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Enclosure:

- ABSTRACT: Suzuki H, Jha V, Walsh M, et al. Poster Presented at: ISN World Congress of Nephrology 2026 (WCN'26); March 28-31, 2026; Yokohama, Japan

Otsuka ABSTRACT

# Effect of Sibeprenlimab on Hematuria in Adults With IgA Nephropathy: Interim Analysis of the VISIONARY Phase 3 Trial

**Authors:** Suzuki H, Jha V, Walsh M, et al.

## Rationale

- Hematuria is a hallmark of active glomerular injury and a common clinical manifestation of IgA nephropathy[1-3]
- Persistent hematuria is associated with increased risk of kidney function decline and poor prognosis[1-3]

## VISIONARY Overview

**Sibeprenlimab SC 400 mg Q4W (n=259)**

**Placebo SC Q4W (n=251)**

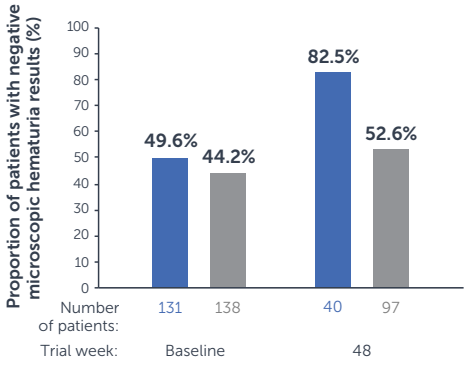
Ongoing, randomized, multicenter, double-blind, placebo-controlled trial evaluating sibeprenlimab vs placebo in adults with IgA nephropathy[4]

At the prespecified interim analysis, sibeprenlimab achieved a **51.2% (*P*<0.001)** placebo-adjusted **reduction** in uPCR-24h after 9 months[4,a]

Sibeprenlimab was generally well tolerated, with **no significant safety concerns** or imbalance of infection risk[4]

## Results[5,6]

**Patients with negative microscopic hematuria based on RBC count**
(0-5/HPF)

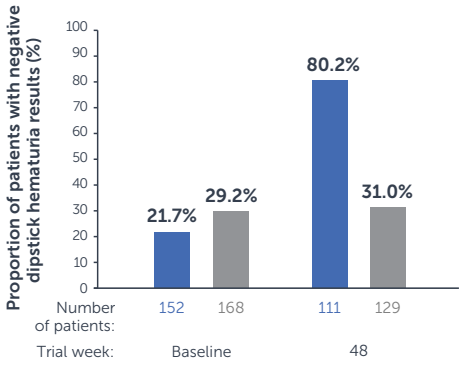



Change in hematuria based on RBC count (>5/HPF) and dipstick test (1+, 2+, 3+ and trace) over time was evaluated as an **exploratory endpoint**

Sibeprenlimab SC 400 mg

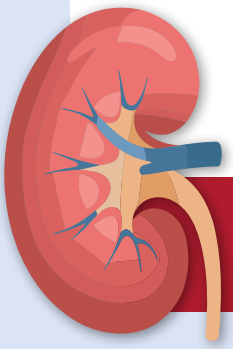
Placebo

**Negative hematuria based on absence of trace or greater on dipstick**




The total number of patients at baseline excludes the patients who were lacking RBC count data at baseline (sibeprenlimab: n=21; placebo: n=30).

## Key Takeaways (scan the QR code to learn more)



- In the interim analysis of the VISIONARY trial, patients treated with sibeprenlimab **demonstrated a greater reduction of microscopic and dipstick hematuria** compared with placebo[6]
- Interpretation of hematuria outcomes is limited by nonstandardized definitions, testing, and variability in urine sample timing and handling, reducing comparability across studies. Hematuria remains an unvalidated exploratory endpoint in clinical trials[1]

**These findings complement sibeprenlimab's effect on Gd-IgA1 and proteinuria, supporting its potential as a disease-modifying therapy in IgA nephropathy by inhibiting APRIL and reducing pathogenic Gd-IgA1 levels[4,6]**

[a]This analysis was performed on patients in the interim analysis set who had a baseline uPCR measured from at least one 24-hour urine sample.[4]

APRIL, a proliferation-inducing ligand; FDA, Food & Drug Administration; Gd-IgA1, galactose-deficient IgA1; IgA, immunoglobulin A; HPF, high-power field; Q4W, every 4 weeks; RBC, red blood cell; SC, subcutaneous; uPCR, urine protein to creatinine ratio; uPCR-24h, 24-hour urine protein to creatinine ratio.

**References: 1.** Floege J, et al. *Clin Kidney J*. 2026;19(2):sfag003. **2.** Coppo R, Fervenza FC. *J Am Soc Nephrol*. 2017;28(10):2831-2834. **3.** Swaminathan S, Chacko B. *Aust J Gen Pract*. 2025;54(10):711-715. **4.** Perkovic V, et al. *N Engl J Med*. 2026;394(7):635-646. **5.** Data on File-SIBE-022. Otsuka America Pharmaceutical, Inc. **6.** Suzuki H, et al. Presented at: WCN. 2026 (poster P201).

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