

Request for Copy of Published Material

The materials provided in response to your request, unless otherwise stated, are the property of the copyright holder. Copyright and other intellectual property laws protect these materials. Reproduction or retransmission of the materials, in whole or in part, in any manner, without the prior written consent of the copyright holder, is a violation of copyright law. A single copy of the materials is provided to you pursuant to a license to do so that has been granted by the copyright holder to us. You may not redistribute or reproduce the materials in any forms without prior written consent of the copyright holder of the materials.

Enclosure:

- ORAL PRESENTATION: Rizk D, Perkovic V. Presented at: GlomCon Hawaii 2026; August 3-7, 2026; Maui, Hawaii, USA.



WELCOME TO GLOMCON HAWAII 2026

AUGUST 3 - 7, 2026

MAUI, HAWAII



Sibeprenlimab in IgA Nephropathy: Topline 24-Month eGFR Results

Dana V. Rizk, MD,¹ and Vlado Perkovic, MB, BS, PhD²

¹Division of Nephrology, Department of Medicine, Heersink School of Medicine, University of Alabama at Birmingham, Birmingham, AL;

² University of New South Wales, Sydney, Australia

On behalf of the VISIONARY trial investigator group

Disclosures

Funding

This study is funded by Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, NJ)

Dr Rizk reports the following disclosures:

Research support: Calliditas Therapeutics, Dimerix, LaRoche, Novartis, Otsuka Pharmaceutical, Sanofi, Takeda, Travere Therapeutics, Vera Therapeutics, Vertex Pharmaceuticals

Consulting fees: BioCryst, Biogen, Biohaven, Calliditas Therapeutics, Chugai, Climb Bio, Emerald Clinical, Jade Biosciences, LaRoche, Novartis, Otsuka Pharmaceutical, Timberlyne Therapeutics, Vera Therapeutics

Honoraria: Alexion Pharmaceuticals, Alpine Immune Science, Argenx, BioCryst, GSK, Novartis, Otsuka Pharmaceutical, Vera Therapeutics

Ownership: Reliant Glycosciences LLC

Dr Perkovic reports the following disclosures:

Advisor for and/or led or served on the Steering Committees of trials funded by AbbVie, Alebund, Astra Zeneca, Bayer, Biogen, Boehringer Ingelheim, Cajal Consulting, CSL, Gilead, GSK, Guard Therapeutics, Incyte, Jade, Janssen, Mineralys, Novartis, Novo Nordisk, Otsuka, Purespring, Remegen, Sidera, Shanxi Micot, Sitala, Travere, and Tricida.

Other (board director; holds shares and options): Emerald Clinical

Introduction and recap to date: The VISIONARY trial

Dr Vlado Perkovic

IgA nephropathy is a progressive, immune-mediated kidney disease

Prevalence and disease burden



IgA nephropathy is the most common glomerulonephritis worldwide, with an annual global incidence of 2.5 cases/100,000 persons^{1,2}



Patients with IgA nephropathy report a considerable impact on their physical, mental, and emotional health that worsens with increased disease severity³



Despite supportive therapy, many patients remain at risk for progressing to kidney failure within 10 to 15 years of diagnosis^{4,5}

KDIGO 2025 IgA nephropathy guidelines recommend⁶:

A treatment goal of reducing the rate of loss of kidney function to **<1 mL/min/y** and proteinuria to <0.5 g/d (ideally <0.3 g/d)

The simultaneous management of **IgA nephropathy-specific drivers** and the generic response to IgA nephropathy-induced nephron loss

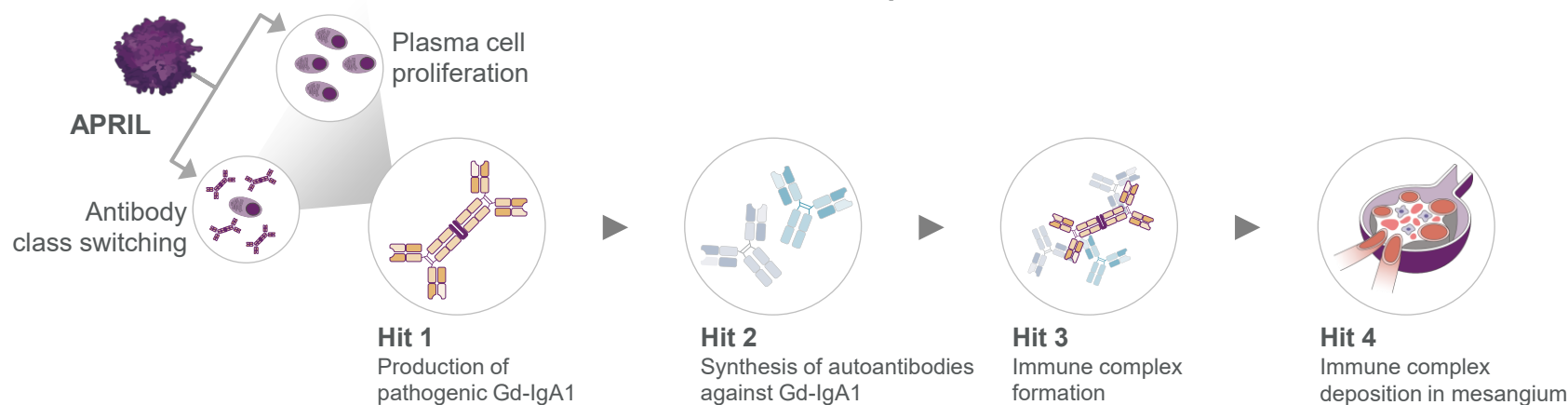
IgA, immunoglobulin A; KDIGO, Kidney Disease: Improving Global Outcomes.

