

 **Lupkynis**[®]
(voclosporina) cápsulas
7,9 mg

*Nuevo inmunosupresor
para el tratamiento de
la nefritis lúpica*



Accede a la ficha
técnica de Lupkynis[®]



11. CONDICIONES DE PRESCRIPCIÓN Y DISPENSACIÓN Medicamento sujeto a prescripción médica. Dispensación hospitalaria sin cupón
precinto. 12. CONDICIONES DE PRESTACIÓN DEL SISTEMA NACIONAL DE SALUD Reembolsable por el Sistema Nacional de Salud. 13.
PRESENTACIONES Y PRECIOS Lupkynis 7,9 mg cápsulas blandas, 180 cápsulas. Precio Notificado autorizado: 780€.

1. Maria Dall'Era et al. Achievement of Proteinuria Targets ≤ 0.4 g/g in Lupus Nephritis: A Post Hoc Analysis of the AURORA 1 Study of Voclosporin,
presentado en European Alliance of Associations for Rheumatology Congress 2025 (Barcelona, España; Jun 11-14); Disponible en:
<https://www.sciencedirect.com/science/article/abs/pii/S0003496725027359> (Consultado en Septiembre 2025).

Fecha de elaboración: Septiembre 2025. ES-LUP-2500118.v1.0

Este medicamento está sujeto a seguimiento adicional, es prioritaria la notificación
de sospechas de reacciones adversas asociadas a este medicamento.

www.nefritislupica.com

**ACHIEVEMENT OF
PROTEINURIA
TARGETS ≤ 0.4 G/G IN
LUPUS NEPHRITIS:
A Post Hoc Analysis of the
AURORA 1 Study of
Voclosporin¹**



Achievement of Proteinuria Targets ≤0.4 g/g in Lupus Nephritis: A Post Hoc Analysis of the AURORA 1 Study of Voclosporin

Maria Dall'Era¹, Brad H. Rovin², Salem Almaani², Lucy S. Hodge³, Vanessa Birardi³, Ernie Yap³

¹University of California San Francisco, San Francisco, United States of America, ²The Ohio State University, Medical Center, Columbus, United States of America, ³Aurinia Pharmaceuticals Inc., Rockville, United States of America

BACKGROUND

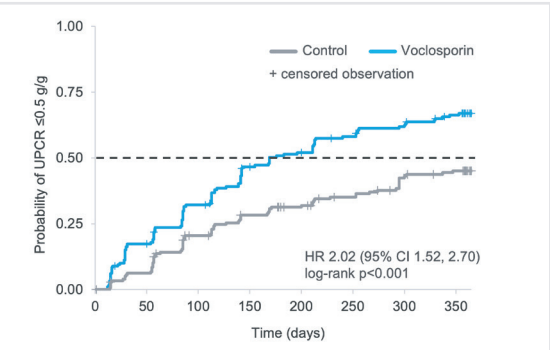
PROTEINURIA IN LUPUS NEPHRITIS

- In lupus nephritis (LN), ongoing immunologic insult to the kidney leads to inflammation and fibrosis, ultimately resulting in proteinuria, one of the most common clinical manifestations of the disease^{1,2}
- Proteinuria has been identified as an independent mediator of progressive kidney damage in LN, with early reductions in proteinuria associated with improved long-term renal outcomes³⁻⁹
- For this reason, current LN treatment recommendations include a target urinary protein to creatinine ratio (UPCR) <0.5-0.7 g/g within the first year of treatment^{10,11}
- However, studies demonstrate that significant histological activity can persist even at UPCR levels ≤0.5 g/g, and even low levels of proteinuria are associated with progressive chronic kidney disease (CKD), cardiovascular mortality, and all-cause mortality¹²⁻¹⁴
- This suggests that targeting lower levels of proteinuria therapeutically may be beneficial

VOCLOSPORIN IN LUPUS NEPHRITIS

- Voclosporin is a second generation calcineurin inhibitor (CNI) approved for the treatment of adults with active LN¹⁵
- In the 52-week Phase 3 AURORA 1 trial, addition of voclosporin to mycophenolate mofetil (MMF) and low-dose glucocorticoids led to significantly earlier and greater reductions in proteinuria¹⁶
- The 2024 American College of Rheumatology LN Guideline recommends a voclosporin-based triple immunosuppressive therapy as an initial treatment option for patients with active LN¹⁷
- Yet, the feasibility of achieving specific UPCR targets below the 0.5 g/g threshold with a voclosporin-based triple immunosuppressive therapy regimen is unknown

AURORA 1 Study: Time to UPCR ≤0.5 g/g¹⁶



Analysis includes all 357 participants of the AURORA 1 study. Median (95% CI) times to event calculated using Kaplan Meier methods. Participants who did not achieve the UPCR target during the study period were censored on the day of their last UPCR assessment. Hazard ratios calculated using Cox proportional hazards model with terms for treatment group, baseline UPCR, biopsy class, MMF use at baseline and region. CI, confidence interval; HR, hazard ratio; MMF, mycophenolate mofetil; UPCR, urine protein creatinine ratio.

