

Patient-Reported Outcomes in Rare Kidney Disease Clinical Trials: Sparsentan Versus Irbesartan

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CONCLUSIONS

Although KDQOL-36 scales did not discriminate between treatment group differences in most cases, the common impact of treatment on burden of kidney disease scores provides some evidence of the sensitivity of this component of the KDQOL-36 in these rare kidney diseases

With preservation of HRQOL as a recognized therapeutic goal in chronic kidney disease, the overall stable results observed with both studies are reassuring

ABBREVIATIONS
ESKD, end-stage kidney disease; FSGS, focal segmental glomerulosclerosis; HRQOL, health-related quality of life; IgAN, immunoglobulin A nephropathy; IRB, irbesartan; KDQOL-36, Kidney Disease Quality of Life-36; LS, least squares; MMRM, mixed model for repeated measures; PRO, patient-reported outcome; QOL, quality of life; SPAR, sparsentan.

DISCLOSURES
KH is an employee and stockholder of Travere Therapeutics, Inc.

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RESULTS

- In PROTECT, baseline KDQOL-36 scores were similar for SPAR and IRB except for Burden of Kidney Disease scores, which were somewhat higher for IRB (Table 1)
- In DUPLEX, baseline KDQOL-36 scores were similar for SPAR and IRB (Table 2)

Table 1. PROTECT: Baseline KDQOL-36 Scores

Subscale, mean (SD)	SPAR (n=188)	IRB (n=183)
Physical Component Summary	51.1 (8.08)	51.7 (7.02)
Mental Component Summary	50.4 (8.30)	51.4 (8.63)
Bodily Pain	52.5 (8.06)	53.8 (6.67)
Burden of Kidney Disease*	70.1 (25.25)	76.9 (22.80)
Symptoms/Problems of Kidney Disease*	88.8 (11.22)	89.2 (11.02)
Effects of Kidney Disease*	88.4 (13.12)	89.0 (12.96)
Summary Score*	85.4 (11.74)	87.0 (11.49)

*SPAR (n=187); IRB (n=182).

Table 2. DUPLEX: Baseline KDQOL-36 Scores

Subscale, mean (SD)	SPAR (n=148)	IRB (n=158)
Physical Component Summary	44.8 (10.38)	46.4 (10.09)
Mental Component Summary	49.8 (8.38)	48.5 (10.12)
Bodily Pain	47.9 (10.81)	49.3 (10.32)
Burden of Kidney Disease	61.5 (25.85)	64.3 (27.74)
Symptoms/Problems of Kidney Disease	82.8 (16.05)	82.9 (16.51)
Effects of Kidney Disease	80.1 (20.34)	82.3 (18.93)
Summary Score	78.5 (16.54)	79.7 (15.66)