1. Cheung CK, et al. *Front Nephrol*. 2024;3:1346769. 2. McGrogan A, et al. *Nephrol Dial Transplant*. 2011;26(2):414-430. 3. Kwon CS, et al. *J Health Econ Outcomes Res*. 2021;8(2):36-45. 4. Pitcher D, et al. *Clin J Am Soc Nephrol*. 2023;18(6):727-738. 5. Sim JJ, et al. *Nephrol Dial Transplant*. 2025;40(11):2104-2117. 6. KDIGO. *Kidney Int*. 2025;108(4S):S1-S71.

APRIL is a key driver of the 4-hit process of IgA nephropathy

- APRIL promotes antibody class switching in activated B cells and survival of plasma cells, leading to the production of IgA and pathogenic Gd-IgA1^{1,2}
- The outcome of the 4-hit process is kidney injury, which culminates in kidney damage³⁻⁶

APRIL and the 4-hit process⁷

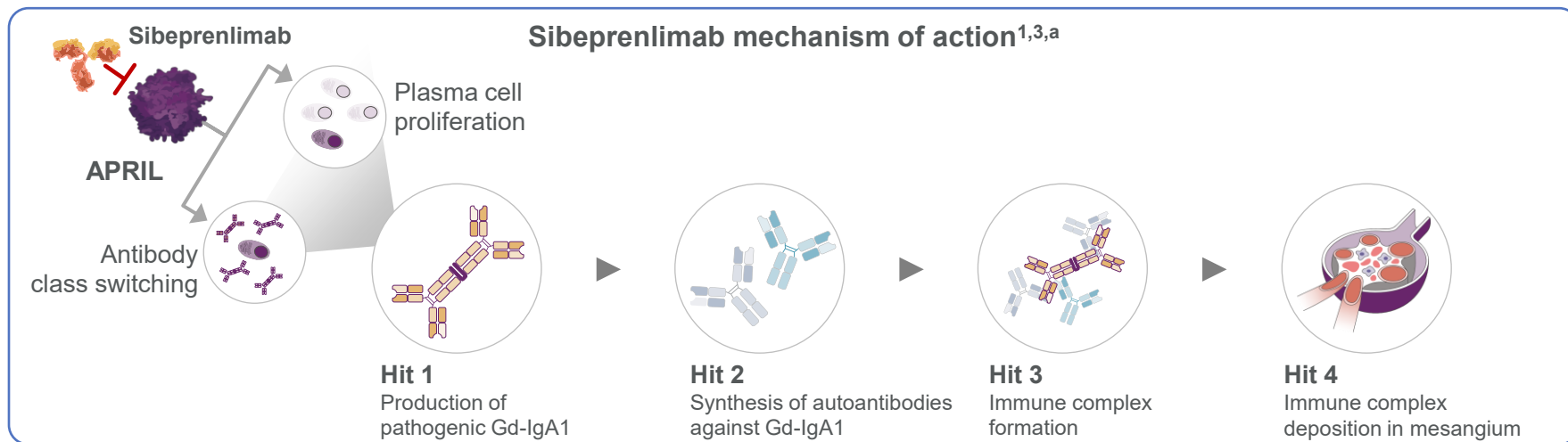


APRIL, a proliferation-inducing ligand; Gd-IgA1, galactose-deficient immunoglobulin A1; IgA, immunoglobulin A.

1. Chacko B, et al. *ASN Kidney News*. 2024;16(1):11-12. 2. Cheung CK, et al. *Front Nephrol*. 2024;3:1346769. 3. Suzuki H, et al. *J Am Soc Nephrol*. 2011;22(10):1795-1803. 4. Mathur M, et al. *J Clin Med*. 2023;12(21):6927. 5. Perše M, Večerić-Haler Ž. *Int J Mol Sci*. 2019;20(24):6199. 6. Lai KN, et al. *Nat Rev Dis Primers*. 2016;2:16001. 7. Cattran DC, et al. *Kidney Int Rep*. 2023;8(12):2515-2528.