STUDY OBJECTIVE

- The objective of this post hoc analysis was to demonstrate that achievement of deep response (UPCR ≤0.4 g/g) is feasible and enhanced with the use of a voclosporin-based triple immunosuppressive therapy regimen

METHODS

- Key inclusion criteria for the Phase 3 AURORA 1 study included biopsy-proven active LN, UPCR ≥1.5 g/g (≥2 g/g for Class V) and estimated glomerular filtration rate (eGFR) >45 mL/min/1.73 m²
- Participants were randomized to either voclosporin (23.7 mg) or matching placebo (control) twice daily, in combination with MMF (target 2 g/day) and low-dose glucocorticoids (intravenous methylprednisolone on Days 1 and 2 [total 1 g], followed by oral prednisone at a starting dose of 20-25 mg/day, tapered to ≤2.5 mg/day by Week 16)
- Achievement of UPCR targets ≤0.4 g/g were assessed along with associated safety outcomes

RESULTS

ACHIEVEMENT OF DEEP RESPONSE (UPCR ≤0.4 g/g)

- Of the 357 participants in AURORA 1, almost half (49.0%) achieved a deep response at least once during the 52-week study, including 109 (60.9%) voclosporin-treated participants and 66 (37.1%) control-treated participants

UPCR, n (%)	Control (n=178)	Voclosporin (n=179)	Overall AURORA 1 (N=357)
≤0.4 g/g	66 (37.1)	109 (60.9)	175 (49.0)
≤0.3 g/g	56 (31.5)	96 (53.6)	152 (42.6)
≤0.2 g/g	42 (23.6)	72 (40.2)	114 (31.9)
≤0.1 g/g	16 (9.0)	37 (20.7)	53 (14.8)

Analysis includes all 357 participants of the AURORA 1 study. UPCR targets are not mutually exclusive; participants may have achieved more than one UPCR cut-off at any study visit. UPCR, urine protein creatinine ratio.

BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS

- Baseline characteristics in participants achieving deep response were similar to those of the overall AURORA 1 population

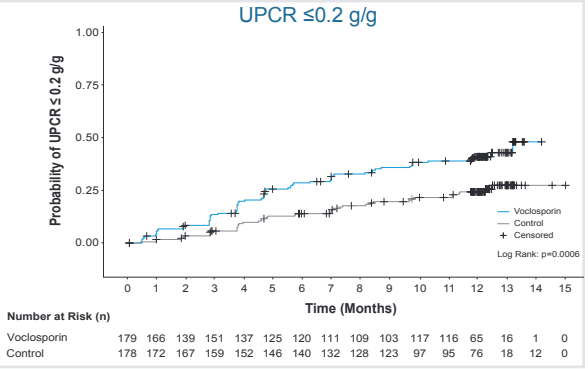
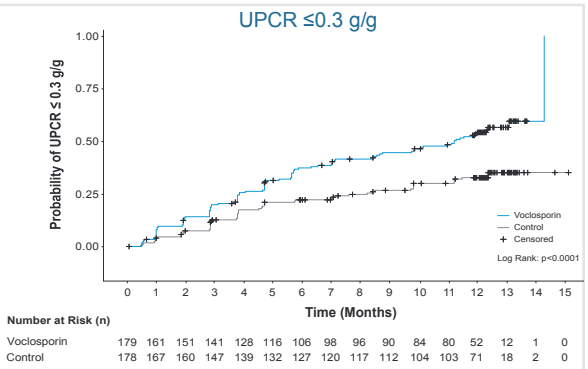
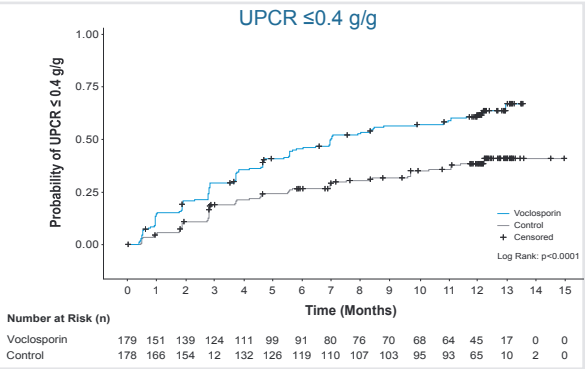
	Control (≤0.4 g/g) n=66	Voclosporin (≤0.4 g/g) n=109	Overall AURORA 1 N=357
Age, years, mean (SD)	35.2 (11.0)	33.3 (11.3)	33.2 (10.96)
Sex, female, n (%)	54 (81.8)	99 (90.8)	313 (87.7)
Race, n (%)			
White	30 (45.5)	43 (39.4)	129 (36.1)
Asian	15 (22.7)	31 (28.4)	109 (30.5)
Black	5 (7.6)	18 (16.5)	34 (9.5)
Other*	16 (24.2)	17 (15.6)	85 (23.8)
Ethnicity, n (%)			
Hispanic or Latino	20 (30.3)	31 (28.4)	116 (32.5)
Not Hispanic or Latino	46 (69.7)	78 (71.6)	240 (67.2)
Duration of LN, years, mean (SD)	4.0 (5.4)	3.0 (4.2)	4.6 (4.97)
Biopsy Class, n (%)			
Class III or IV	41 (66.7)	66 (60.6)	215 (60.2)
Class V	11 (16.7)	17 (15.6)	50 (14.0)**
Mixed Class V and III or IV	14 (21.2)	25 (22.9)	89 (24.9)
Corrected eGFR mL/min/1.73m ² , mean (SD)	79.3 (17.1)	80.1 (14.3)	77.8 (16.4)
UPCR, g/g, mean (SD)	3.2 (2.1)	3.5 (2.4)	4.0 (2.5)

