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Sibeprenlimab in IgA Nephropathy: Phase 3 VISIONARY Kidney Outcomes Data

TH-PO1258

Dana V. Rizk, MD,[1] Jonathan Barratt, PhD,[2] Yusuke Suzuki, MD, PhD,[3] Hong Zhang, MD, PhD,[4] Muh Geot Wong, MBBS, FRCP, PhD,[5] Adrian Liew, MBBS, MRCP,[6] Richard Lafayette, MD,[7] Vladimír Tesař, MD, PhD,[8] Hernán Trimarchi, MD, PhD,[9] Kevin Carroll, PhD,[10] Ian S.D. Roberts, MBChB, FRCPath,[11] Vivekanand Jha, MD,[12-14] Alejandra Quevedo, MD,[15] Seung Hyeok Han, MD, PhD,[16] Rosnawati Yahya, FRCP, MBBCh, MRCP,[17] Chee Kay Cheung, MBChB, PhD,[2,18] Raja Ramachandran, DM, MD,[19] Michael Walsh, PhD,[20,21] Bobby Chacko, MD, DM, FRACP,[22] Manuel Praga, PhD,[23] Jin-Bor Chen, MD,[24] José Suassuna, MD, PhD,[25] Jing Xia, PhD,[26] Lokesh Shah, MD, MS,[26] and Vlado Perkovic, MB, BS, PhD[27] for the VISIONARY Trial Investigators Group

[1]Division of Nephrology, Department of Medicine, Heersink School of Medicine, University of Alabama at Birmingham, Birmingham, AL; [2]University of Leicester, Leicester, United Kingdom; [3]Juntendo University Faculty of Medicine, Tokyo, Japan; [4]Peking University First Hospital, Beijing, China; [5]Concord Repatriation General Hospital, Concord, Australia; [6]Mount Elizabeth Novena Hospital, Singapore; [7]Stanford University Medical Center, Stanford, CA; [8]General University Hospital, Charles University, Prague, Czech Republic; [9]Hospital Británico, Buenos Aires, Argentina; [10]KJC Statistics Ireland Ltd., Dublin, Ireland; [11]Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom; [12]Manipal Academy of Higher Education, Manipal, India; [13]School of Public Health, Imperial College London, London, United Kingdom; [14]George Institute for Global Health, UNSW, New Delhi, India; [15]Investigación Clínica Aplicada SRL, Buenos Aires, Argentina; [16]Yonsei University College of Medicine, Seoul, Republic of Korea; [17]Sunway Medical Centre, Kuala Lumpur, Malaysia; [18]University Hospitals of Leicester NHS Trust, United Kingdom; [19]Department of Nephrology, Postgraduate Institute of Medical Education and Research, Chandigarh, India; [20]Department of Medicine, McMaster University, Hamilton, Ontario, Canada; [21]Population Health Research Institute, Hamilton Health Sciences, McMaster University, Hamilton, Ontario, Canada; [22]Nephrology and Transplantation, John Hunter Hospital and University of Newcastle, Newcastle, New South Wales, Australia; [23]Department of Medicine, Complutense University, Madrid, Spain; [24]Division of Nephrology, Kaohsiung Chang Gung Memorial Hospital, Chang Gung University College of Medicine, Taiwan; [25]Clinical and Academic Unit of Nephrology, Rio de Janeiro State University, Rio de Janeiro, Brazil; [26]Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ; [27]University of New South Wales, Sydney, Australia

BACKGROUND

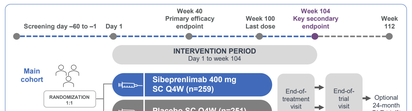
- Sibeprenlimab is a humanized IgG2 monoclonal antibody that selectively blocks a proliferation-inducing ligand (APRIL), a key driver of IgA nephropathy pathogenesis[1-3]
- In the prespecified interim analysis of the VISIONARY trial (NCT05248646),[4] sibeprenlimab significantly reduced proteinuria at 9 months from baseline, as compared with placebo (primary endpoint)[3]
- This final 24-month analysis provides the first report of the effect of selective APRIL inhibition on kidney function decline and kidney failure in a Phase 3 IgA nephropathy trial

METHODS

- VISIONARY: randomized, double-blind, placebo-controlled trial (**Figure 1**)[3]

Figure 1. Study design[3]

Key inclusion criteria
- Biopsy-confirmed IgA nephropathy
- Age ≥18 years
- uPCR ≥0.75 g/g or urine protein ≥1.0 g/d
- eGFR ≥30 mL/min/1.73 m²
- Stable or maximally tolerated dose of ACEi and/or ARB with or without SGLT2i for ≥3 months