Sibeprenlimab selectively binds to and blocks APRIL

- Sibeprenlimab is a humanized IgG2 mAb that selectively blocks APRIL¹
- Sibeprenlimab decreases Gd-IgA1 production and immune complex formation^{1,2}



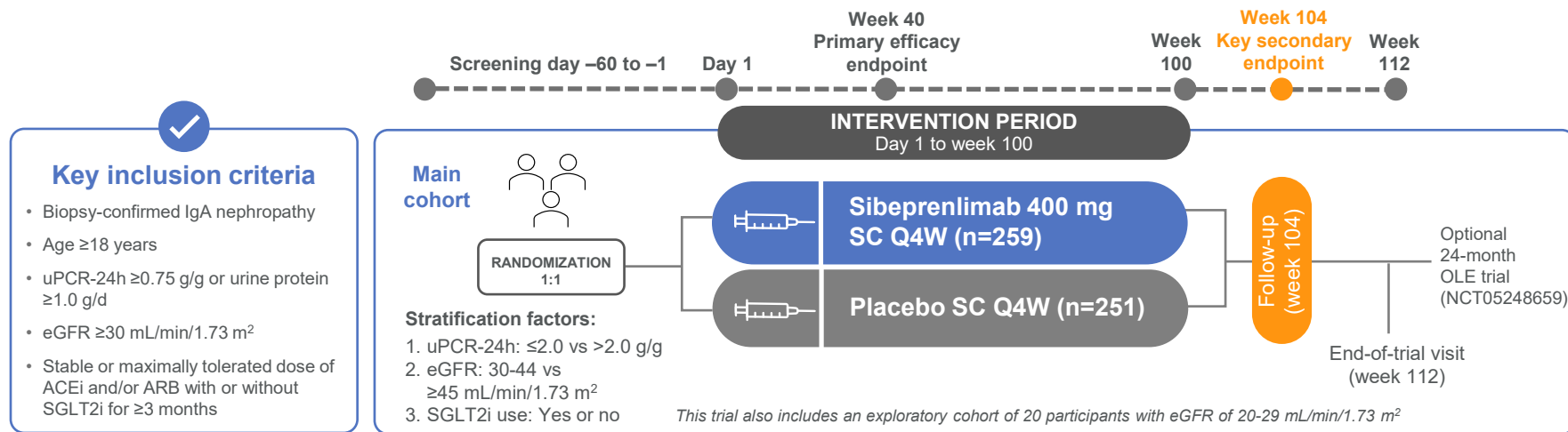
^aSibeprenlimab binds to APRIL in a 3:3 ratio.⁴

APRIL, a proliferation-inducing ligand; Gd-IgA1, galactose-deficient immunoglobulin A1; IgG2, immunoglobulin G2; mAb, monoclonal antibody.

1. Mathur M, et al. *N Engl J Med*. 2024;390(1):20-31. 2. Barratt J, et al. Presented at: American Society of Nephrology annual meeting; October 23-27, 2024; San Diego, CA (abstr FR-OR59). 3. Mathur M, et al. *J Clin Med*. 2023;12(21):6927.

4. Myette JR, et al. *Kidney Int*. 2019;96(1):104-116.

VISIONARY Phase 3: Trial design



510 patients were randomized 1:1 to sibeprenlimab 400 mg or placebo every 4 weeks for a 104-week treatment period, with an 8-week safety follow-up

VISIONARY Phase 3: uPCR-24h and spot uPCR

Change from baseline in uPCR-24h (g/g)
at month 9 (primary endpoint; ANCOVA)^{a,b}



Placebo:
2.1% increase
(95% CI: -8.5, 13)

n=168

Placebo-adjusted
treatment difference^c

51.2%

(96.5% CI: 42.9, 58.2; $P < 0.0001$)



Sibeprenlimab:
50.2% reduction
(95% CI: 44, 55.6)

n=152

Spot uPCR at month 9^d

At month 9, the mean change from baseline in spot uPCR showed **rapid separation** between the groups, with a substantial difference observed at 8 weeks and **sustained through 12 months**

The primary endpoint (9-month uPCR-24h) was met in the prespecified interim analysis of 320 patients

^aThe interim analysis set comprised the first 320 randomized participants who had the opportunity to complete the 9-month (week 40) 24-hour uPCR evaluation at the interim data cut. ^bThe percentage reduction of uPCR-24h at month 9 was compared with baseline using ANCOVA, calculated as $(1 - \text{GM of uPCR-24h ratio estimated from ANCOVA model}) \times 100\%$. ^cThe percentage reduction for treatment effect was calculated as $(1 - \text{ratio of GM of uPCR-24h ratio for sibeprenlimab 400 mg SC over placebo estimated from ANCOVA model}) \times 100\%$. The 95% CI corresponds to the treatment-specific reductions, while the 96.5% CI corresponds to the between-treatment difference, aligned with the predefined split alpha of 0.035 used for testing the 24-hour uPCR endpoint in the interim analysis. ^dAssessed using mixed model for repeated measures by visit as compared with baseline.

ANCOVA, analysis of covariance; CI, confidence interval; GM, geometric mean; SC, subcutaneous; uPCR, urine protein to creatinine ratio; uPCR-24h, urine protein to creatinine ratio based on 24-hour urine collections. Perkovic V, et al. *N Engl J Med*. 2026;394(7):635-646.

