Aurinia™

AURORA Phase 3 Study Demonstrates Voclosporin Statistical Superiority Over Standard of Care in Lupus Nephritis

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Disclosures

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Exagen: Research Grant

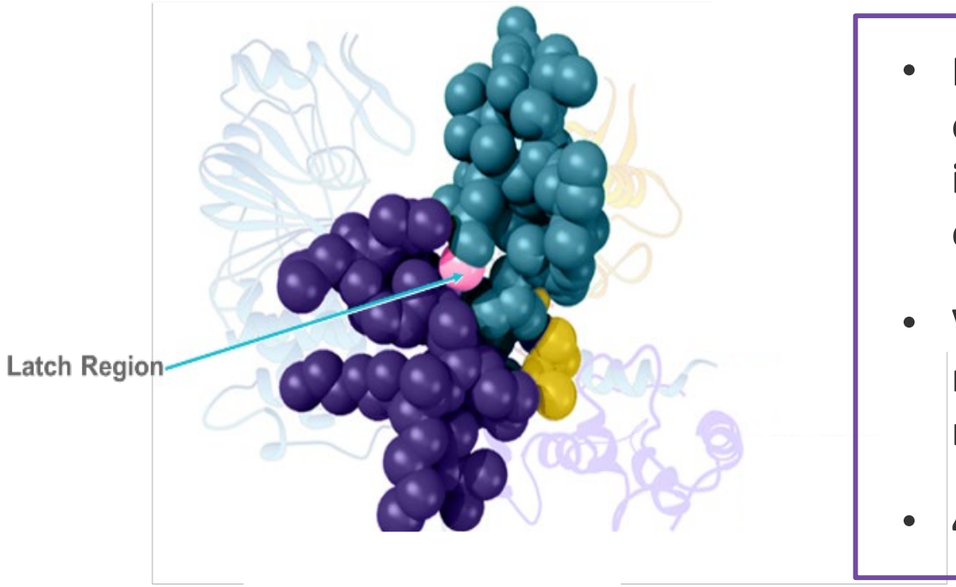
Consulting Fees (advisory boards)

AstraZeneca

GSK

BMS

Voclosporin: A Novel CNI



- Novel CNI developed as a structural change from cyclosporine A, incorporating a single carbon extension with a double-bond
- Voclosporin has a consistent dose response potentially eliminating the need for therapeutic drug monitoring
- 4x potency over cyclosporine A

CNIs in Renal Disease: Two Separate Mechanisms of Action

1. Inhibition of calcineurin reduced cytokine activation of t-cells
2. Potential disease-modifying podocyte stabilization, which protects against proteinuria

Source: Aurinia. Data on file.

Aurinia Studies Evaluating Voclosporin in Active Lupus Nephritis

Completed Trials

AURION (Proof of Concept)

- Single arm, twin center exploratory study
- Biomarkers at 8 weeks: 25% reduction in UPCR. C3/C4, anti-dsDNA normalization
- N = 7
- Primary analysis: # patients achieving biomarkers and # of these patients who go on to achieve Week 24 or Week 48 remission

AURA-LV (Phase 2 RCT)

- Phase 2
- Double blind RCT
- N = 265
- Active control
- Primary endpoint: 24 week renal response
- Statistically significant result in active LN patients

AURORA (Phase 3 RCT)

- Phase 3
- Double blind RCT
- N = 357
- Active control
- Primary endpoint: 52 week renal response

The AURORA Phase 3 Study Had Similar Inclusion Criteria and Primary Endpoints as AURA-LV Phase 2 Study

Bold = change from AURA-LV

AURORA

Select Inclusion Criteria

Diagnosis of SLE according to ACR criteria

+

Kidney biopsy within 6 months of study entry confirming histologic diagnosis of LN*

+

Biopsy proven LN [Class III, IV or Class V (alone or in combination w/Class III or IV)]

+

Proteinuria of ≥1.5 mg/mg
OR ≥2 mg/mg**

Primary Endpoint

Renal Response at **Week 52**

UPCR of ≤0.5 mg/mg

+

eGFR ≥60 mL/min/1.73m^2 or no confirmed decrease from baseline in eGFR of ≥20%

+

Presence of sustained, low dose steroids (≤10mg prednisone from Week 44-52)

