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

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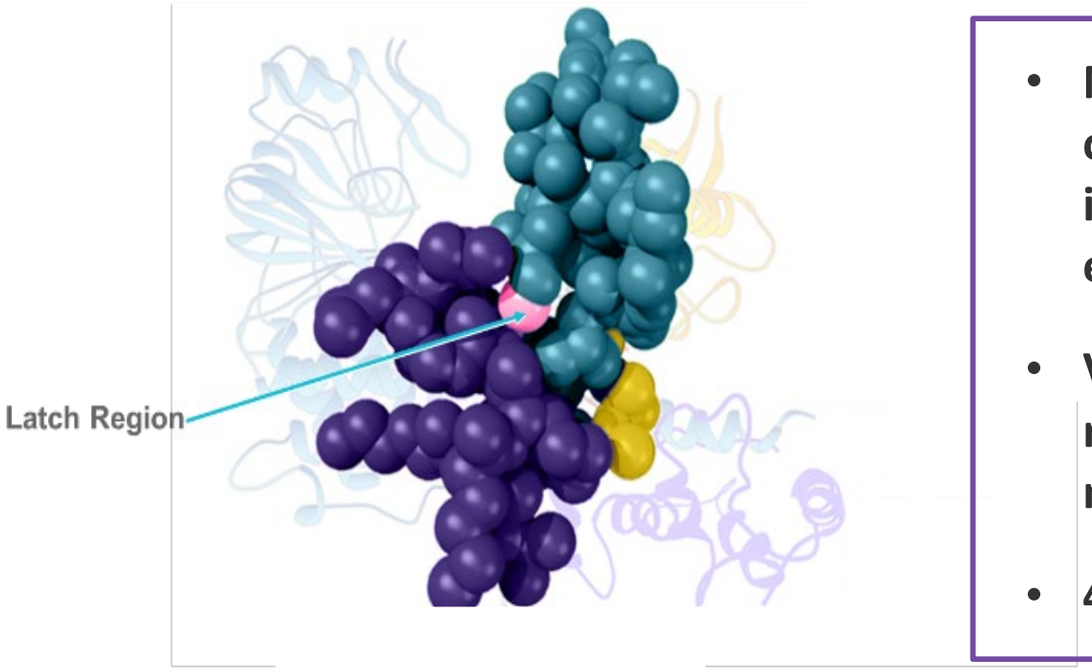
Voclosporin: A Novel CNI



- 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

Abbreviations: UPCR = urinary protein to creatinine ratio

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)