VISIONARY Phase 3: Endpoints and assessments

Analysis	Assessment	
Interim analysis, N=320 ^a		
Primary endpoint	Ratio of uPCR at 9 months vs baseline based on 24-hour urine collection	✓
Final analysis, N=510 ^b		
Key 2-year endpoint	Annualized slope of eGFR estimated over 24 months from week 4 ^c	Tested hierarchically in the following order
Secondary endpoints	Mean change of eGFR estimated from baseline at 24 months	
	Time to the first occurrence of a composite kidney outcome of kidney function decline or kidney failure ^d	
	Proportion of patients experiencing at least one composite kidney outcome event through 24 months	
Subgroups	Subgroup analysis of the annualized eGFR slope	
Post hoc	Sensitivity analysis of the annualized eGFR slope estimated from baseline through 24 months ^e	
Safety	Safety assessment of treatment-emergent adverse events (secondary endpoint) ^f	

The highlighted items will be discussed in this presentation

^aThe interim analysis set comprised the first 320 randomized patients who had the opportunity to complete the 9-month (week 40) uPCR-24h evaluation and had the baseline uPCR-24h evaluation at the interim data cut. ^bComprised the full analysis set, which included all randomized patients with available baseline assessment of the primary efficacy endpoint. ^cThe 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period, with first measurement starting from week 4 to week 104. ^dThe composite kidney outcome was defined as meeting one or more of the following criteria of sustained doubling of serum creatinine compared with baseline, sustained 40% reduction in eGFR compared with baseline, sustained eGFR <15 mL/min/1.73 m², or the requirement of kidney replacement therapy. ^eThe post hoc 24-month annualized eGFR slope evaluates the rate of eGFR change with the first measurement starting from baseline to week 104. ^fSafety set comprises all randomized patients who received at least one dose of study treatment (used for the analysis of safety endpoints).

eGFR, estimated glomerular filtration rate; uPCR, urine protein to creatinine ratio; uPCR-24h, 24-hour urine protein to creatinine ratio.

Statistical analysis

Endpoints and assessments ^{a,b}	Analysis plan
Final analysis (N=510)^c	
Key 2-year endpoint: annualized slope of eGFR estimated over 24 months	A linear mixed-effects model was used to model eGFR at each post-baseline visit, starting from week 4 through week 104
Secondary endpoint: mean change of eGFR estimated from baseline at 24 months	A mixed model for repeated measures was used to model the change from baseline of eGFR at each post-baseline visit, starting from week 4 through week 104
Secondary endpoint: safety ^d	Summary statistics for incidence of TEAEs
Post hoc sensitivity analysis	Analysis of the annualized eGFR slope estimated from baseline through week 104 using linear mixed-effects model

^aStatistical analysis shown for results included in this presentation. ^bFor all reported baseline measurements, baseline was defined as the last available assessment at or before the first dose of study treatment. ^cComprised the full analysis set, which included all randomized patients with available baseline assessment of the primary efficacy endpoint. ^dSafety set comprises all randomized patients who received at least one dose of study treatment (used for the analysis of safety endpoints). eGFR, estimated glomerular filtration rate; TEAEs, treatment-emergent adverse events.

24-month eGFR and safety results from the Phase 3 VISIONARY trial

Dr Dana Rizk

Baseline demographics (N=510)

Demographic characteristics	Sibeprenlimab 400 mg SC (n=259)	Placebo (n=251)
Age, years, median (range)	41.0 (18.0-75.0)	43.0 (18.0-83.0)
Sex, n (%)		
Female	103 (39.8)	107 (42.6)
Race, n (%)^a		
Asian	159 (61.4)	142 (56.6)
White	91 (35.1)	96 (38.2)
Black or African American	1 (0.4)	3 (1.2)
Other	8 (3.1)	10 (4.0)
Geographic region, n (%)^b		
East Asia	83 (32.0)	76 (30.3)
South/Southeast Asia	69 (26.6)	63 (25.1)
Europe	56 (21.6)	58 (23.1)
North America	35 (13.5)	30 (12.0)
South America	16 (6.2)	24 (9.6)

^aRace was reported by investigators at the trial sites.

^bNorth America includes Canada and United States of America; South America includes Argentina and Brazil; Europe includes Belgium, Czech Republic, Germany, Spain, France, United Kingdom, Greece, Croatia, Hungary, Israel, Italy, Netherlands, Poland, and Portugal; East Asia includes China, Hong Kong, Japan, Korea, and Taiwan; South/South East Asia includes Australia, India, Sri Lanka, Malaysia, Philippines, Singapore, Thailand, and Vietnam.

Baseline clinical characteristics (N=510)

Clinical characteristics ^a	Sibeprenlimab 400 mg SC (n=259)	Placebo (n=251)
Time from qualifying biopsy to randomization, median (range), years	1.3 (0.0-23.7)	1.5 (0.0-34.0)
Baseline uPCR-24h, g/g		
Mean (SD)	1.6 (1.0)	1.5 (0.8)
Median (range)	1.3 (0.5-7.8)	1.3 (0.5-5.5)
Baseline eGFR,^b mL/min/1.73 m²		
Mean (SD)	65.0 (25.0)	63.4 (25.7)
Median (range)	61.0 (25.0-134.0)	59.0 (27.0-130.0)
Prior use of immunosuppressive drugs,^c n (%)	14 (5.4)	8 (3.2)
Background regimen, n (%)		
RASi ^d	254 (98.1)	245 (97.6)
SGLT2i use ^e	112 (43.2)	119 (47.4)
Baseline dipstick hematuria, n (%)		
Positive ^f	206 (79.5)	183 (72.9)
Negative	53 (20.5)	68 (27.1)

^aBaseline measurements were defined as the last available assessment at or before the first dose of study treatment. ^bCalculated by the 2021 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation using serum creatinine.

