Baseline Characteristics of the ALIGN Trial: A Phase 3 Randomized, Double-blind, Placebo-controlled Clinical Trial of Atrasentan in Patients with IgAN

Methods and Cohort

- Global Phase 3 RCT
- Double blind Placebo
- Biopsy proven IgAN
- Proteinuria ≥ 1g/day
- eGFR ≥ 30ml/min/1.73m²
- **Exploratory SGLT2i stratum only**
  SGLT2i at least 12wks (FLOZIN)

Intervention

- Atresentan 0.75mg orally once daily for 132 weeks
- Placebo orally once daily for 132 weeks

Baseline Demographics and Clinical Characteristics

	#Main Stratum (N=339)	Exploratory SGLT2i Stratum (N=64)
Mean age, year±SD	44.7±12.0	47.2±12.0
Male, %	57.8	59.4
Female, %	42.2	40.6
Asia, %	45.4	25.0
Europe, %	12.1	32.8
North America, %	15.6	32.8
LatAm & Caribbean	20.6	3.1
Median 24hr UPCR g/g (Q1, Q3)	1.4 (1.1, 2.0)	1.4 (1.0, 2.0)
Mean eGFR ml/min/1.73m² ± SD	58.7±23.8	53.0±22.2
On ACEi, %	29.5	29.7
On ARB, %	69.6	68.8
On SGLT2i, %	2.4	93.8

#Patients that were randomized and received at least one dose of the assigned treatment are reported

Outcomes

PRIMARY ENDPOINT* *Week 36*

Δ UPCR

KEY SECONDARY ENDPOINT** *Week 136*

Δ eGFR

**Δ UPCR-Change in urine protein creatinine ratio from baseline, **Δ eGFR-Change in eGFR from baseline*

Conclusion: ALIGN has enrolled a globally representative range of patients with IgAN. ALIGN will explore the potential benefits and risks of adding the endothelin A receptor antagonist, Atrasentan, to evidence-based therapy including RAS inhibition, in patients with IgAN and severe proteinuria who are at high risk of kidney failure. This trial is ongoing and will report results at a future date.

Heerspink H et al
WCN24-AB-2099
VA by Priya John
@drpriyajohn

WCN'24