Key efficacy results of lifitegrast ophthalmic solution 5.0% across 12-week multicenter randomized controlled trials (ITT population with LOCF)

Study	Symptom endpoint	Sign endpoint
Phase 2	• Visual-related function subscale (secondary, change from baseline to day 84): TE 0.37, nominal *P*=0.0394.	• Primary endpoint of ICSS at day 84 not met. • ICSS (secondary, change from baseline to day 84): TE 0.35, nominal *P*=0.0209.
OPUS-1	• Coprimary endpoint of change from baseline to day 84 on visual-related function subscale not met.	• ICSS (co-primary, change from baseline to day 84): TE 0.24, *P*=0.0007.
OPUS-2	• EDS (VAS; co-primary, change from baseline to day 84): TE 12.61, *P*<0.0001.	• Coprimary endpoint of change from baseline to day 84 in ICSS not met.
OPUS-3	• EDS (VAS; primary, change from baseline to day 84): TE 7.16, *P*=0.0007.	• ICSS (ad hoc, change from baseline to day 84): TE 0.17, nominal *P*=0.0144.

Eye dryness score (EDS; visual analogue scale [VAS]); ICSS, inferior corneal staining score; ITT, intention-to-treat; LOCF, last observation carried forward; TE, treatment effect.

P=0.0007), and OPUS-3 (ad hoc; 0.17, nominal *P*=0.0144). LIF reduced EDS (VAS) versus PBO in OPUS-2 (co-primary; 12.61, *P*<0.0001) and OPUS-3 (primary; 7.16, *P*=0.0007). The OPUS-1 co-primary symptom endpoint of visual-related function subscale, and the OPUS-2 co-primary sign endpoint of ICSS, did not achieve statistical significance. In the pooled safety analysis, total exposure was 415.65 person-years for LIF, and 332.15 person-years for PBO. Adverse events were mostly mild or moderate in severity. There were no serious ocular treatment-emergent adverse events (TEAEs) and withdrawals due to TEAEs were infrequent (LIF, 7.0%; PBO, 2.6%).

Conclusions: LIF improved signs and symptoms of DED in adults with DED and appeared to be well tolerated with no serious ocular TEAEs reported.

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LB0002 48 WEEK COMPLETE REMISSION OF ACTIVE LUPUS NEPHRITIS WITH VOCLOSPORIN

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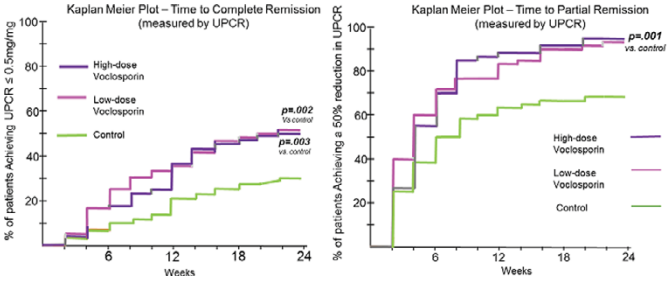
Background: Voclosporin (VCS) is a novel CNI intended for use in the treatment of autoimmune diseases such as lupus nephritis (LN). VCS's unique structure allows for less pharmacokinetic-pharmacodynamic variability and a potentially improved safety profile compared to other CNIs.

Objectives: Achievement of complete remission (CR) as assessed at week 24 (primary objective) and assessment of the efficacy over 48 weeks (secondary objective), with 2 doses of VCS (low dose VCS: 23.7mg BID and high dose VCS: 39.5mg BID) vs. placebo in subjects with active LN.

Methods: The double blind placebo controlled AURA study enrolled 265 subjects with active LN in 20 countries. Patients were randomized into 3 arms (placebo, low dose VCS or high dose VCS) in addition to MMF 2g/day and steroids (with rapid tapering). CR was defined as a confirmed urine protein/creatinine ratio (UPCR) of ≤0.5 mg/mg using first morning void and confirmed estimated glomerular filtration rate (eGFR, CKD-EPI equation) ≥60 mL/min/1.73 m^2 or no decrease from baseline in eGFR of ≥20% in the presence of low dose steroids. Partial remission (PR) was defined as a 50% reduction in UPCR. UPCR assessments were made at each visit, together with biomarker data at regular intervals.

Results: We now present the 48 week data showing improved CR rates over the 24 week data. The rate of CR was significantly higher in the low dose VCS compared to the control group (32.6% vs. 19.3%; OR: 2.03, p=0.045) at 24 weeks. It was 27.3% in the high dose VCS group (p=NS). Both doses of voclosporin demonstrated superiority to control using time to CR, PR (50% reduction in proteinuria) and time to PR.

At 48 weeks, 23.9% of patients on the control arm achieved CR comparted to 49.4% low dose (OR: 3.21, p<0.001) and 39.8% high dose (OR: 2.10, p<0.026). Over 92% of subjects experienced at least one adverse event (AE) with the most common two being infections (58% low, 66% high and 55% placebo) and GI disorders (43% low, 52% high and 38% placebo). The overall rate of serious adverse events (SAEs) was numerically higher in both voclosporin groups (28% low, 25% high, 19% placebo) with the nature of SAEs consistent with those observed in patients with highly active LN. Most deaths occurred in the first 2 months and were: low dose (infection3, ARDS2, thrombotic3, cardiac tamponade, pulmonary hemorrhage), high dose (infection, PE) and control (CVA). All were considered unrelated to drug exposure by the investigators. 3 additional deaths occurred in placebo patients after the conclusion of the 48 weeks of treatment.



Conclusions: The AURA-LV study is the first global study demonstrating the beneficial effect of VCS, in combination with MMF and steroids, in the treatment of LN. Remission rate was rapid. VCS treatment resulted in increasing CR and PR seen by week 6 despite rigorous steroid taper (mean steroid dose 4 mg at week 16). Adverse events were higher in the treated patient group with the nature in keeping with immunosuppression. These promising data will be used to plan subsequent studies of voclosporin in LN.

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Axial spondyloarthritis from risk factor to clinical outcomes

OP0238 MEASUREMENT OF SPINAL MOBILITY IN AXIAL SPONDYLOARTHRITIS USING INERTIAL SENSORS: RELIABILITY AND VALIDATION PRELIMINARY RESULTS

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Background: Axial spondyloarthritis (axSpA) is a chronic rheumatic disease that causes reduction of mobility in the patients' spine. There are several indices to analyze this mobility: BASMI, which lacks precision and sensitivity to change according to different authors, and UCOASMI (1) based on motion capture, which needs extensive resources that limit its practical applicability. Inertial measurement unit sensors (IMU) give, in real time, the 3D orientation of any anatomical place