^cPrevious use included systemic corticosteroids and other immunosuppressive drugs or therapies. ^dIncludes patients on an ACEi and/or ARB. ^eIncludes patients on ACEi and/or ARB and SGLT2i and those on SGLT2i only. ^fPositive dipstick hematuria is defined as trace, 1+, 2+, or 3+.

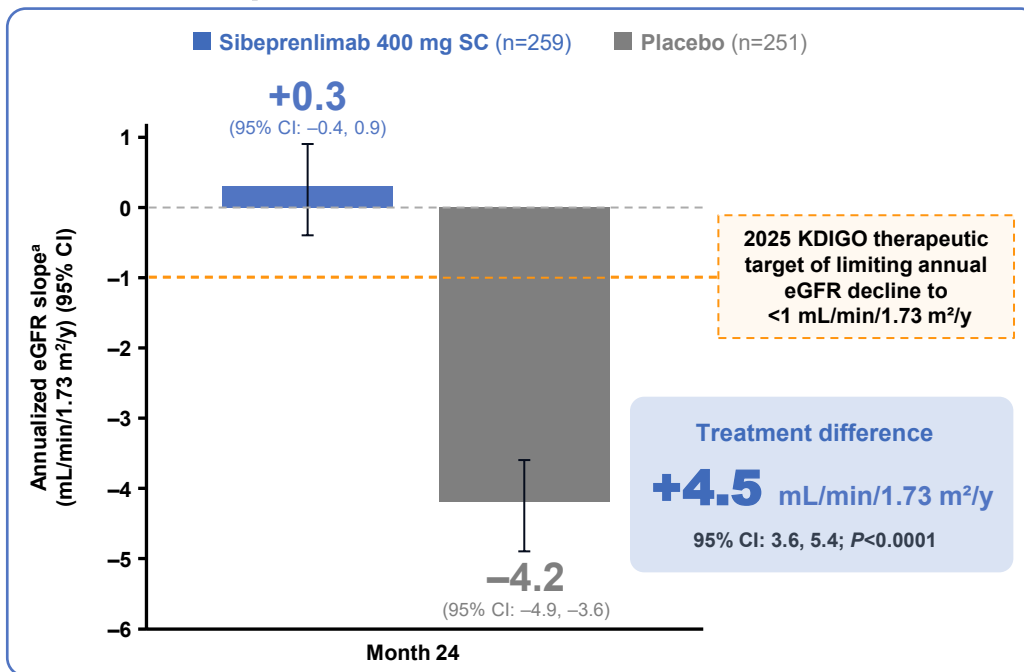
ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; eGFR, estimated glomerular filtration rate; RASi, renin-angiotensin system inhibitor; SC, subcutaneous; SD, standard deviation; SGLT2i, sodium-glucose cotransporter 2 inhibitor; uPCR, urine protein to creatinine ratio; uPCR-24h, 24-hour urine protein to creatinine ratio.

VISIONARY Phase 3: Endpoints and assessments

Analysis	Assessment
Interim analysis, N=320 ^a	
Primary endpoint	Ratio of uPCR at 9 months vs baseline based on 24-hour urine collection 
Final analysis, N=510 ^b	
Key 2-year endpoint	Annualized slope of eGFR estimated over 24 months from week 4 ^c 
Post hoc	Sensitivity analysis of the annualized eGFR slope estimated from baseline through 24 months ^d
Subgroups	Subgroup analysis of the annualized eGFR slope
Secondary endpoint	Mean change of eGFR estimated from baseline at 24 months
Safety	Safety assessment of treatment-emergent adverse events (secondary endpoint) ^e

^aThe interim analysis set comprised the first 320 randomized patients who had the opportunity to complete the 9-month (week 40) uPCR-24h evaluation and had the baseline uPCR-24h evaluation at the interim data cut. ^bComprised the full analysis set, which included all randomized patients with available baseline assessment of the primary efficacy endpoint. ^cThe 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period with first measurement starting from week 4 to week 104. ^dThe post hoc 24-month annualized eGFR slope evaluates the rate of eGFR change with the first measurement starting from baseline to week 104. ^eSafety set comprises all randomized patients who received at least one dose of study treatment (used for the analysis of safety endpoints).
eGFR, estimated glomerular filtration rate; uPCR, urine protein to creatinine ratio.

Annualized eGFR slope estimated over 24 months



^aAnnualized slope of eGFR was estimated over 24 months using a linear mixed model. The 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period, with first measurement starting from week 4 to week 104. CI, confidence interval; eGFR, estimated glomerular filtration rate; KDIGO, Kidney Disease: Improving Global Outcomes; SC, subcutaneous.

