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Enclosure:

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Effect of Sibeprenlimab on eGFR in Adults With IgA Nephropathy: A Prespecified Interim Analysis of the VISIONARY Phase 3 Trial

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INTRODUCTION

- Sibeprenlimab is a humanized IgG2 monoclonal antibody that selectively blocks APRIL, a key driver of IgA nephropathy pathogenesis[1]
- In a prespecified IA of the global phase 3 VISIONARY trial (NCT05248648), treatment with sibeprenlimab resulted in a placebo-adjusted reduction in uPCR-24h of 51.2% (96.5% CI, 42.9%-58.2%; *P*<0.0001) at 9 months (primary endpoint) and 54.3% (95% CI, 46.4%-60.9%) at 12 months (exploratory endpoint)[1]
- At the time of the interim analysis, regulatory agencies requested that eGFR data not be reported while participants were still undergoing treatment in the VISIONARY trial. As all participants have completed the randomized treatment period, we now report effects of sibeprenlimab on eGFR at the interim analysis time point

AIM

- To assess the effects of sibeprenlimab on eGFR in a prespecified exploratory analysis at 12 months

METHODS

Phase 3 randomized, double-blind, placebo-controlled study in adults with biopsy-proven IgA nephropathy

240 sites in 31 countries

Randomized 1:1 to sibeprenlimab (400 mg SC Q4W) or placebo

Primary endpoint: uPCR-24h vs baseline at 9 months
Exploratory endpoints: Annualized slope of eGFR and eGFR change from baseline at 12 months[b]

RESULTS

- 320 patients (sibeprenlimab, n=152; placebo, n=168) were included in the analysis

Table 1. Baseline demographic and clinical characteristics

Baseline characteristics	Sibeprenlimab (n=152)	Placebo (n=168)
Median age (range), y	42 (18-75)	43 (18-83)
Sex, female, n (%)	52 (34.2)	68 (40.5)
Mean uPCR-24h (SD), g/g	1.58 (1.09)	1.50 (0.84)
Mean eGFR (SD), mL/min/1.73 m^2	63.5 (24.4)	63.4 (25.3)
SGLT2i use, yes, n (%)	54 (35.5)	72 (42.9)

Table 2. Annualized eGFR slope estimated over 12 months

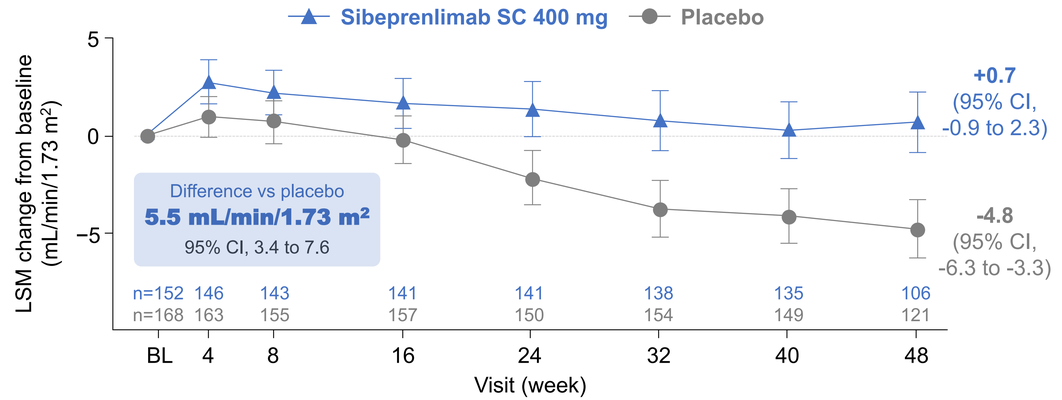
Treatment	Annualized slope (95% CI) (mL/min/1.73 m^2 per year)
Sibeprenlimab (n=152)	−3.0 (−4.6, −1.4)
Placebo (n=168)	−7.6 (−9.1, −6.1)

Treatment effect vs placebo
4.6 mL/min/1.73 m^2
95% CI, 2.5 to 6.8

Analysis used a linear mixed model. Errors bars are 95% CI.

- The rate of eGFR decline over 12 months was slower with sibeprenlimab than with placebo

Figure 1. LSM change from baseline in eGFR over 12 months



Analysis used a linear mixed model using a mixed model for repeated measures. Error bars are 95% CI.

CONCLUSIONS

- In the prespecified IA, treatment with sibeprenlimab resulted in a slower eGFR decline over 12 months relative to placebo
- IA results from the Phase 3 VISIONARY trial are consistent with the Phase 2 ENVISION trial,[2] providing evidence to support the potential of sibeprenlimab to slow eGFR decline, which may result in preservation of kidney function relative to placebo through 24 months
- The VISIONARY trial will evaluate long-term safety, annualized slope of eGFR (key secondary efficacy endpoint), and eGFR change from baseline (secondary efficacy endpoint) over 24 months; additional longer-term assessments are planned in the Phase 2/3 open-label extension study (NCT05248659)

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ABBREVIATIONS

APRIL, a proliferation-inducing ligand; BL, baseline; eGFR, estimated glomerular filtration rate; IA, interim analysis; Ig, immunoglobulin; LSM, least-squares mean; Q4W, once every 4 weeks; SC, subcutaneous; SGLT2i, sodium-glucose cotransportor-2 inhibitor; uPCR-24h, 24-hour urine protein to creatinine ratio.

FOOTNOTES

[a]Employee of Otsuka Pharmaceutical Development & Commercialization, Inc. at the time of submission.
[b]12 months: Month 12 corresponds to 48 weeks

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