Background

- Voclosporin is a novel calcium inhibitor (CNI) recently approved in the US for the treatment of adults with lupus nephritis.
- As a CNI, voclosporin has two complementary mechanisms of action pertinent to the treatment of lupus nephritis: inhibition of calcineurin 1) reduces activation of T-cells, and 2) stabilizes podocytes, reducing proteinuria.
- Voclosporin has a consistent dose-concentration relationship, eliminating the need for therapeutic drug monitoring.
- Compared to other CNIs, voclosporin has an improved lipid profile and no drug-drug interaction with mycophenolate mofetil (MMF).
- In clinical trials, compared to MMF and low-dose steroids alone, the addition of oral voclosporin 23.7 mg BD increased complete renal response (CR) by ≥26% in Phase 2 AURA-UV (OR 3.21, p<0.001) and 18% in Phase 3 AURORA 1 (OR 2.65, p<0.001) at one-year of treatment.

Methods

- AURORA 2 is an ongoing, global, multi-center, double-blind, two-year Phase 3 extension study of AURORA 1, evaluating efficacy and safety of voclosporin compared to placebo in patients with lupus nephritis.
- Phase 3 AURORA 1 enrolled patients with a diagnosis of systemic lupus erythematosus, biopsy-proven active lupus nephritis and proteinuria ≥1.5 mg/mg (>2 mg/mg for Class V). Patients were randomized to receive voclosporin (23.7 mg BD) or placebo, in combination with MMF (1 g BD) and rapidly tapered low-dose oral steroids for one-year of treatment.
- AURORA 2 patients continued the same randomized treatment as in AURORA 1 for up to an additional two-years.
- Presented here is an interim analysis of patients that enrolled into AURORA 2 including integrated data of two-years of total treatment (AURORA 1 and AURORA 2) at the time of the interim analysis.

Results

**Key Demographics and Baseline Characteristics of AURORA 2 Patients**

- **Age, years**
  - Mean (SD): Control (n=100) 34.4 (11.6), Voclosporin (n=101) 30.3 (9.3)
- **Race, n (%)**
  - White: 40 (40.0), 44 (43.1)
  - Asian: 30 (30.0), 33 (32.7)
  - Black: 7 (7.0), 11 (10.9)
  - Other: 23 (23.0), 22 (21.8)
- **Sex, n (%)**
  - Male: 54 (54.0), 57 (56.5)
  - Female: 45 (45.0), 44 (43.5)
- **Region of the world, n (%)**
  - North and Latin America: 35 (35.0), 33 (32.7)
  - Europe and South Africa: 37 (37.0), 38 (37.3)
  - Asia: 27 (27.0), 30 (29.8)

**UPCR Change from Baseline**

The LS mean change in UPCR from pre-treatment baseline to year two was -3.1 mg/mg for the voclosporin arm (n=73) and -2.1 mg/mg for the control arm (n=51).

**SUMMARY OF ADVERSE EVENTS**

- No unexpected adverse events were observed in the AURORA 2 extension study.
- The interim analysis from the ongoing AURORA 2 extension study showed patients in the voclosporin arm had significantly greater improvements in renal function compared to controls, in combination with MMF.

**Conclusions**

- This interim analysis from the ongoing AURORA 2 extension study showed patients in the voclosporin arm had significantly greater improvements in renal function compared to controls, in combination with MMF.
- No unexpected AEs were observed in the AURORA 2 extension study.
- This analysis provides further support on the positive benefit-risk profile of voclosporin seen in both the Phase 2 AURA-UV and Phase 3 AURORA 1 studies, representing the largest LN clinical program to date.

**References**

1. Voclosporin (LUPKYNIS) Full Prescribing Information.

**Disclosures**

All authors participated in advisory boards for Eli Lilly, Bristol-Myers Squibb, Merck, Novartis, Gilead, and Genentech, and are clinical trial chairs for Aurinia Pharmaceuticals Inc. External support provided by MedAdvisor Partners Ltd.

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