total of 2 serious adverse events (both neuropsychiatric symptoms), in a single subject, were reported as treatment related. **Conclusions:** In virologically suppressed patients, a switch from a PI-based to an EFV-based regimen, including a once daily regimen containing ddI EC + 3TC, appears safe and efficacious with a low incidence of virologic failure through Week 24.

Week 24 Results	Arm A n=92	Arm B n=94	p-value (b/n groups)
<400 c/mL, n (%)	80(87.0)	81(86.2)	0.875
<50 c/mL, n (%)	76(82.6)	78(83.0)	0.947
Mean CD4 cells/mm^3	609.8	602.8	0.252
Reasons for discontinuation, n:			
Adverse event	3	2	
Protocol violation	0	1	
Withdrew consent	2	3	
Virologic failure or disease progression	0	1	
Other	0	2	

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