+

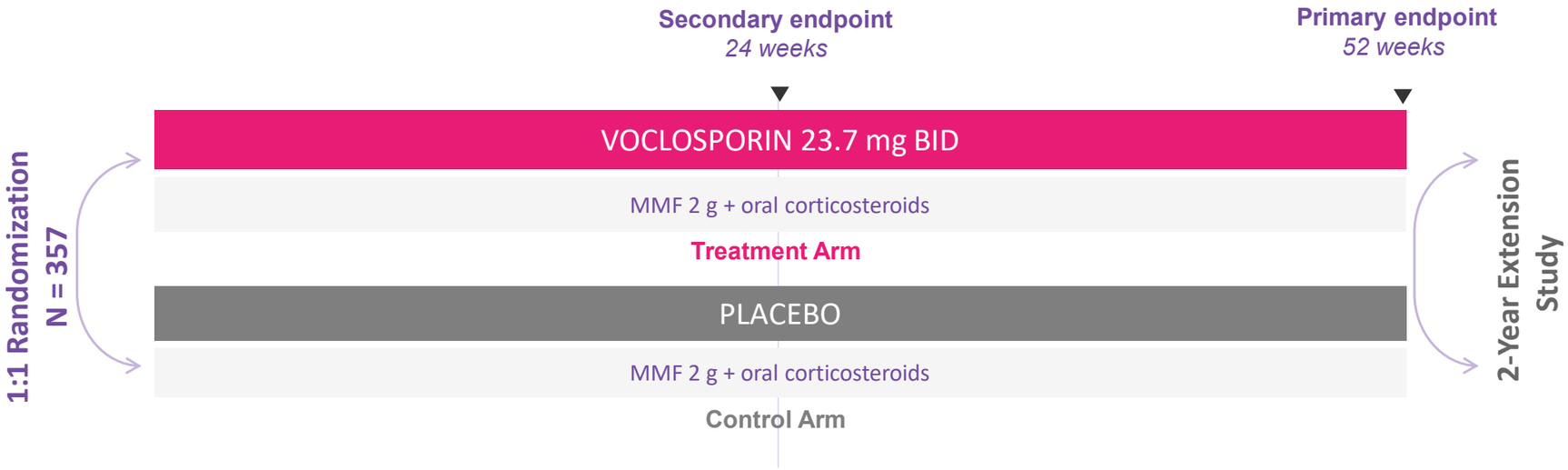
No administration of rescue medications

* **Up to 2 years if accompanied by laboratory evidence of recent LN flare**
** Class V patients