Endpoints and assessments

Efficacy

Proteinuria
- Ratio of uPCR at 9 months vs baseline based on 24-hour urine collection *(primary)*[3]
- Change in spot uPCR from baseline at 24 months (*exploratory*)

eGFR
- Annualized slope of eGFR over 24 months *(key secondary)*
- Mean change of eGFR from baseline at 24 months *(secondary)*

Composite kidney outcome *(secondary)*
- Time to the first occurrence of a composite kidney outcome (sustained 40% reduction in eGFR, sustained doubling of serum creatinine, sustained eGFR <15 mL/min/1.73 m², or requirement for kidney replacement therapy)
- Incidence of patients experiencing at least one composite kidney outcome event through 24 months

Hematuria *(exploratory)*
- Dipstick hematuria over time as compared with baseline

Biomarkers

Pharmacodynamics
- Change from baseline in total serum IgA, IgG, and IgM (*secondary*)
- Evaluation of free APRIL and serum Gd-IgA1 concentrations over time (*exploratory*)

Safety
- Safety assessment of treatment-emergent adverse events (*secondary*)

[a]Patients who completed ≥20 doses and the end-of-trial visit at week 112 were eligible to enter an open-label extension trial (NCT05248659).[5]

RESULTS

- Demographics and clinical characteristics were balanced among the 510 randomized patients (**Table 1**)

Table 1. Demographic and clinical characteristics

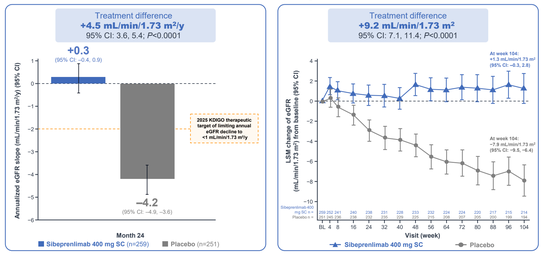
	Sibeprenlimab 400 mg SC (n=259)	Placebo (n=251)
Age, years, median (range)	41.0 (18.0-75.0)	43.0 (18.0-83.0)
Sex, female, n (%)	103 (39.8)	107 (42.6)
Asian race, n (%)	159 (61.4)	142 (56.6)
White race, n (%)	91 (35.1)	96 (38.2)
Black or African American race, n (%)	1 (0.4)	3 (1.2)
Other race, n (%)	8 (3.1)	10 (4.0)
Baseline uPCR-24h, g/g, mean (SD)	1.6 (1.0)	1.5 (0.8)
Baseline eGFR, mL/min/1.73 m², mean (SD)	65.0 (25.0)	63.4 (25.7)
Prior use of immunosuppressive drugs,[a] n (%)	14 (5.4)	8 (3.2)
RASi[b] background regimen, n (%)	254 (98.1)	245 (97.6)
SGLT2i use[c] background regimen, n (%)	112 (43.2)	119 (47.4)
Positive[d] baseline dipstick hematuria, n (%)	206 (79.5)	183 (72.9)
Negative baseline dipstick hematuria, n (%)	53 (20.5)	68 (27.1)

[a]Includes systemic corticosteroids and other immunosuppressive drugs or therapies. [b]Includes ACEi and/or ARB. [c]Includes SGLT2i only or in combination with ACEi and/or ARB. [d]Positive dipstick hematuria is defined as trace, 1+, 2+, or 3+.

Efficacy: eGFR and composite kidney outcome

- Between-group difference in annualized eGFR slope estimated over 24 months: 4.5 mL/min/1.73 m²/y (95% CI: 3.6, 5.4; *P*<0.0001) (**Figure 2A**)
- Between-group difference in least-squares mean change in eGFR from baseline at 24 months: 9.2 mL/min/1.73 m² (95% CI: 7.1, 11.4; *P*<0.0001) (**Figure 2B**)

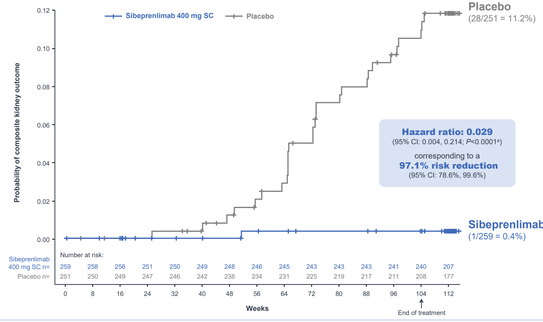
Figure 2. eGFR



[a]Annualized slope estimated during planned treatment period with first measurement starting week 4, through week 104, using a linear mixed-effects model. [b]Analyzed by the repeated measures model.

