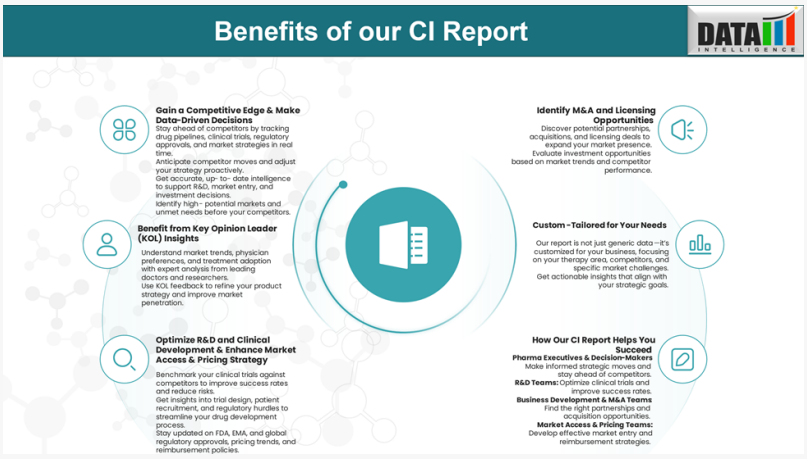
Groundbreaking Advances in IgA Nephropathy: New Therapies Reduce Proteinuria, Offer Hope in the US and Japan

Latest IgA nephropathy therapies—from sibeprenlimab in the US to sparsentan trials in Japan—promise improved outcomes and precision care reducing proteinuria.



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AUSTIN, TX, UNITED STATES, June 16, 2025 /EINPresswire.com/ -- 1. Disease Overview: Understanding IgA Nephropathy

Immunoglobulin A nephropathy (IgAN), or Berger's disease, is a chronic kidney disorder characterized by deposition of IgA antibodies in the glomeruli, which leads to inflammation and progressive renal damage. Over time, this results in impaired filtration capacity and eventual risk of kidney failure. IgAN is the most prevalent primary glomerular disease in the U.S. and worldwide, driven by mechanisms defined in the "four-hit" hypothesis—starting with abnormal IgA1 production through immune complex deposition and uncontrolled inflammation

> Modern IgAN therapies mark a turning point: precise biologics and targeted inhibitors now reshape treatment, delivering safer, effective options and redefining kidney disease care."
>
> *DataM Intelligence*

2. Epidemiology: Current Landscape & Forecast

IgAN affects millions globally, making it a leading cause of end-stage kidney disease (ESKD). In North America, growing awareness and improved diagnostic tools have amplified prevalence estimates . The global IgAN therapeutics market is projected to expand rapidly from 2025–2035 fueled by enhanced detection, biomarker-led intervention, and regulatory acceleration in renal therapies. As more countries approve first□in□class treatments, North America remains a growth pioneer, propelled by advanced care systems, while Asia, led by Japan, embarks on clinical programs and adaptive regulations.

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3. New and Approved Therapies: Improving the Standard of Care
• Tarpeyo® (budesonide DR)
A targeted-release corticosteroid that modulates Peyer's patches to decrease proteinuria with minimal systemic side effects. It holds distinction as the first FDA-approved IgAN therapy.

• Filspari® (sparsentan)
This dual endothelin/angiotensin receptor antagonist offers a non‑immunosuppressive, once-daily oral administration, rapidly reducing proteinuria. It received full FDA approval in September 2024 and EU standard approval in early 2025

• Vanrafia® (atrasentan)
Selective endothelin‑A receptor antagonist newly approved by the FDA in April 2025. It has demonstrated significant proteinuria reduction while maintaining favorable cardiovascular safety.

• Fabhalta® (iptacopan)
An oral Factor‑B inhibitor targeting the complement pathway. Early-phase data reveal around 43.8% proteinuria reduction, signaling promise as precise, complement-focused therapy.