VISIONARY Phase 3: Endpoints and assessments

Analysis	Assessment	
Interim analysis, N=320^a		
Primary endpoint	Ratio of uPCR at 9 months vs baseline based on 24-hour urine collection	
Final analysis, N=510^b		
Key 2-year endpoint	Annualized slope of eGFR estimated over 24 months (at week 4)^c	
Post hoc	Sensitivity analysis of the annualized eGFR slope estimated from baseline through 24 months^d	
Subgroups	Subgroup analysis of the annualized eGFR slope	
Secondary endpoint	Mean change of eGFR estimated from baseline at 24 months	
Safety	Safety assessment of treatment-emergent adverse events (secondary endpoint)^e	

^aThe interim analysis set comprised the first 320 randomized patients who had the opportunity to complete the 9-month (week 40) uPCR-24h evaluation and had the baseline uPCR-24h evaluation at the interim data cut. ^bComprised the full analysis set, which included all randomized patients with available baseline assessment of the primary efficacy endpoint. ^cThe 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period with first measurement starting from week 4 to week 104. ^dThe post hoc 24-month annualized eGFR slope evaluates the rate of eGFR change with the first measurement starting from baseline to week 104. ^eSafety set comprises all randomized patients who received at least one dose of study treatment (used for the analysis of safety endpoints).
eGFR, estimated glomerular filtration rate; uPCR, urine protein to creatinine ratio.

Post hoc sensitivity analysis of the annualized eGFR slope estimated from baseline

Treatment	n	Annualized eGFR slope ^a (mL/min/1.73 m ² /y) (95% CI)	Slope difference (mL/min/1.73 m ² /y) (95% CI)
Sibeprenlimab 400 mg SC	259	+0.5 (-0.2, 1.1)	+4.7 (3.8, 5.6)
Placebo	251	-4.2 (-4.9, -3.6)	

^aPost hoc analysis of annualized slope of eGFR, was estimated over 24 months using a linear mixed model. The 24-month annualized eGFR slope evaluates the rate of eGFR change with the first measurement starting from baseline to week 104. CI, confidence interval; eGFR, estimated glomerular filtration rate; SC, subcutaneous.

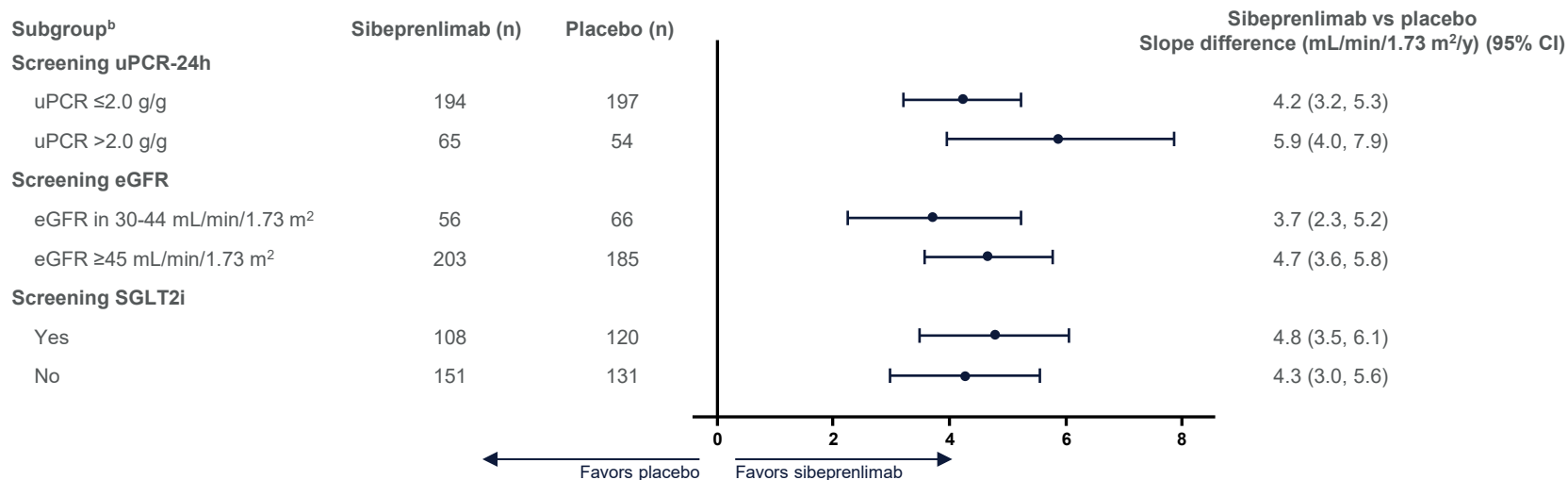
VISIONARY Phase 3: Endpoints and assessments

Analysis	Assessment	
Interim analysis, N=320^a		
Primary endpoint	Ratio of uPCR at 9 months vs baseline based on 24-hour urine collection	
Final analysis, N=510^b		
Key 2-year endpoint	Annualized slope of eGFR estimated over 24 months (at week 4)^c	
Post hoc	Sensitivity analysis of the annualized eGFR slope estimated from baseline through 24 months^d	
Subgroups	Subgroup analysis of the annualized eGFR slope	
Secondary endpoint	Mean change of eGFR estimated from baseline at 24 months	
Safety	Safety assessment of treatment-emergent adverse events (secondary endpoint)^e	

^aThe interim analysis set comprised the first 320 randomized patients who had the opportunity to complete the 9-month (week 40) uPCR-24h evaluation and had the baseline uPCR-24h evaluation at the interim data cut. ^bComprised the full analysis set, which included all randomized patients with available baseline assessment of the primary efficacy endpoint. ^cThe 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period with first measurement starting from week 4 to week 104. ^dThe post hoc 24-month annualized eGFR slope evaluates the rate of eGFR change with the first measurement starting from baseline to week 104. ^eSafety set comprises all randomized patients who received at least one dose of study treatment (used for the analysis of safety endpoints).
eGFR, estimated glomerular filtration rate; uPCR, urine protein to creatinine ratio.