+

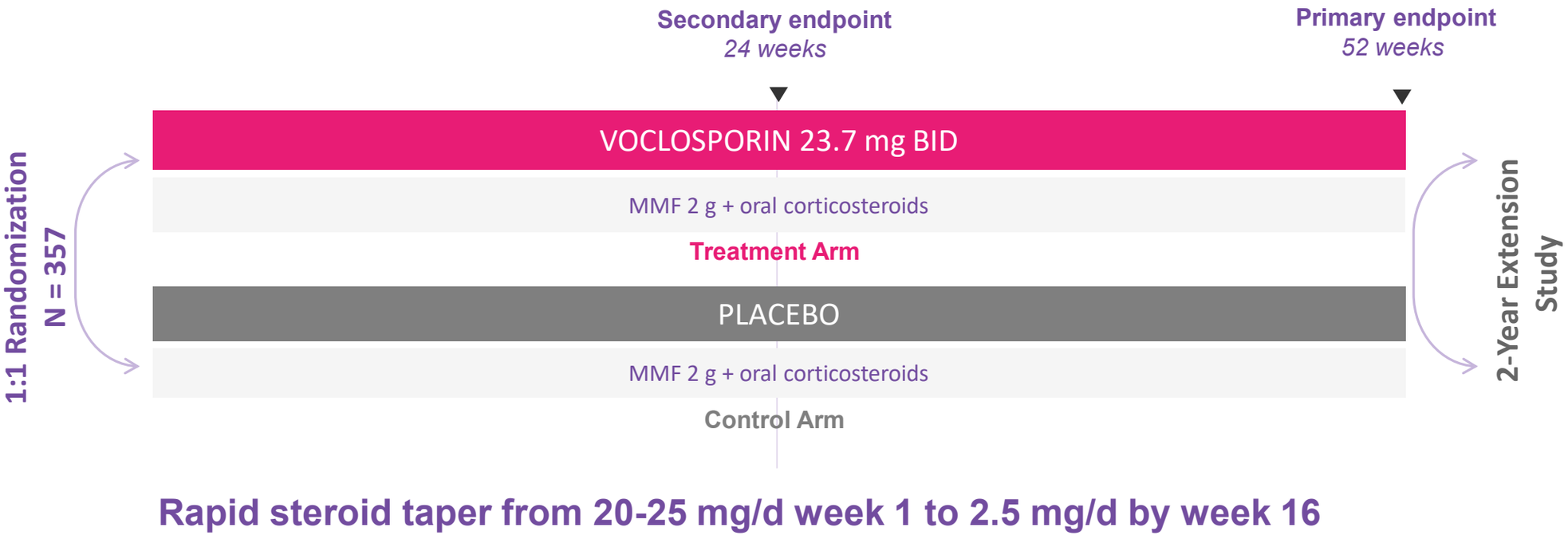
No administration of rescue medications

* **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

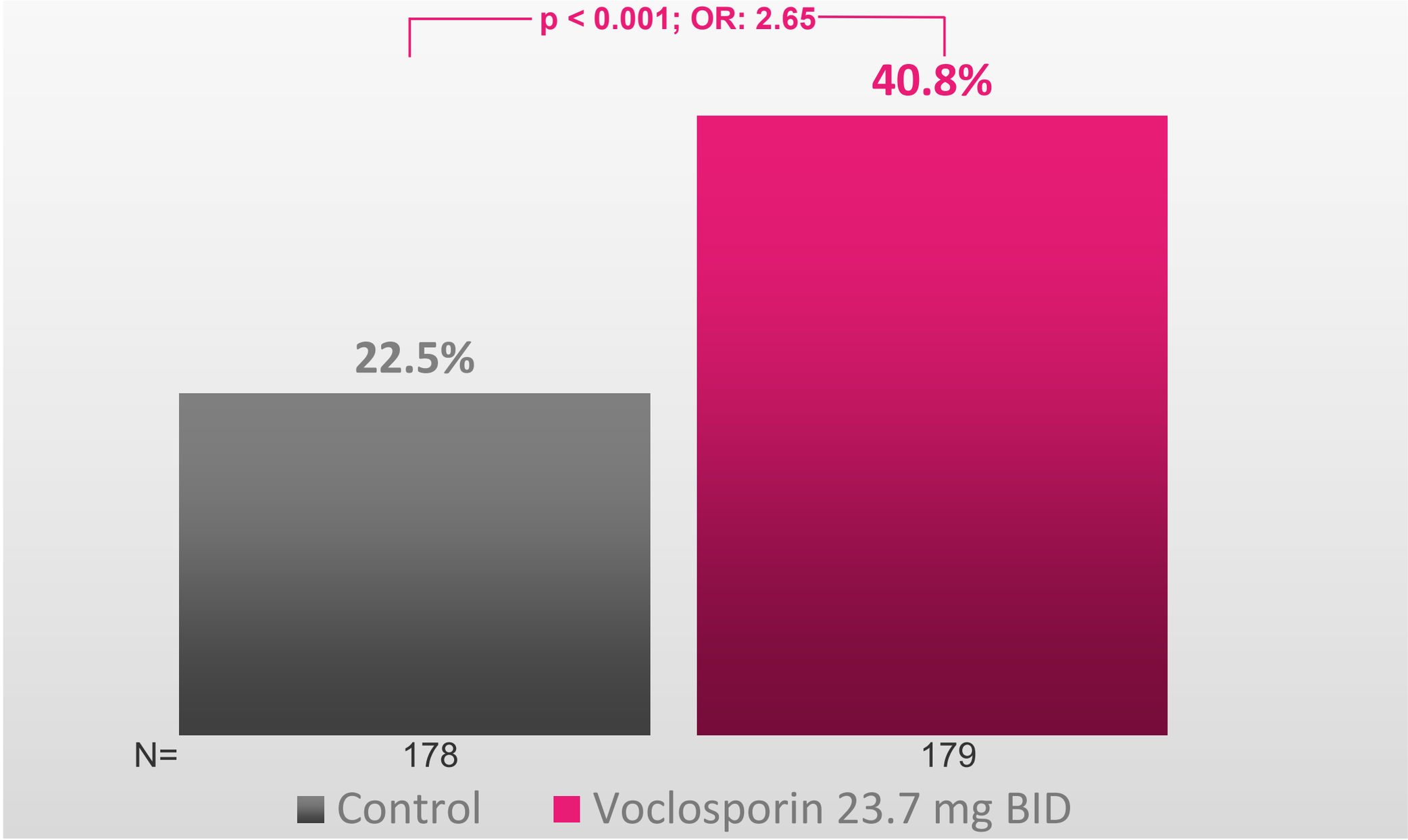


Abbreviations: BID = twice a day ; MMF = mycophenolate mofetil

AURORA Baseline Renal Characteristics

	Control N = 178	Voclosporin 23.7 mg BID N = 179	Total N = 357
Baseline eGFR (mL/min/1.73m^2)			
n	178	178	356
