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Otsuka Unveils Unprecedented Phase 3 VISIONARY Two-Year eGFR Results Demonstrating VOYXACT® (sibeprenlimab-szsi) Stabilizes Kidney Function Decline to Baseline Physiologic Rate, Fundamentally Altering Disease Progression in IgA Nephropathy (IgAN)

Otsuka Pharmaceutical Co., Ltd. (Otsuka) and Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) announced new data from the Phase 3 VISIONARY trial demonstrating that VOYXACT® (sibeprenlimab-szsi) stabilizes estimated glomerular filtration rate (eGFR) returning kidney function decline to baseline physiologic rate over two years (24 months) in adults with primary IgA nephropathy (IgAN) at risk for disease progression.

There is no change to the Company's consolidated earnings forecast for the fiscal year ending December 2026 at this time. However, the Company regards VOYXACT as one of its key future growth drivers, and believes that this achievement represents an important milestone toward enhancing its medium- to long-term corporate value.

- *Phase 3 VISIONARY study met its key secondary endpoint, showing an annualized estimated eGFR slope of +0.3 (95% CI, -0.4 to 0.9) mL/min/1.73 m²/year with sibeprenlimab versus -4.2 (95% CI, -4.9 to -3.6) mL/min/1.73 m²/year with placebo*
- *VOYXACT is the first-and-only U.S. FDA-approved IgAN treatment to show stabilization of kidney function, with evidence of improvement, and a safety profile consistent with placebo over two years*
- *Adds to clinical evidence confirming VOYXACT's selective APRIL inhibition as a disease-modifying therapeutic approach that targets a key IgAN driver to halt disease progression*
- *New findings complete the Phase 3 VISIONARY study, marking another milestone in Otsuka's rolling submission of a supplemental Biologics License Application (sBLA) to the U.S. FDA for traditional approval of VOYXACT*

Results presented during a late-breaking oral presentation at the GlomCon Hawaii 2026 conference showed the study achieved its key secondary endpoint, with an annualized eGFR slope of +0.3 (95% CI, -0.4 to 0.9) mL/min/1.73 m²/year with sibeprenlimab versus -4.2 (95% CI, -4.9 to -3.6) mL/min/1.73 m²/year with placebo, demonstrating a statistically significant treatment effect of +4.5 (95% CI, 3.6 to 5.4; p<0.0001) mL/min/1.73 m²/year at two years (24 months). VOYXACT is the first IgAN treatment to achieve the KDIGO therapeutic goal of effectively halting progressive kidney function decline to physiologic rate (<1 mL/min/1.73 m²/year for most adults)[1]. The overall safety profile of sibeprenlimab remained consistent through two years (24 months) and was comparable to placebo, with similar rates of overall adverse events (90.7% vs 90.0%), infections and infestations (51.4% vs 51.0%), and injection site reactions (35.1% vs 32.2%). No new safety signals were identified, and rates of serious infections were lower with sibeprenlimab than placebo (1.9% vs 4.0%), alongside lower rates of serious and severe adverse events and treatment discontinuations. A complete analysis of the Phase 3 VISIONARY two-year (24-month) results will be presented at an upcoming scientific congress.

“For nephrologists, stabilization of kidney function in IgAN patients represents a major advancement in the clinical management of this disease," said Dr. Dana Rizk, professor of medicine in the division of nephrology at the University of Alabama at Birmingham and VOYXACT VISIONARY study site principal investigator and co-chair of the steering committee. “The VISIONARY two-year eGFR results achieved the KDIGO treatment goal of reducing kidney function decline to near physiological level, fundamentally altering the disease progression. The magnitude and consistency of benefit across pre-specified sub-groups, coupled with the reassuring safety profile of VOYXACT, delivers new hope for better long-term outcomes in patients living with this progressive condition.”

The annualized eGFR slope (the study's key secondary endpoint) was estimated using a prespecified linear mixed-effects model that evaluated repeated eGFR measurements from Week 4 through Week 104 (24 months) to estimate the annual rate of kidney function change. At two years (24 months), the least square mean change from baseline in eGFR showed +1.3 mL/min/1.73 m² with sibeprenlimab (95% CI, −0.3 to 2.8), compared with −7.9 mL/min/1.73 m² with placebo (95% CI, −9.5 to −6.4), for a treatment difference of +9.2 mL/min/1.73 m² (95% CI, 7.1 to 11.4; p<0.0001). The least square mean change from baseline in eGFR at two years (24 months) was evaluated as a complementary secondary endpoint and was analyzed using a Mixed Model for Repeated Measures (MMRM) to assess the overall difference in kidney function from study entry to the two-year (24-month) timepoint.

“The VISIONARY trial provides the largest Phase 3 study in IgAN, with 24 months of follow-up in a broad, representative, patient population reflective of real-world clinical practice,” said John Kraus, M.D., Ph.D., executive vice president and chief medical officer, OPDC. “These transformative results deliver the largest treatment effect reported in a Phase 3 IgAN trial, with a magnitude of benefit demonstrating stabilization of kidney function and halting of disease progression beyond symptom management, with the potential to redefine the treatment landscape. This data adds to the body of evidence supporting selective APRIL inhibition as a safe, durable and disease-modifying therapeutic approach that targets underlying IgAN drivers.”