Subgroup analysis of annualized eGFR slope

Change in annualized eGFR slope^a over 24 months, according to stratification factors



^aAnnualized slope of eGFR was estimated over 24 months using a linear mixed model. The 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period with first measurement starting from week 4 to week 104.

^bBased on IRT record.

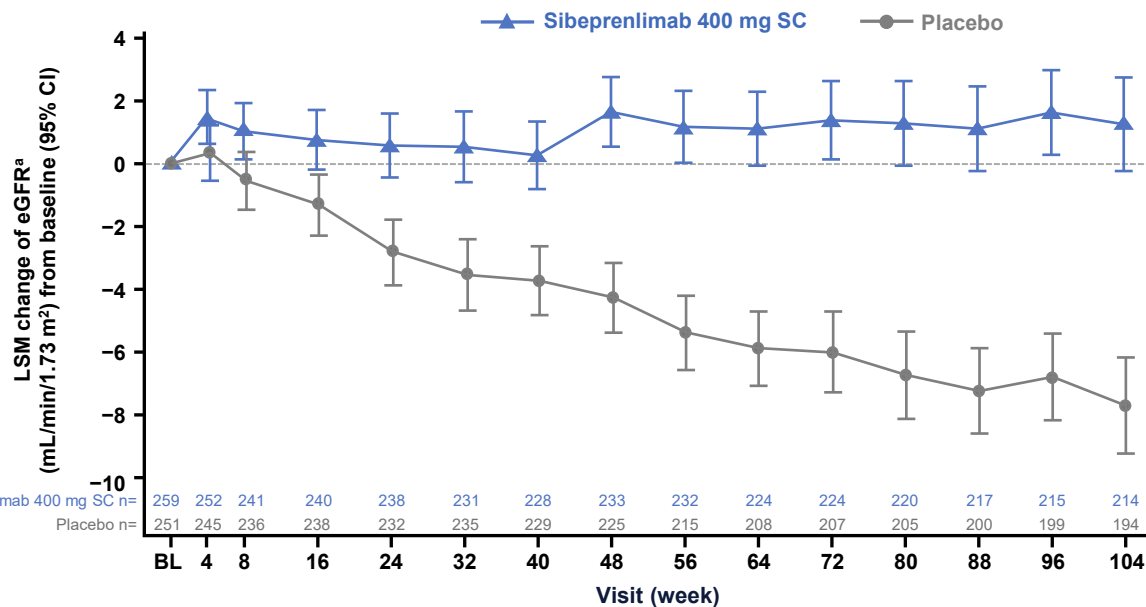
CI, confidence interval; eGFR, estimated glomerular filtration rate; IRT, interactive response technology; SC, subcutaneous; SGLT2i, sodium-glucose cotransporter-2 inhibitor; uPCR, urine protein to creatinine ratio.

VISIONARY Phase 3: Endpoints and assessments

Analysis	Assessment	
Interim analysis, N=320^a		
Primary endpoint	Ratio of uPCR at 9 months vs baseline based on 24-hour urine collection	
Final analysis, N=510^b		
Key 2-year endpoint	Annualized slope of eGFR estimated over 24 months from week 4^c	
Post hoc	Sensitivity analysis of the annualized eGFR slope estimated from baseline through 24 months^d	
Subgroups	Subgroup analysis of the annualized eGFR slope	
Secondary endpoint	Mean change of eGFR estimated from baseline at 24 months	
Safety	Safety assessment of treatment-emergent adverse events (secondary endpoint)^e	

^aThe interim analysis set comprised the first 320 randomized patients who had the opportunity to complete the 9-month (week 40) uPCR-24h evaluation and had the baseline uPCR-24h evaluation at the interim data cut. ^bComprised the full analysis set, which included all randomized patients with available baseline assessment of the primary efficacy endpoint. ^cThe 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period with first measurement starting from week 4 to week 104. ^dThe post hoc 24-month annualized eGFR slope evaluates the rate of eGFR change with the first measurement starting from baseline to week 104. ^eSafety set comprises all randomized patients who received at least one dose of study treatment (used for the analysis of safety endpoints).
eGFR, estimated glomerular filtration rate; uPCR, urine protein to creatinine ratio.

Change from baseline in eGFR over 24 months



At week 104^b:
+1.3 mL/min/1.73 m²
(95% CI: -0.3, 2.8)

Treatment difference
+9.2 mL/min/1.73 m²
95% CI: 7.1-11.4; P<0.0001

At week 104^b:
-7.9 mL/min/1.73 m²
(95% CI: -9.5, -6.4)

Error bars are 95% CI.

^aAnalysis used a mixed model for repeated measures. ^bWeek 104 corresponds to month 24.

BL, baseline; CI, confidence interval; eGFR, estimated glomerular filtration rate; LSM, least-squares mean.

