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Raltegravir clinical efficacy against B subtype and non-B subtype HIV-1 is similar

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Purpose of the study

Raltegravir (RAL) is the first approved HIV integrase inhibitor and has demonstrated potent efficacy in both treatment-experienced and -naïve HIV-infected patients (pts). This analysis reports long-term efficacy data from one Phase II and two Phase III studies in pts infected with non-B subtype virus.

Methods

Each study was double-blind and randomized; all pts received a background ART regimen (see table in Figure 1). Primary results have been presented for each study. Protocol (P) 004 in treatment-naïve pts was a dose-ranging study of RAL vs. efavirenz (EFV) until week 48 after which all pts in RAL groups received 400 mg BID. BENCHMRK-1 and -2 were identical Phase III studies using RAL at 400 mg BID vs. placebo (PBO) in highly treatment-experienced pts with multi-drug resistant virus failing other therapies. Each of the three studies showed potent clinical efficacy for RAL-treated pts. In this analysis, P004 results are shown for all RAL dose groups combined at week 96, and BENCHMRK-1 and -2 results are shown combined at week 48. Non-B subtypes were combined for the analyses due to small numbers of each specific non-B subtype.

Summary of results

In total, 622 pts were randomized to RAL and 275 to comparator across the three studies. Non-B subtype virus was isolated at baseline in 62 pts in the RAL groups (23 from P004), and in 23 pts in the comparator groups (8 from P004). Subtypes AE and D were most common, isolated in 40 and eight pts, respectively. Data are available for 58/62 and 22/23 of pts with non-B subtype virus using the observed failure approach for % with RNA < 50 copies/mL (see table in Figure 1). RAL-treated pts demonstrated increases from baseline in CD4 of 216 and 250 cells/mm^3 for B and non-B, respectively, at week 96 in P004, and of 105 and 150 cells/mm^3, for B and non-B, respectively, at week 48 in BENCHMRK-1 and -2.

Conclusion

In these studies, RAL showed similar and potent clinical efficacy in patients with B subtype and non-B subtype HIV in both treatment-naïve and treatment-experienced populations.

		P004#		BENCHMRK-1 & -2*	
		At Week 96		At Week 48	
Subtype		RAL	EFV	RAL	PBO
B	% (n/N)	91 (111/122)	92 (24/26)	64 (256/399)	34 (71/211)
Non-B†	% (n/N)	100 (22/22)	88 (7/8)	67 (24/36)	36 (5/14)
Background regimen: #Tenofovir + 3TC; * Optimized background therapy †including Subtypes AE, D, A, A1, A/D, AG, B/G, BF, C, D, D/F, F, F1, G, and Complex					

Figure 1
Percent of pts with HIV RNA <50 copies/ml.