Mean (SD)	90 ± 29	92 ± 31	91 ± 30
Median	97	91	94
Baseline UPCR (mg/mg)			
n	178	178	356
Mean (SD)	3.9 ± 2.4	4.1 ± 2.7	4.0 ± 2.5
Median	3.1	3.4	3.2
Biopsy Class n (%)	178	179	357
Class III or IV (+/- V)	153 (86%)	154 (86%)	307 (86%)
Class V	25 (14%)	25 (14%)	50 (14%)

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

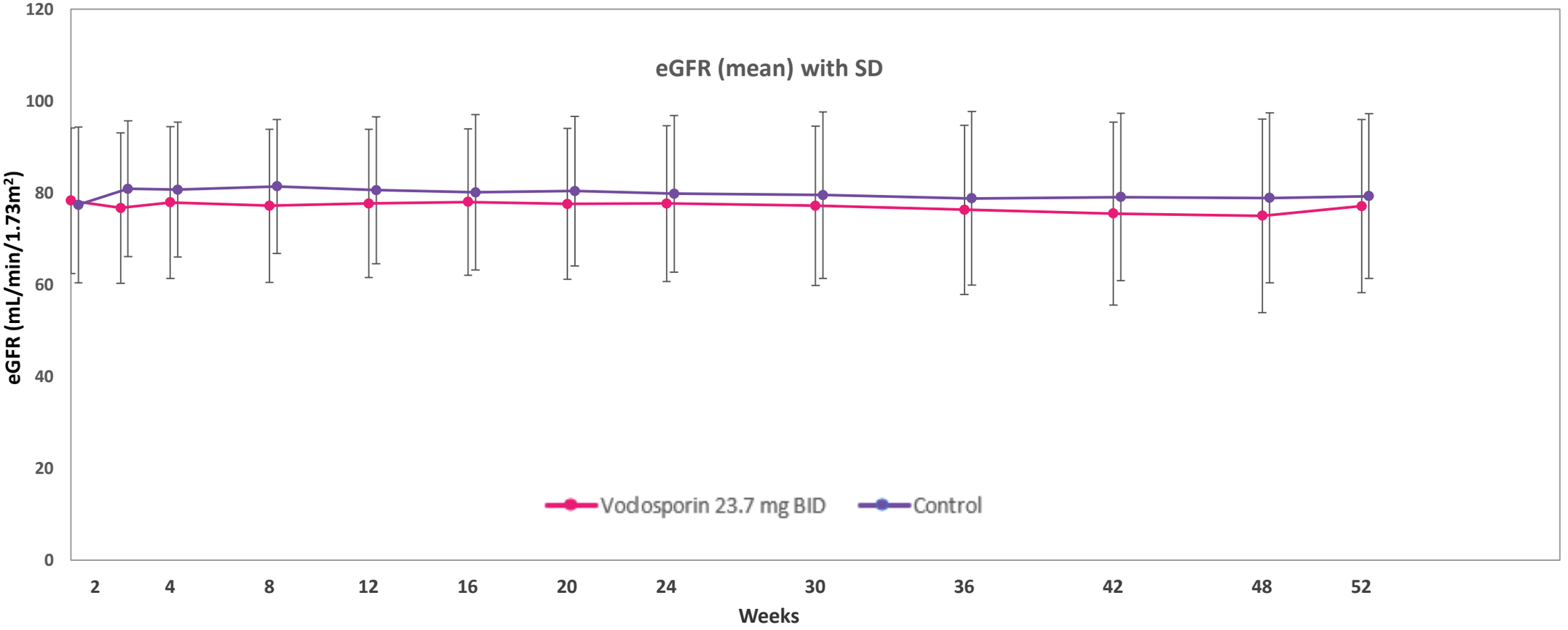
*Partial Renal Response: 50% reduction from baseline in UPCR