VISIONARY Phase 3: Endpoints and assessments

Analysis	Assessment	
Interim analysis, N=320^a		
Primary endpoint	Ratio of uPCR at 9 months vs baseline based on 24-hour urine collection	
Final analysis, N=510^b		
Key 2-year endpoint	Annualized slope of eGFR estimated over 24 months from week 4^c	
Post hoc	Sensitivity analysis of the annualized eGFR slope estimated from baseline through 24 months^d	
Subgroups	Subgroup analysis of the annualized eGFR slope	
Secondary endpoint	Mean change of eGFR estimated from baseline at 24 months	
Safety	Safety assessment of treatment-emergent adverse events (secondary endpoint)^e	

^aThe interim analysis set comprised the first 320 randomized patients who had the opportunity to complete the 9-month (week 40) uPCR-24h evaluation and had the baseline uPCR-24h evaluation at the interim data cut. ^bComprised the full analysis set, which included all randomized patients with available baseline assessment of the primary efficacy endpoint. ^cThe 24-month annualized eGFR slope evaluates the rate of eGFR change during planned treatment period with first measurement starting from week 4 to week 104. ^dThe post hoc 24-month annualized eGFR slope evaluates the rate of eGFR change with the first measurement starting from baseline to week 104. ^eSafety set comprises all randomized patients who received at least one dose of study treatment (used for the analysis of safety endpoints).
eGFR, estimated glomerular filtration rate; uPCR, urine protein to creatinine ratio.

Safety

Adverse events occurring during the treatment period in the main cohort^a

	Sibeprenlimab 400 mg SC (n=259)	Placebo (n=251)
	<i>number of patients (%)</i>	
Treatment-emergent adverse event (TEAE) occurring during treatment period^b	235 (90.7)	226 (90.0)
Treatment-related adverse events (TRAEs)	91 (35.1)	82 (32.7)
Serious TEAEs occurring during treatment period	21 (8.1)	32 (12.7)
Infections and infestations	5 (1.9)	10 (4.0)
Serious TRAEs	2 (0.8)	3 (1.2)
Severe TEAEs occurring during treatment period	10 (3.9)	19 (7.6)
TEAEs leading to discontinuation of sibeprenlimab or placebo	3 (1.2)	10 (4.0)
Deaths	0	0

^aThe safety population consisted of all the patients who received at least one dose of sibeprenlimab or placebo. ^bAdverse events are coded according to the Medical Dictionary for Regulatory Activities (MedDRA), version 29.0. SC, subcutaneous; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

Safety (Cont'd)

Adverse events occurring in ≥5% of patients during the treatment period in the main cohort^a

	Sibeprenlimab 400 mg SC (n=259)	Placebo (n=251)
	<i>number of patients (%)</i>	
TEAEs in ≥5% of patients in either trial group^b		
Any adverse event	188 (72.6)	204 (81.3)
Infections and infestations	133 (51.4)	128 (51.0)
Upper respiratory tract infection	58 (22.4)	53 (21.1)
Nasopharyngitis	51 (19.7)	48 (19.1)
Influenza	38 (14.7)	29 (11.6)
COVID 19	31 (12.0)	22 (8.8)
Gastroenteritis	14 (5.4)	17 (6.8)
Injection-site erythema	41 (15.8)	36 (14.3)
Injection-site pain	30 (11.6)	27 (10.8)
Injection-site swelling	20 (7.7)	18 (7.2)
Diarrhea	30 (11.6)	24 (9.6)
Pyrexia	25 (9.7)	16 (6.4)
Edema peripheral	9 (3.5)	23 (9.2)

^aThe safety population consisted of all the patients who received at least one dose of sibeprenlimab or placebo. ^bAdverse events are coded according to the Medical Dictionary for Regulatory Activities (MedDRA), version 29.0. SC, subcutaneous; TEAE, treatment-emergent adverse event.

Conclusions



Sibeprenlimab, a selective APRIL blocker, demonstrated stable eGFR over 24 months compared with continued decline in placebo-treated patients



The eGFR effects in the VISIONARY trial are the largest reported to date for a Phase 3 trial in IgA nephropathy and meet the eGFR treatment goal proposed by the 2025 KDIGO IgA nephropathy guideline ($<1 \text{ mL/min/1.73 m}^2/\text{y}$)



Sibeprenlimab showed consistent treatment effects across prespecified stratification subgroups, indicating broad therapeutic applicability in patients with IgA nephropathy



At 24 months, safety remained favorable, with similar rates of overall adverse events and infections between groups



Further analysis of the VISIONARY two-year results will be presented at an upcoming scientific congress



THANK YOU!

We sincerely thank the patients and their families, investigators, study site personnel, and all clinical and operational teams whose dedication and collaboration made the Phase 3 VISIONARY trial possible



Investigators and study sites

JUDITH BELLS
Preeti Chandra
James Tumlin
Lama Nouredine
Ashraf El-Meanawy
Olga Zhdanova
Evamaria Anvari
Leslie Thomas*
Anjali Acharya
Ankur Shah
Kumar Sharma
Meghan Sise
Richard Lafayette
George Fadda
Sayna Norouzi
Elizabeth Nguyen
Ashar Luqman
Jingyin Yan
Cristiane Carvalho
Raymond Hsu
Bernard Fischbach
Rania El Fekih
Saif Muhsin*

Vietnam

Vu Thi Minh Hoa
Cuong Nguyen
Phan Ngoc Tam