Data presented are from 175 AURORA 1 participants who achieved UPCR ≤0.4 g/g at any study visit as well as from the overall AURORA 1 population (N=357). Renal function assessed with corrected eGFR (Chronic Kidney Disease Epidemiology Collaboration equation) using a prespecified ceiling of 90 mL/min/1.73 m². eGFR, estimated glomerular filtration rate; LN, lupus nephritis; SD, standard deviation; UPCR, urine protein creatinine ratio. Deep response is defined as UPCR ≤0.4 g/g. *Includes American Indian or Alaska Native, Multiple Race, and Other. **Includes one patient with mixed Class II and Class V.

TIME TO UPCR REDUCTIONS

- The median time to UPCR ≤0.4 g/g for the voclosporin group was 7.0 months; a median time was not determinable for the control group as less than 50% achieved the endpoint within the study period (difference between groups hazard ratio [HR] 2.15; 95% confidence interval [CI] 1.58, 2.93; p<0.0001)
- Similar trends were observed regarding achievement of UPCR ≤0.3 g/g and ≤0.2 g/g, with HR values >1 indicating a benefit of voclosporin-based triple immunosuppressive therapy

Median time to UPCR (95% CI), months	Control (n=178)	Voclosporin (n=179)	HR (95% CI) p-value vs. control
≤0.4 g/g	ND	7.0 (1.58, 2.93)	2.15 (1.58, 2.93), <0.0001
≤0.3 g/g	ND	11.1 (8.3, 12.9)	2.04 (1.46, 2.84), <0.0001
≤0.2 g/g	ND	ND (12.4, ND)	2.04 (1.40, 3.00), 0.0002



Analysis includes all 357 participants of the AURORA 1 study. Events that occurred at any point during the 52-week treatment period were included in the analysis. Participants who did not achieve the UPCR target during the study period were censored on the day of their last UPCR assessment. Some participants were late for their final Month 12 visit, resulting in the censoring of participants after the end of the study. Median time to event (95% CI) calculated using Kaplan Meier methods. HR and 95% CI were derived from a Cox proportional hazards model with terms for treatment group and baseline UPCR. Hazard ratios >1 indicate events occurring earlier in the voclosporin group. CI, confidence interval; HR, hazard ratio; ND, not determinable due to either the endpoint not being met by 50% of the cohort within the study period or limited additional participants achieving the endpoint after the median timepoint but before the end of the study; UPCR, urine protein creatinine ratio.

SAFETY OUTCOMES

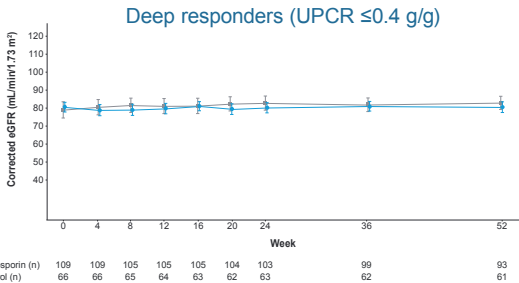
- Rates of adverse events (AEs) in voclosporin-treated participants were similar regardless of UPCR achieved
 - The most common AEs in voclosporin-treated participants were GFR decreased and infections, consistent with findings from previous clinical studies
- Across voclosporin and control groups, infections were the most commonly reported serious AE
- Control-treated participants who didn't achieve deep response had higher rates of AEs, including AEs leading to study drug discontinuation