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)

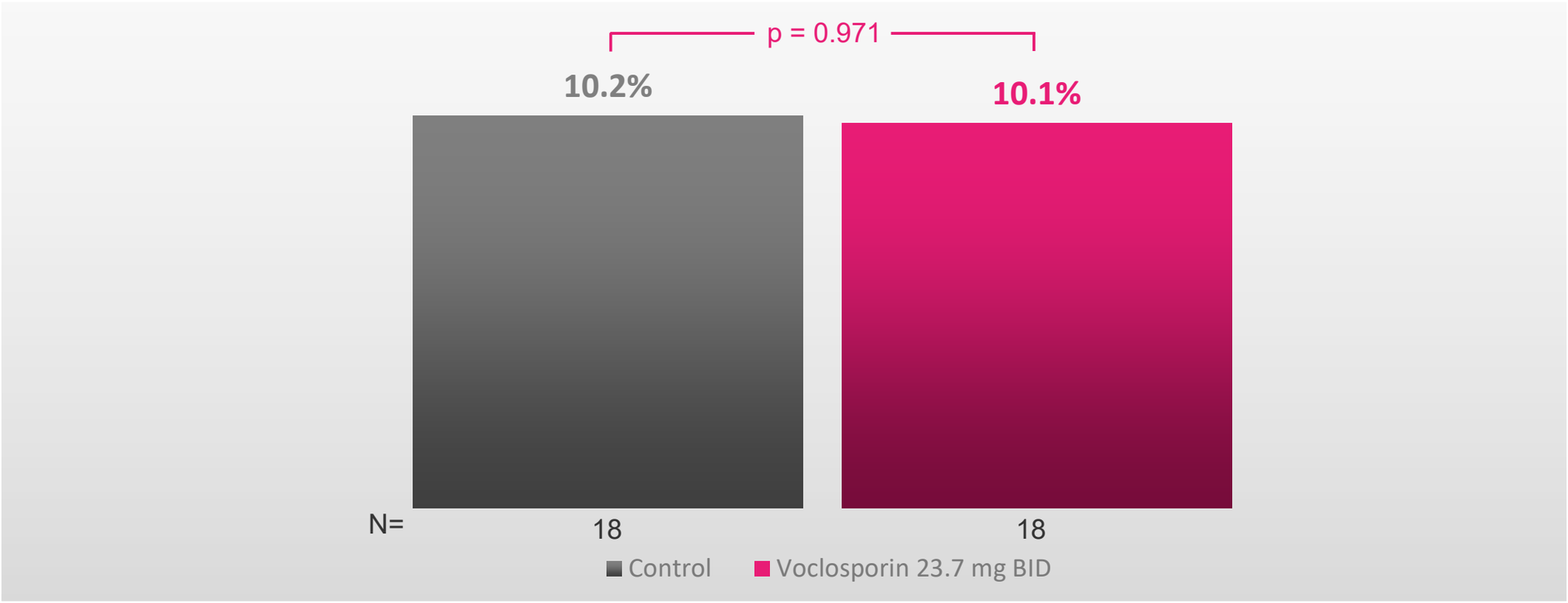
* *2 deaths in control group and 1 death in voclosporin group occurred as a result of AEs starting >30 days after discontinuation of study drug.*

AURORA Corrected eGFR Over Time



Voclosporin eGFR change from baseline to week 52 not significant (-1.2 ml)

Percentage of Patients With Decreases in eGFR > 30% Was Similar in Voclosporin and Control Group



Mean Baseline	Control	Voclosporin 23.7 mg BID
eGFR (mL/min)	72.4	79.4
UPCR (mg/mg)	3.87	4.66

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.

- In AURORA, the voclosporin mean effect on eGFR is not clinically meaningful, confirming the data seen in AURA-LV; furthermore the percentage of patients with severe declines in eGFR (>30%) was similar to control.