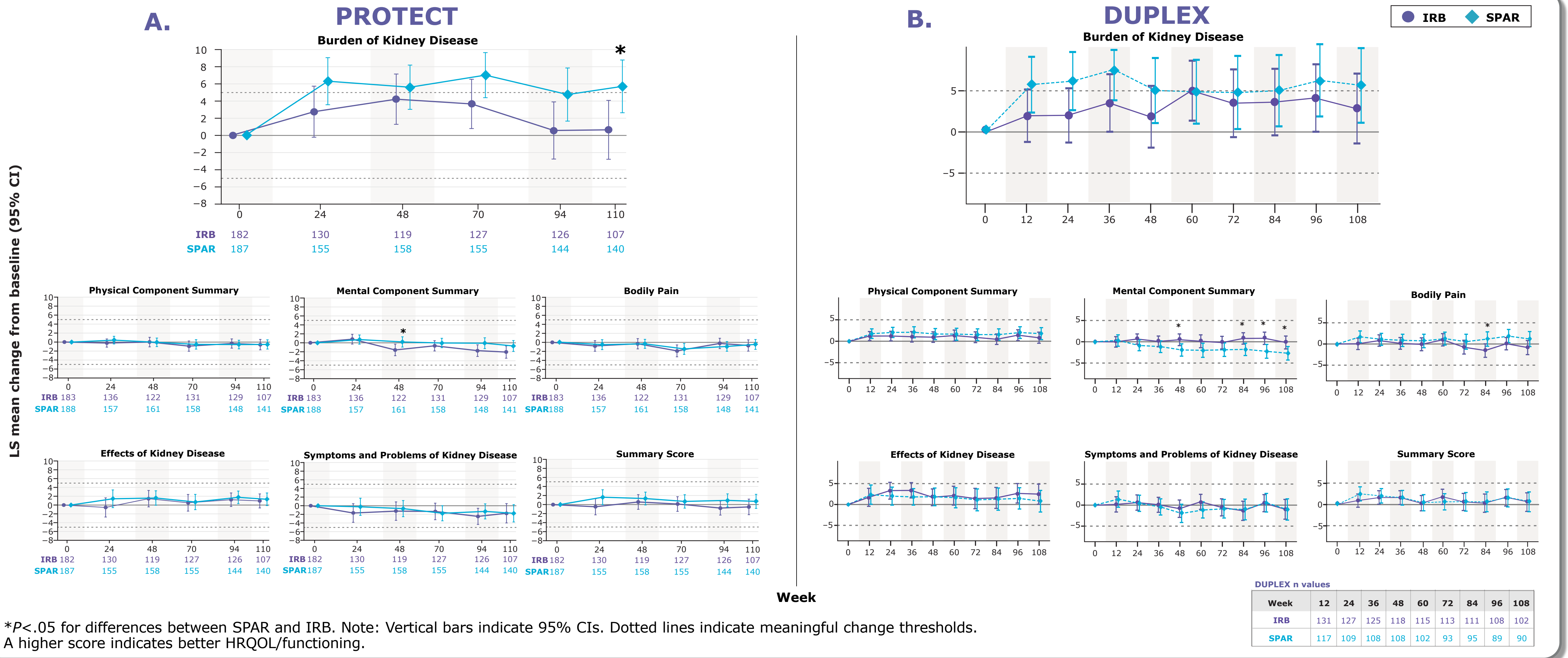
- Sparsentan (SPAR) demonstrated a greater sustained antiproteinuric effect compared with maximally dosed irbesartan (IRB) in patients with immunoglobulin A nephropathy (IgAN) in PROTECT (NCT03762850) and focal segmental glomerulosclerosis (FSGS) in DUPLEX (NCT03493685)^{1,2}

OBJECTIVE

- To evaluate the effect of SPAR compared with IRB on PROs in adults with IgAN (PROTECT) and FSGS (DUPLEX) (double-blind periods of each trial)

- In PROTECT, SPAR exhibited consistent within-group improvements in Burden of Kidney Disease scores at all follow-up visits with a week 110 between-group difference (SPAR-IRB) of 5.1 (P=.0316) and directional within-group improvement or stability for SPAR in other KDQOL-36 scores (Figure 1A)
- In DUPLEX, within-group improvements were observed in Burden of Kidney Disease scores in both SPAR and IRB groups, with a clinically meaningful within-group change observed for 8 of 10 time points through week 108 for SPAR, but only at week 60 for IRB; however, no clinically meaningful between-group differences were observed (Figure 1B)
- Overall, based on KDQOL-36 data, there was no detrimental impact for patients in either trial

Figure 1. LS Mean Changes From Baseline in KDQOL-36 Scores By Treatment and Visit



*P<.05 for differences between SPAR and IRB. Note: Vertical bars indicate 95% CIs. Dotted lines indicate meaningful change thresholds. A higher score indicates better HRQOL/functioning.

BACKGROUND

METHODS

- In both trials, the KDQOL-36 PRO instrument was chosen to measure more general physical and mental components of HRQOL and more specific Symptoms and Problems of Kidney Disease, Effects of Kidney Disease, and Burden of Kidney Disease domains (range, 0 to 100, with higher scores representing better QOL)^{3,4}
- The KDQOL-36 was administered at baseline and each visit of the double-blind treatment period of both trials
- Score changes from baseline were analyzed using LS means from MMRMs with a score change of 5 considered clinically meaningful⁵⁻⁷

LIMITATIONS

- PROTECT and DUPLEX were not powered to evaluate treatment differences in PROs
- Although Burden of Kidney Disease scores may be sensitive to HRQOL changes in rare kidney diseases because this scale covers the impacts of kidney disease generally, other KDQOL-36 scales (which are more tailored to individuals with ESKD) may not be sensitive enough to detect all the differences associated with the between-treatment-arm differences in clinical parameters observed in both studies