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ASIA EDITION

Otsuka Reports Phase III Data Showing VOYXACT Preserved Kidney Function in IgA Nephropathy

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The interim VISIONARY analysis supports VOYXACTâ??s positioning as a targeted APRIL inhibitor for adults with primary IgA nephropathy at risk of progression.



Otsuka has reported positive interim Phase III VISIONARY data showing that VOYXACT preserved kidney function over 12 months in adults with primary IgA nephropathy at risk for disease progression.

The data support the role of targeted APRIL inhibition in IgA nephropathy, a progressive kidney disease where slowing loss of kidney function is central to delaying dialysis, transplantation and long-term complications. VOYXACT is described as the first and only US FDA-approved selective APRIL inhibitor for primary IgA nephropathy.

In the prespecified interim analysis of the global Phase III VISIONARY trial, patients receiving VOYXACT showed a mean eGFR change from baseline of +0.7 mL/min/1.73 m², compared with a decline of -4.8 mL/min/1.73 m² in the placebo group. This represented a treatment effect of 5.5 mL/min/1.73 m² over 12 months.

The annualised eGFR slope was -3.0 mL/min/1.73 m² per year with VOYXACT compared with -7.6 mL/min/1.73 m² per year with placebo. The overall safety profile was comparable to placebo, with infections and injection site reactions among the most common adverse events.

Otsuka has initiated a rolling supplemental Biologics License Application submission to the US FDA for traditional approval of VOYXACT, based on the 24-month eGFR endpoint data. The interim results were presented at the European Renal Association Congress 2026 in Glasgow.

Adoption will depend on long-term data, payer assessment, clinician confidence in selective APRIL inhibition and positioning within an increasingly competitive IgA nephropathy treatment landscape. The self-administered, once-every-

four-weeks subcutaneous profile may support long-term treatment convenience.

The data reflect the continued shift in nephrology toward disease-modifying therapies that target upstream immune drivers. If longer-term outcomes remain consistent, targeted biologics could increasingly reshape care pathways for patients with progressive IgA nephropathy.