AURORA Phase 3 Study Design

Primary endpoint: Renal Response at Week 52

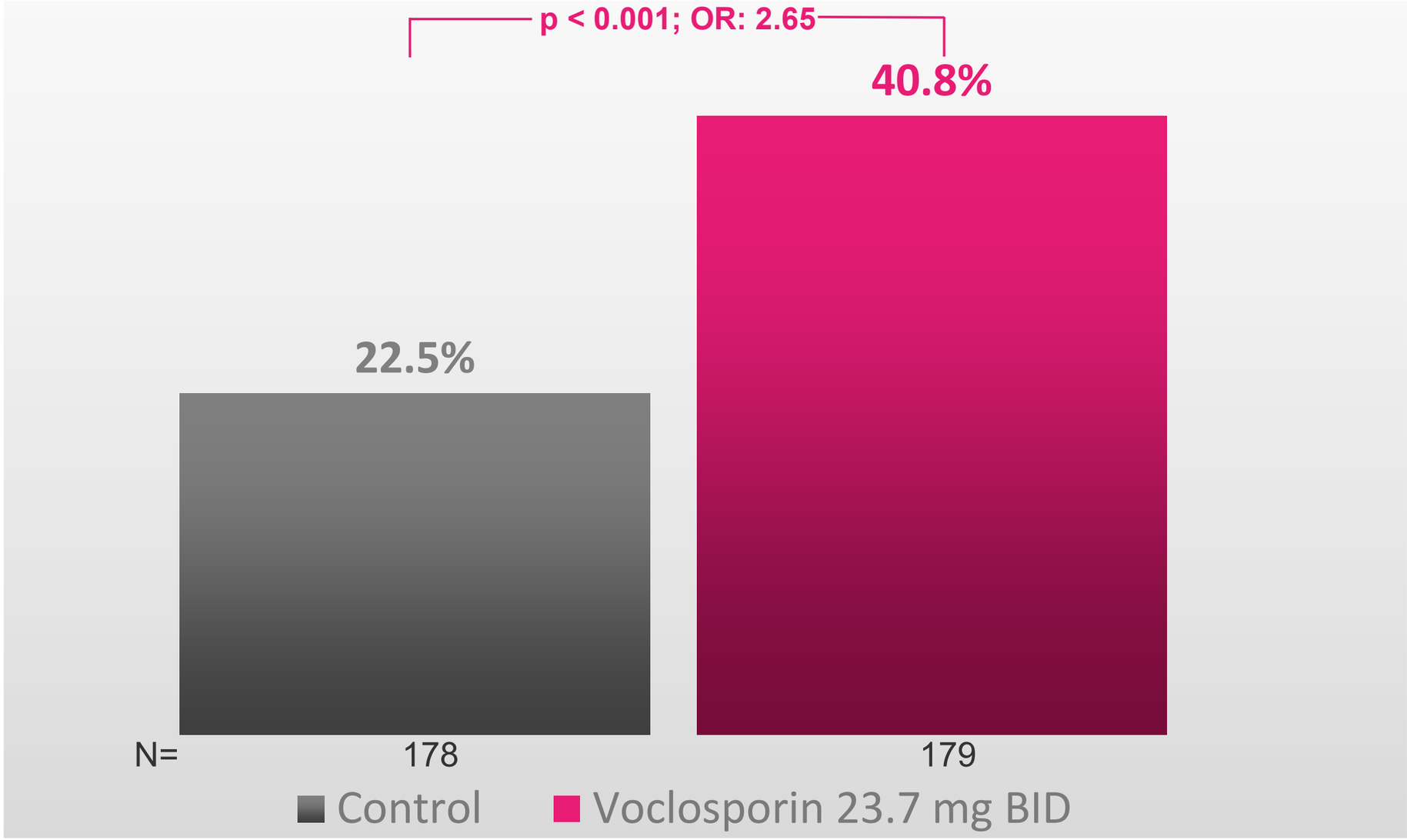
- UPCR of ≤0.5 mg/mg
- eGFR ≥60 mL/min/1.73m^2 or no confirmed decrease from baseline in eGFR of ≥20%
- Presence of sustained, LD steroids (≤10mg pred. from Week 44-52)
- No rescue medications



