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



Outcomes

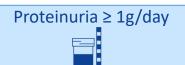
PRIMARY

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Global Phase 3 RCT				

Methods and Cohort







 $eGFR \ge 30ml/min/1.73m^2$



SGLT2i at least 12wks

Intervention

Atresentan 0.75mg orally once daily

for 132 weeks

Placebo orally once daily

for 132 weeks

Baseline Demographics and Clinical Characteristics

			*Main Stratum	Exploratory SGLT2i Stratum
	<u> </u>	Mean age, year±SD	44.7±12.0	47.2±12.0 N=64
	o [*]	Male, %	57.8	59.4
	Q	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/1.73m ² ± SD	58.7±23.8	53.0±22.2
	ACEI	On ACEi, %	29.5	29.7
	ARB	On ARB, %	69.6	68.8
	FLOZIN	On SGLT2i, %	2.4	93.8

ENDPOINT*
Week 36

Δ UPCR

KEY SECONDARY ENDPOINT** Week 136



 $^{\prime\prime}$ Patients that were randomized and received at least one dose of the assigned treatment are reported

 $^*\Delta$ UPCR-Change in urine protein creatinine ratio from baseline, $^{**}\Delta$ 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.



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