Otsuka would like to thank the patients, families, advocates, and investigators who participated in the Phase 3 VISIONARY trial, and who continue to advance IgAN research with the shared goal and persistent pursuit of delivering breakthroughs on patients' behalf.

VOYXACT is the first-and-only U.S. FDA-approved selective A-PRoliferation-Inducing-Ligand (APRIL) inhibitor, offering an early, targeted therapy that addresses key drivers of IgAN to alter disease progression[2]. VOYXACT was granted accelerated approval by the U.S. FDA in November 2025 after meeting the Phase 3 VISIONARY study's primary endpoint of statistically significant proteinuria reduction compared to placebo at nine months. VOYXACT was well tolerated, with a favorable safety profile comparable to placebo. The two-year eGFR results build on previously observed reductions in Gd-IgA1, proteinuria, and hematuria, underscoring VOYXACT's ability to modify the disease and improve long-term clinical outcomes in IgAN[2]. These new findings complete the Phase 3 VISIONARY study dataset, marking another milestone in Otsuka's rolling submission of a supplemental Biologics License Application (sBLA) to the U.S. FDA for VOYXACT traditional approval.

About the VISIONARY Study

VISIONARY (NCT05248646) is a global, randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy and safety of VOYXACT (sibeprenlimab-szsi) in adults with primary IgAN at risk for disease progression. The primary efficacy endpoint assessed proteinuria reduction, as measured by the change in 24-hour urine protein-to-creatinine ratio (uPCR-24h) from baseline compared with placebo after nine months of treatment. The key secondary endpoint evaluates annualized eGFR slope over 24 months (two years), providing an assessment of kidney function over time. The least square mean change from baseline in eGFR at month 24 was also evaluated as a secondary endpoint, offering a complementary measure of overall treatment effect at a defined timepoint[1,2]. This program continues to advance the science in IgAN, with future data forthcoming in an open-label, long-term extension study (NCT05248659).

About IgAN

IgA nephropathy (IgAN) is a progressive, immune-mediated, chronic kidney disease that typically manifests in adults aged 20-40 years and can lead to kidney failure (KF) over the lifetime of most patients[3-5]. IgAN is characterized by the accumulation of Gd-IgA1 complexes in the kidneys[7]. IgAN can lead to progressive loss of kidney function and, eventually, KF, imposing a significant burden on patients[5]. Despite supportive care, there is an unmet need for treatments that address the root causes of the condition[6]. Continued research in IgAN remains crucial to uncovering opportunities for advancement in our understanding and treatment of patients[6].

About VOYXACT® (sibeprenlimab-szsi)

VOYXACT (sibeprenlimab-szsi) is a humanized monoclonal antibody that binds to and blocks APRIL, which plays a key role in the 4-hit process of IgAN pathogenesis and is an important initiating and sustaining factor in IgAN progression by promoting the production of pathogenic galactose-deficient IgA1 (Gd-IgA1)[2,6,7]. Inhibition of APRIL results in reduced levels of serum galactose-deficient IgA1 (Gd-IgA1), which is implicated in the

pathogenesis of IgAN. VOYXACT is a self-administered, subcutaneous injection dosed once every four weeks. VOYXACT is the first-and-only U.S. FDA-approved treatment for adults with primary IgAN at risk for disease progression that selectively inhibits APRIL, a key immune driver of the disease[2]. VOYXACT is the only U.S. FDA-approved selective APRIL inhibitor to demonstrate stabilization of eGFR compared with placebo over two years. VOYXACT was granted accelerated approval by the U.S. FDA on November 25, 2025. Otsuka has initiated a rolling submission of an sBLA to the U.S. FDA for VOYXACT traditional approval, which will include the 24-month (two-year) eGFR findings.

References

1. Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney Int. 2025;108(4S):S1-S71.
2. Perkovic, V., Trimarchi, H., Tesar, V., Lafayette, R., Wong, M. G., Barratt, J., Suzuki, Y., Liew, A., Zhang, H., Carroll, K., Jha, V., Quevedo, A., Han, S. H., Praga, M., Chacko, B., Sahay, M., Cheung, C. K., Kooienga, L., Walsh, M., … Rizk, D. V. (2026). Sibeprenlimab in IGA nephropathy — interim analysis of a phase 3 trial. New England Journal of Medicine, 394(7), 635–646. https://doi.org/10.1056/nejmoa2512133
3. Pitcher, D. Braddon, et. al Long-term outcomes in IGA nephropathy. Clinical journal of the American Society of Nephrology: CJASN. https://pubmed.ncbi.nlm.nih.gov/37055195/.
4. Cheung, Chee Kay & Boyd, JKF & Feehally, J.. (2012). Evaluation and management of IgA nephropathy. Clinical Medicine. 12. s27-s30. 10.7861/clinmedicine.12-6-s27.
5. Lai K. Iga nephropathy. Nature reviews. Disease primers. 2016
6. Cheung CK, Barratt J, Liew A, Zhang H, Tesar V, Lafayette R. The role of BAFF and April in IGA nephropathy: Pathogenic mechanisms and targeted therapies. Frontiers in nephrology. February 1, 2024.
7. Chang S, Li XK. The Role of Immune Modulation in Pathogenesis of IgA Nephropathy (nih.gov)