Rapid steroid taper from 20-25 mg/d Week 1 to 2.5 mg/d by Week 16

Abbreviations: BID = twice a day ; MMF = mycophenolate mofetil

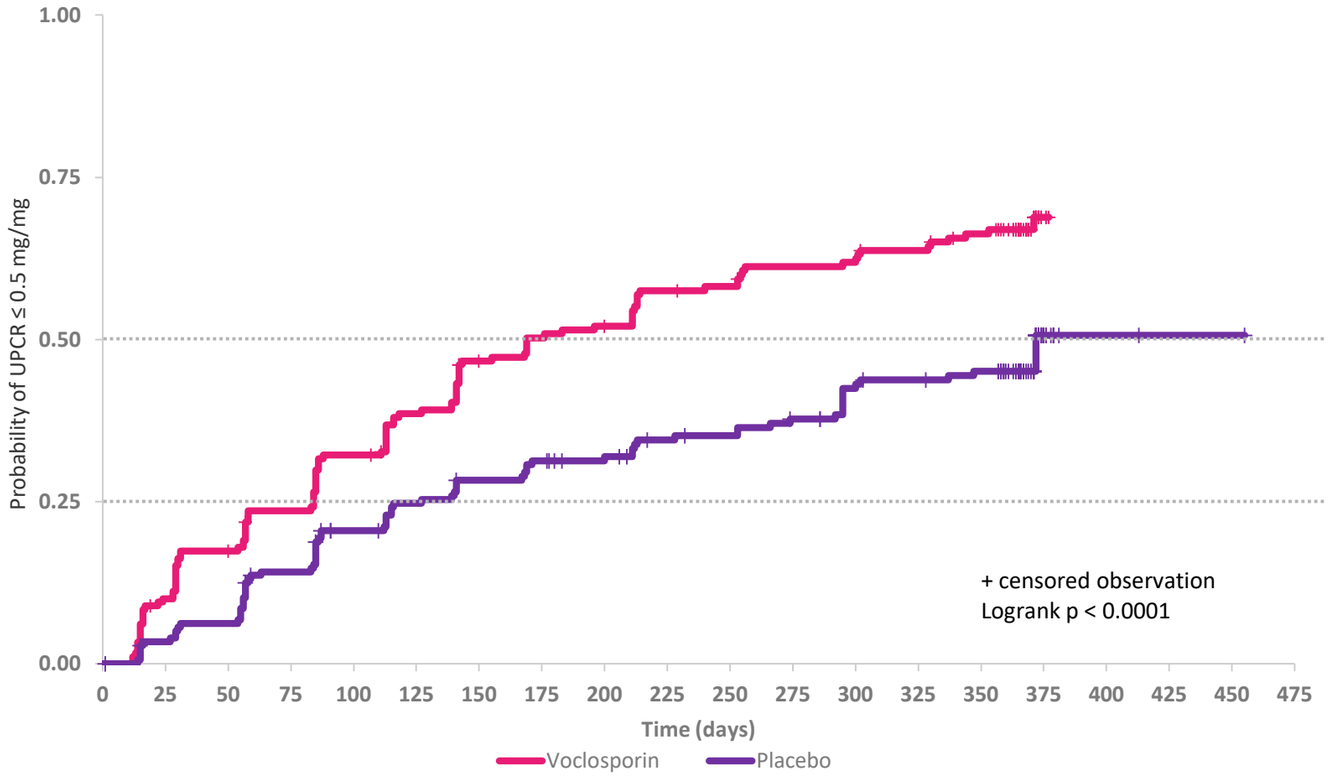
AURORA Primary Efficacy Endpoint: Week 52 Renal Response (ITT)



AURORA Hierarchical Secondary Endpoints (ITT)

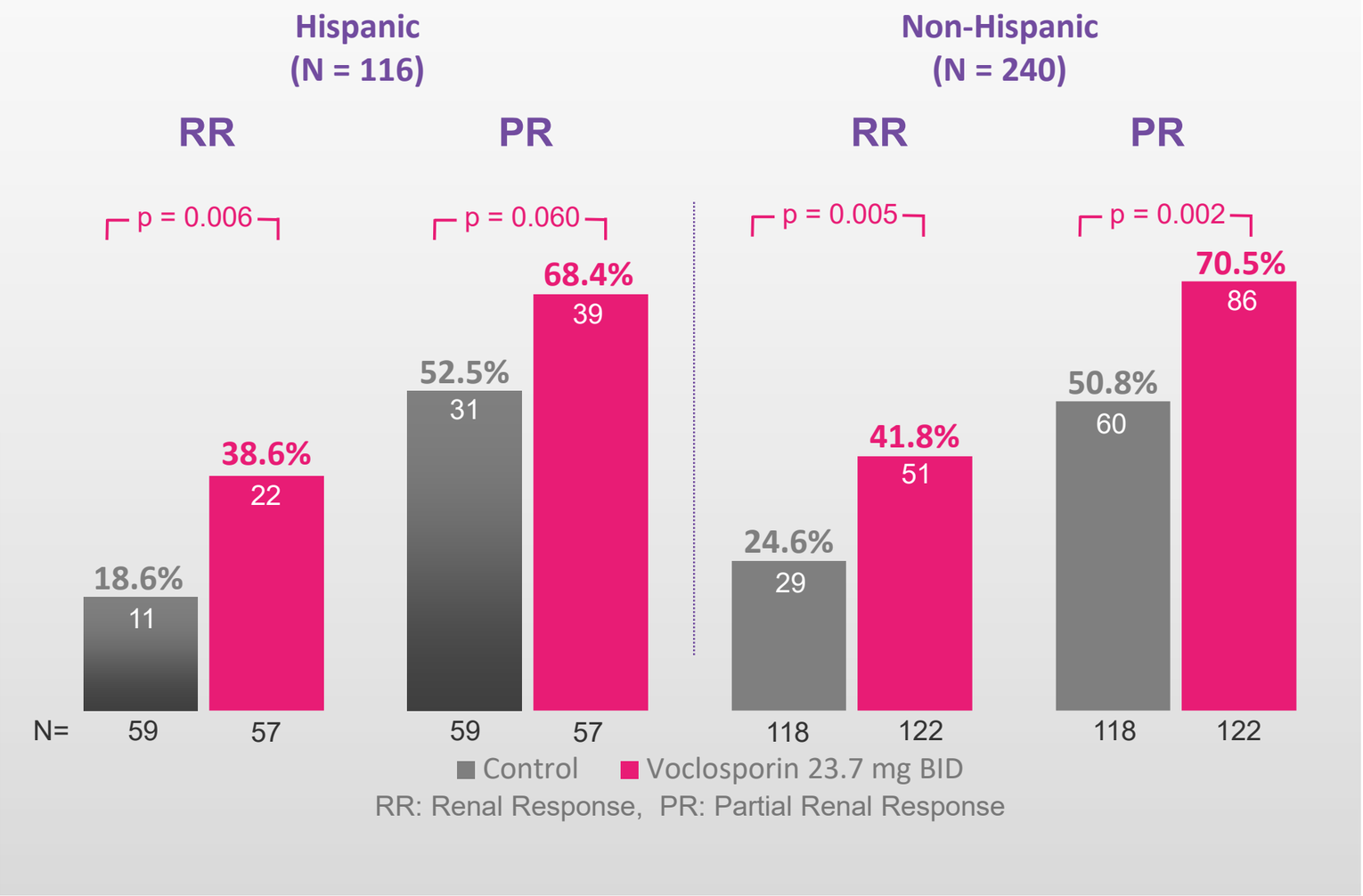
Measure	Result	Odds Ratio [95% CI]	p-value
Renal Response at 24 weeks	Voclosporin 32.4% Control 19.7%	2.23 [1.34, 3.72]	0.002
Partial Renal Response at 24 weeks	Voclosporin 70.4% Control 50.0%	2.43 [1.56, 3.79]	< 0.001
Partial Renal Response at 52 weeks	Voclosporin 69.8% Control 51.7%	2.26 [1.45, 3.51]	< 0.001
Time to UPCR ≤ 0.5 mg/mg	Voclosporin faster than Control	2.02 [1.51, 2.70] Hazard Ratio	< 0.001
Time to 50% reduction in UPCR	Voclosporin faster than Control	2.05 [1.62, 2.60] Hazard Ratio	< 0.001