4. Pipeline & Emerging Treatments in 2025
• Sibeprenlimab (anti‑APRIL mAb) – Otsuka (US & Japan)
In the Phase‑3 VISIONARY trial, adult IgAN patients showed a 51.2% proteinuria reduction at nine months versus placebo (P<0.0001). Favorable safety outcomes position this therapy—targeting APRIL in the four-hit cascade—for FDA approval under Priority Review, with a PDUFA date of November 28, 2025

• Sparsentan – Japan Registrational Phase‑III (Renalys Pharma)
Japan's phase‑III enrollment has concluded ahead of schedule, with top-line proteinuria data expected in late 2025. This study, led by Renalys under Renalys–Travere partnership, builds on orphan designation and aims for PMDA approval in primary IgAN.

• Atacicept (anti‑BAFF/APRIL) – Vera Therapeutics
The ORIGIN Phase‑3 trial in adults with IgAN recently reported a 46% proteinuria reduction, emphasizing upstream targeting of mucosal immunity drivers of IgA overproduction.

• Zigakibart (BION‑1301) – Novartis (via Chinook)
In late-stage BEYOND trials, this anti‑APRIL monoclonal antibody continues to evaluate efficacy and safety in global cohorts.

• Sefaxersen (antisense CFB inhibitor) – Roche/Ionis

Currently in Phase□2/3 trials, this oligonucleotide therapy disrupts alternative complement activation, potentially offering synergies with other targeted modalities.

5. Biomarkers & Diagnostics Innovations
At ERA 2025 held in Vienna, researchers unveiled a multibiomarker urine-based model comprising seven markers (EGF, MCP□1, DKK□3, L□FABP, β□□microglobulin, NGAL, KIM□1) that predicts kidney fibrosis non-invasively—over 60% predictive accuracy. This innovation can reduce biopsy reliance, personalize treatment initiation, and monitor drug response dynamically.

6. Competitive Landscape & Strategic Positioning
The IgAN ecosystem spans Big Pharma, biotech, and CDMOs:
• Otsuka moves ahead with sibeprenlimab's dual U.S.–Japan development.
• Travere Therapeutics/Renalys integrates sparsentan’s Asia-focused expansion.
• Novartis, via Fabhalta and zigakibart, executes a dual MoA strategy (complement + APRIL).
• Vera Therapeutics is positioned with atacicept as a BAFF/APRIL frontrunner.
• Roche/Ionis pioneers antisense therapy via sefaxersen.

Each emerging agent targets distinct aspects of IgAN pathology—immune regulation, complement activation, endothelial control—positioning them for sequential or combinational use, especially alongside ACEi/ARB or SGLT2 inhibitors.

7. hallenges & Unmet Needs
Clinical & Translational
• Must demonstrate ≥□50% proteinuria reduction with sustained eGFR preservation.
• Show robust efficacy in high□risk subgroups (e.g., steroid-resistant, pediatrics, Asian patients).
• Implement global trials with hard endpoints like time-to-dialysis and biopsy-based remission.

Safety & Delivery
• Maintain favorable safety vs. steroids/combo therapies—minimizing immunosuppression, fluid retention, GI/CV side effects.
• Prioritize oral or sub□cutaneous agents with home-based dosing and simplified monitoring.

Access & Economics
• With lifelong progression, cost-effectiveness, installment/outcome-based reimbursement, and payor education are critical.
• Manufacturing and cold-chain logistics must scale to meet increasing demand affordably.

8. Future Outlook & Strategic Implications
2025 marks a watershed in IgAN care:
• US – Sibeprenlimab’s likely FDA nod and atacicept’s promising Phase 3 are set to diversify therapeutic options.
• Japan – PMDA engagement, orphan designations, and home-grown trials are fostering a supportive environment for rapid take-up.

• Biomarkers – Non-invasive fibrosis models enhance personalized monitoring and support regulatory submissions with histologic endpoints.

Moving forward, therapies that combine targeted immune modulation, proven biomarker tracking, and patient-centric access will define leadership in IgAN care.

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Sai Kumar
DataM Intelligence 4market Research LLP
+1 877-441-4866
sai.k@datamintelligence.com
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