	Control (n=178)		Voclosporin (n=179)	
	UPCR ≤0.4 g/g n=66	UPCR >0.4 g/g n=112	UPCR ≤0.4 g/g n=109	UPCR >0.4 g/g n=69
Any AE	55 (83.3)	104 (92.9)	98 (89.9)	64 (92.8)
Serious AE	11 (16.7)	27 (24.1)	23 (21.1)	14 (20.3)
AE Leading to Study Drug Discontinuation	3 (4.5)	23 (20.5)	10 (9.2)	10 (14.5)
AE Leading to Death	0	3 (2.7)	0	0

Analysis includes all 357 participants of the AURORA 1 study. AE, adverse event; UPCR, urine protein creatinine ratio.

MEAN eGFR OVER TIME

- Similar to the overall AURORA 1 population, least square mean corrected eGFR values remained stable and within the normal range in both treatment arms in participants achieving deep response



Data presented are from 175 AURORA 1 participants who achieved UPCR ≤0.4 g/g at any study visit. Baseline least square means and 95% CIs are calculated from a model including a covariate for treatment group. Post-baseline least square means and 95% CIs are calculated from a model including covariates for treatment group and baseline value. Renal function assessed with corrected eGFR (Chronic Kidney Disease Epidemiology Collaboration equation) using a prespecified ceiling of 90 mL/min/1.73 m². CI, confidence interval; eGFR, estimated glomerular filtration rate.

CONCLUSION

- Early reduction in proteinuria to the lowest possible level and long-term preservation of kidney health are key goals of therapy in LN
- Nearly half of the AURORA 1 population achieved a deep response at least once during the 52-week study, surpassing treatment targets recommended by current guidelines for the management of LN
- A greater proportion of participants treated with voclosporin-based triple immunosuppressive therapy achieved deep response and did so significantly earlier than control-treated participants, with comparable rates of AEs
- Participants achieving this target also demonstrated stable mean eGFR throughout the 52-week study
- These data suggest that lower UPCR targets are feasible and enhanced with the use of voclosporin-based triple immunosuppressive therapy

References

- Lech M et al. J Am Soc Nephrol. 2013;24(9):1357-1366.
- Fu SM et al. Clin Immunol. 2017;185:51-58.
- Nolin AC et al. Am J Physiol Renal Physiol. 2016;311(6):F1271-F1279.
- Davies DJ et al. Pathology. 1985;17(3):412-419.
- Cravedi P et al. Br J Clin Pharmacol. 2013;76(4):516-523.
- Dall'Era M et al. Arthritis Care Res (Hoboken). 2011;63(3):351-357.
- Dall'Era M et al. Lupus Sci Med. 2015;2(1):e000089.
- Ugolini-Lopes MR et al. Lupus Sci Med. 2017;4(1):e000213.
- Tamirou F et al. Lupus Sci Med. 2015;2(1):e000123.
- Fanouriakis A et al. Ann Rheum Dis. 2024;83(1):15-29.
- Rovin BH et al. Kidney Int. 2024;105(1):S1-S69.
- De Rosa M, et al. Kidney Int Rep. 2020;5(7):1086-1098.
- Cherif A, et al. Kidney Int Rep. 2020;5(12):2333-2340.
- Wakasugi D, et al. J Rheumatol. Jan 2012;39(1):79-85.
- LUPKYNIS [package insert]. Rockville, MD: Aurinia Pharma Inc.; 2021. Revised: 4/2024.
- Rovin BH et al. Lancet. 2021;397(10289):2070-2080.
- Sammaritano LR et al. Arthritis Rheumatol. 2025; Epub ahead of print.

Disclosures

MDE is a consultant for Annexon Biosciences, AstraZeneca, Aurinia Pharmaceuticals Inc., Biogen, GSK plc., and Pfizer. BHR is a consultant for Alexion, AstraZeneca, Aurinia Pharmaceuticals Inc., Biogen, Bristol Myers Squibb, Exagen, Genentech, GSK plc., Kezar Life Sciences, Kyverna, Novartis, and Otsuka. SA is a consultant for Amgen, Aurinia Pharmaceuticals Inc., Cabaletta Bio, Cantor Fitzgerald, Kezar, and Otsuka. LSH, VB, and EY are all employees and shareholders of Aurinia Pharmaceuticals Inc.

Editorial support provided by MediComm Partners Ltd. Aurinia Pharmaceuticals Inc. provided funding for the study and presentation.