Abstract: [HI-OR05] AURA-LV: Successful Treatment of Active Lupus Nephritis with Voclosporin

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Background: In lupus nephritis (LN), complete (CR) or partial remission (PR) is associated with improved renal survival. Voclosporin (VCS) is a novel CNi with improved safety and predictable PK-PD profile. **Methods:** The trial primary objective was CR defined as a urine protein/creatinine ratio (UPCR) of ≤0.5 mg/mg using first morning void with an eGFR ≥ 60 mL/min without a decrease of ≥20%. Entry criteria:renal biopsy within 6 months (Class III-V LN, ISN/RPS); UPCR>1.5 (III-IV) or 2.0 mg/mg (V);serologic evidence of active LN; and eGFR >45ml/min. Low (23.7 mg BID) or high dose VCS (39.5 mg BID) was administered with MMF and steroids. **Results:** 265 patients were enrolled. Baseline UPCR (mg/mg) was 4.4 (placebo), 5.2 (low dose VCS) and 4.5 (high dose VCS). 24 week CR: **19.3%** (placebo), **32.6%** (low dose) and **27.3%** (high dose) (OR: 2.03, p=0.045 low dose vs. placebo). The results were confirmed by 24 hour urine collections (p=.047). Both the low and high dose VCS were statistically superior to placebo in PR and time to CR and PR. In the VCS groups, eGFR fell by a median of 8-9 ml/min by week 4 and then stabilized. Mean blood pressure between groups was similar. Over 90% of subjects experienced at least one adverse event with the most common being infectious and GI events. More patients experienced serious adverse events in both voclosporin groups (25.8% low, 25.0% high, 15.8% placebo) with the nature of SAEs consistent with those observed in patients with highly active LN. There were 13 deaths (1 placebo, 10 low, 2 high) with 11/13 in Asia. Causes were multi-factorial including sepsis and other lupus-related complications. None were considered related to VCS by investigators. **Conclusions:** The AURA study is the first global study to demonstrate the positive effects of VCS in the treatment of active LN. Adverse events were higher in the treated patient group, consistent with increased immunosuppression. There was a higher mortality rate in the low-dose group with heterogenous causation. These favorable data will help plan subsequent studies of voclosporin in LN.
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