AURORA Secondary Endpoint: Time to UPCR ≤ 0.5 mg/mg

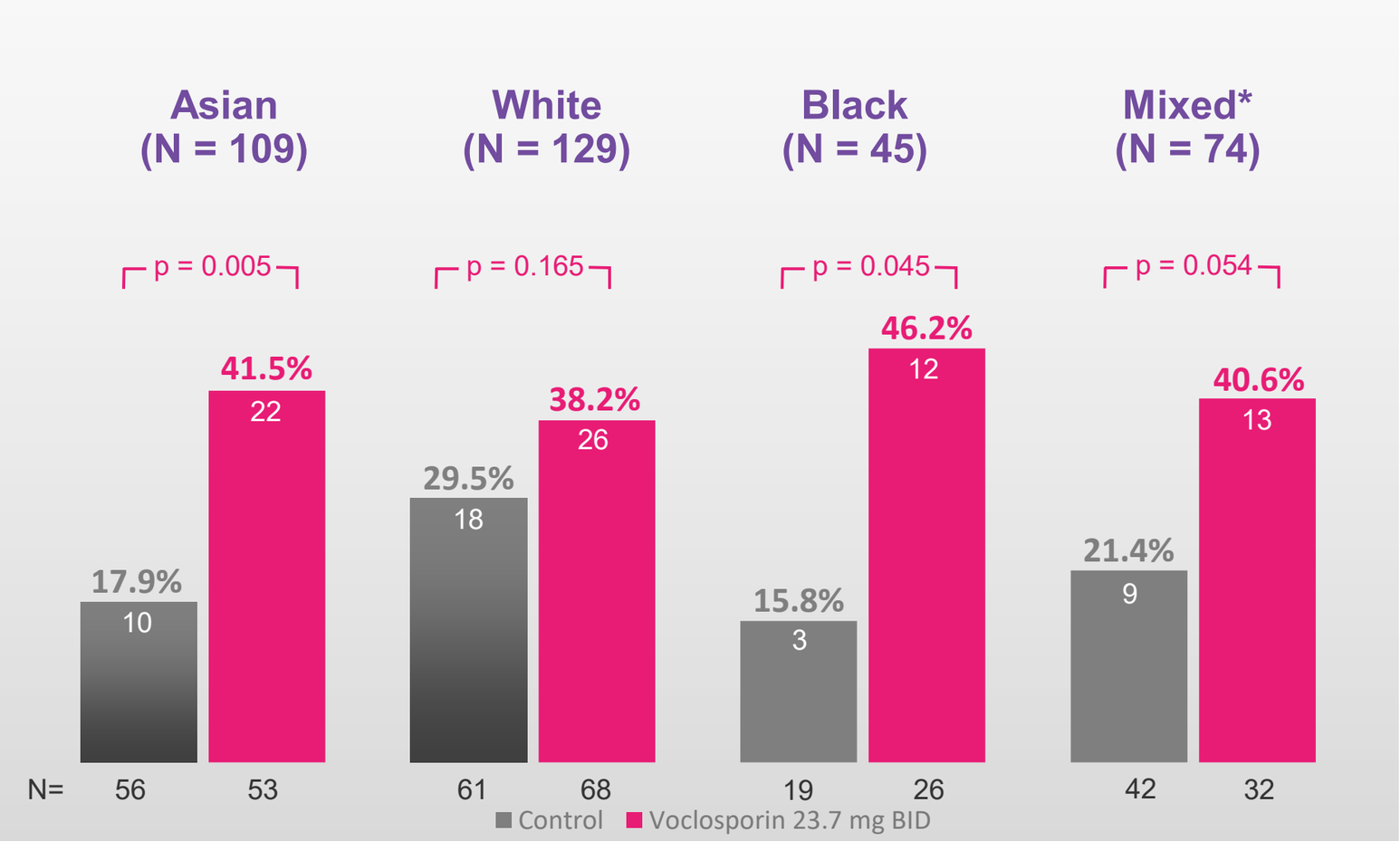


Measure	Result (Days)	p-value
Median Time (50%) to UPCR ≤ 0.5 mg/mg	Voclosporin:169 Control: 372	< 0.001
Median Time (25%) to UPCR ≤ 0.5 mg/mg	Voclosporin: 84 Control: 127	< 0.001

AURORA Renal Response, Partial Renal Response by Ethnicity



AURORA Renal Response by Race



* Mestizo, Mulato, Other

AURORA Overall Summary of Adverse Events

	Control (N = 178) N (%)	Voclosporin 23.7 mg BID (N = 178) N (%)
Any Adverse Event (AE)	158 (88.8)	162 (91.0)
Any Serious Adverse Event (SAE)	38 (21.3)	37 (20.8)
- Serious infection	20 (11.2)	18 (10.1)
Any treatment-related SAE	8 (4.5)	8 (4.5)
Any AE leading to voclosporin/placebo discontinuation	26 (14.6)	20 (11.2)
Death*	5 (2.8)	1 (0.6)
Treatment-related AE leading to death	0	0
Disease-related AE	87 (48.9)	96 (53.9)
Disease-related SAE	16 (9.0)	18 (10.1)

* *2 deaths in control group and 1 death in voclosporin group occurred as a result of AEs starting >30 days after discontinuation of study drug.*

AURORA Overall Summary of Adverse Events by Hispanic Ethnicity

	Hispanic		Non-Hispanic	
	Control N (%)	Voclosporin 23.7 mg BID N (%)	Control N (%)	Voclosporin 23.7 mg BID N (%)
SAEs	13 (22.0)	13 (23.2)	24 (20.3)	24 (19.7)
Serious Infections and Infestations	10 (16.9)	4 (7.1)	10 (8.5)	14 (11.5)

AURORA Study Conclusions

- The positive benefit-risk profile observed in AURORA (n=357) confirms the treatment effect seen in AURA-LV (n=265) when comparing voclosporin 23.7 mg BID in combination with background standard of care versus standard of care alone.

- The odds of achieving Renal Response on voclosporin therapy were 2.65x greater than control, while maintaining a comparable safety profile.

- Hispanic ethnicity and Black race LN patients, often severe and difficult to treat subgroups, also noted improved Renal Response with voclosporin.

Thank you to the
AURORA Study patients, investigators, coordinators, and staff.