

POSTER PRESENTATION

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Analysis of BENCHMRK 1 & 2 using PhenoSense[®] assay for darunavir (DRV/r) resistance and exploration of functional monotherapy with RAL vs DRV

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Purpose of the study

Previous analyses of the 2 BENCHMRK studies of raltegravir (RAL) vs placebo (Pbo) plus optimized background therapy (OBT) in treatment-experienced HIV-infected patients (pts) by PSS as contributed by OBT used assumptions of susceptibility to DRV/r based on prior use, since commercial phenotyping was not available. Re-analysis is now performed using newly available DRV/r phenotype data.

Methods

In BENCHMRK pts who used DRV/r in OBT, baseline PSS was recalculated using the DRV/r PhenoSense[®] result (Monogram Bioscience). A new analysis by PSS score of RNA <50c/mL for wk 48 and wk 156 was performed using the upper clinical cutoff (UC) of OBTs, including DRV/r. An exploratory analysis compared

outcomes for pts whose only fully active ART was RAL or DRV/r.

Results

184 pts in the RAL group and 99 in Pbo group used DRV/r in OBT at study entry; of these 166 and 90 pts, respectively, had no prior use of DRV/r and were previously considered DRV/r susceptible. 165 pts in the RAL group and 91 in Pbo group had baseline DRV/r PhenoSense results: 7% and 7% of pts previously assumed susceptible to DRV/r showed phenotypic resistance; 17% and 44% assumed resistant to DRV/r were found to be susceptible.

Overall results at wk 48 were 64% vs 34% with RNA <50c/mL for RAL vs Pbo. Wk 48 virologic outcomes by PSS score are shown in table 1. Wk 156 outcomes by PSS were consistent (not shown). In the

Table 1

Efficacy at week 48, RNA<50 copies/mL %, (n/N)				
Initial approach (DRV/r phenotype assumed)		New analysis (DRV/r phenotype data)		
PSS	RAL	Placebo	RAL	Placebo
0	51 (17/33)	8 (1/12)	52 (16/31)	8 (1/13)
1	48 (34/71)	13 (7/54)	45 (34/79)	15 (8/55)
2	67 (107/160)	30 (26/88)	69 (102/148)	29 (24/83)
≥3	73 (112/153)	60 (39/65)	72 (113/156)	59 (38/64)

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exploratory analysis comparing functional monotherapy with RAL (PSS=0) vs DRV/r (Pbo, PSS=1) at wk 48: 52% vs 30% of pts had vRNA <50 c/mL. Wk 156 results (not shown) were consistent with wk 48.

Conclusions

In BENCHMRK, prior use of DRV predicted DRV susceptibility similarly to the UC phenotypic criteria. Re-analysis of virologic responses by PSS score incorporating the UC PhenoSense result for DRV/r demonstrated consistent treatment differences between RAL and Pbo groups for all PSS scores, generally similar to the earlier analyses. In an exploratory analysis approximating a direct comparison of RAL vs DRV/r as sole active agents, virologic responses using UC appeared higher for RAL than DRV at both time points, although numbers of pts receiving DRV monotherapy were small.

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