- Time to progression to first occurrence of a composite kidney event favored sibeprenlimab vs placebo (hazard ratio, 0.029; 95% CI: 0.004, 0.214; *P*<0.0001), corresponding to a 97.1% risk reduction (**Figure 3**)
- Fewer patients progressed to at least one composite kidney outcome event with sibeprenlimab vs placebo (**Table 2**), and the adjusted incidence difference was −10.8% (95% CI: −14.8, −6.9)

Figure 3. Progression to composite kidney outcome



[a]Stratified log-rank test was used to obtain *P* value. Cox proportional hazards model was used for the hazard ratio and its CI.

Table 2. Components of the composite kidney outcome

Number of patients	Sibeprenlimab 400 mg SC (n=259)	Placebo (n=251)
Proportion of patients experiencing ≥1 event (%)	0.4	11.2
Odds ratio[a]	0.026 (95% CI: 0.003, 0.197; *P*<0.001)	
Adjusted incidence difference	−10.8% (95% CI: −14.8, −6.9)	
Sustained 40% reduction in eGFR	1	28
Sustained doubling of serum creatinine	0	13
Sustained eGFR <15 mL/min/1.73 m²	1	10
Kidney replacement therapy	0	5

[a]Incidence of the composite kidney outcome was compared using a logistic regression model.

Biomarkers

- Mean percentage change from baseline over 24 months in sibeprenlimab vs placebo groups was respectively:
  - IgA: −74.8% vs 4.2%; IgG: −37.4% vs 5.8%; IgM: −77.4% vs 1.1%
  - Gd-IgA1: −63.0% vs 19.5%; APRIL: −95.8% vs −3.0%

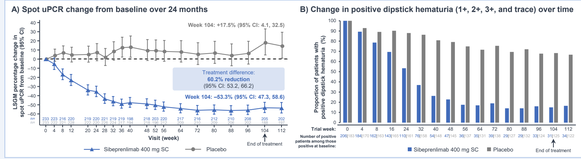
CONCLUSIONS

- Sibeprenlimab, a selective APRIL blocker, demonstrated stabilization of eGFR and reduced the risk of significant kidney function decline or kidney failure by 97.1% over 24 months. In addition, sibeprenlimab showed sustained reductions in Gd-IgA1 and proteinuria and greater resolution of dipstick hematuria
- The safety profile of sibeprenlimab was comparable to placebo, including overall AEs, infection rates, and injection-site reactions
- By achieving the 2025 KDIGO eGFR preservation target (<1 mL/min/1.73 m²/y),[6] reducing the risk of progression to kidney function loss and kidney failure, and reducing disease biomarkers, sibeprenlimab has the potential for disease modification and long-term kidney protection in IgA nephropathy

Efficacy: Proteinuria and hematuria

- The adjusted between-group difference in spot uPCR was a 60.2% (95% CI: 53.2, 66.2) reduction (**Figure 4A**)
- Hematuria resolution (negative dipstick) occurred in 162/206 patients (78.6%) with sibeprenlimab vs 37/183 in the placebo group (20.2%) (**Figure 4B**)

Figure 4. Change in spot uPCR and dipstick hematuria



Safety

Table 3. Adverse events during the treatment period (MedDRA v29.0)

	Sibeprenlimab 400 mg SC (n=259)	Placebo (n=251)
	Number of patients (%)	
TEAEs occurring during treatment period	235 (90.7)	226 (90.0)
TRAEs	91 (35.1)	82 (32.7)
Serious TEAEs occurring during treatment period	21 (8.1)	32 (12.7)
Serious 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
Overall TEAEs (≥5%) in either trial group	188 (72.6)	204 (81.3)
Infections and infestations	133 (51.4)	128 (51.0)
Injection-site reactions (erythema, pain, swelling)	91 (35.1)	81 (32.3)

- Safety was comparable between groups, including overall AEs, infections, and injection-site reactions. There was no increase in serious infections, and no deaths were reported (**Table 3**)

ABBREVIATIONS

ADA, anti-drug antibody; ACEi, angiotensin-converting enzyme inhibitor; AE, adverse event; APRIL, a proliferation-inducing ligand; ARB, angiotensin receptor blocker; BL, baseline; CI, confidence interval; eGFR, estimated glomerular filtration rate; Gd-IgA1, galactose-deficient immunoglobulin A1; Ig, immunoglobulin; KDIGO, Kidney Disease: Improving Global Outcomes; LSGM, least-squares geometric mean; LSM, least-squares mean; MedDRA, Medical Dictionary for Regulatory Activities; OLE, open-label extension; Q4W, every 4 weeks; RASi, renin-angiotensin system inhibitor; SC, subcutaneous; SD, standard deviation; SGLT2i, sodium-glucose cotransporter 2 inhibitor; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; uPCR, urine protein to creatinine ratio; uPCR-24h, 24-hour urine protein to creatinine ratio.

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DISCLOSURES

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