VOYXACT® (sibeprenlimab)

The anatomy of a Drug to Watch

Key evaluation criteria in rare and chronic diseases like IgAN and how VOYXACT was selected as a Drug to Watch 2026

Clarivate analysts rely on actionable data and market intelligence from our suite of products to identify each year's Drugs to Watch — the blockbusters and treatment paradigm-shifters.

Identifying high-impact therapies in rare and chronic diseases

Competition in rare and chronic diseases is accelerating as many of the conditions become more mechanistically defined and commercially validated, driving additional innovation by established and new players alike. To narrow the field, our analysts need a clear understanding of which drugs are likely to launch and succeed within the Drugs to Watch target timeframe.

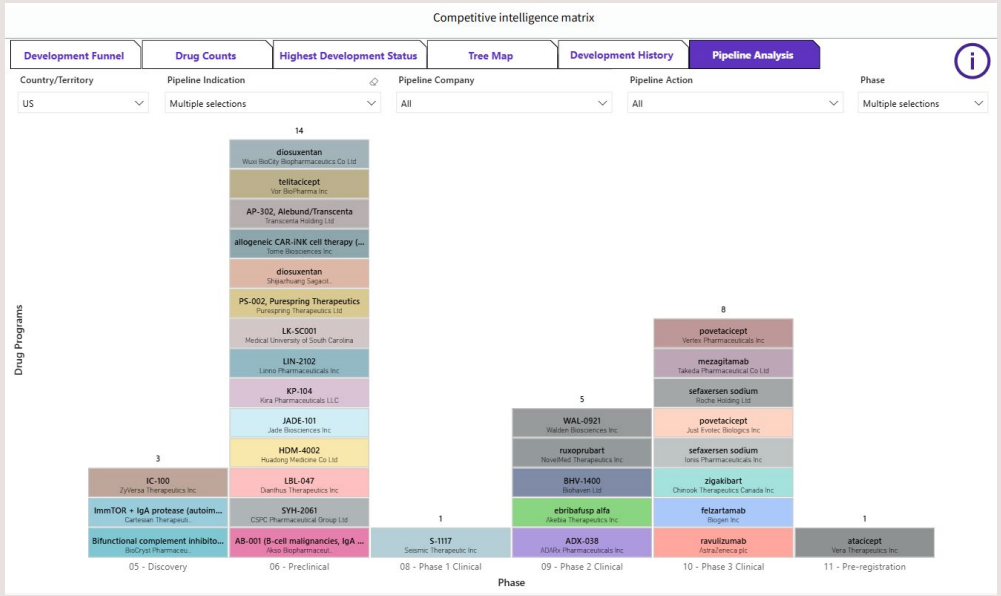
Mapping the therapeutic landscape: Cortellis Competitive Intelligence

Our analysts gain a broad view of the status and potential success of drugs for rare and chronic diseases using Cortellis Competitive Intelligence, which:

- Covers the entire development lifecycle
- Provides clinical, deals, regulatory and patent intelligence for each drug and company
- Predicts the likelihood and timing of drug launches with the Drug Timeline & Success Rates statistical modeling methodology and ML-based predictive analytics

By mapping competing therapies by mechanism and timeline, Clarivate analysts narrow the field to a short list of assets that warrant deeper investigation as Drugs to Watch, including those for IgA nephropathy (IgAN). Multiple clinical- and commercial-stage therapies, such as VOYXACT (Otsuka Pharmaceutical Co Ltd), target distinct disease pathways, creating a competitive environment.

Figure 1: Overview of the investigational therapy pipeline for IgAN in Cortellis Competitive Intelligence.



VOYXACT (sibeprenlimab)

First-in-class APRIL-targeting therapy with disease-modifying impact

Cortellis Competitive Intelligence

Demonstrates VOYXACT's role as a disease-modifying therapy rather than add-on symptomatic control, based on the first-in-class APRIL blockade with robust phase 3 proteinuria reduction.

- First-in-class selective APRIL inhibitor targeting the root immunopathology of IgAN (Gd-IgA1 production and immune complex formation)
- Higher placebo-adjusted UPCR reduction at 9 months of 51.2% compared with competitors: TARPEYO®, 31%; VANRAFIA®, 36.1%; atacicept, 42%
- Differentiated on depth of proteinuria reduction and selective APRIL targeting based on mapping the competitive IgAN landscape across APRIL/BAFF, complement and SGLT2/RAAS-based approaches

Learn more

Cortellis Clinical Trials Intelligence

Underscores VOYXACT's consistent proteinuria benefits paired with placebo-level safety, positioning it as a compelling option for early-stage intervention and long-term disease control.

- Evaluated in ~685 adults with IgAN to date: 155 patients in the global phase 2 trial and 530 patients in the global pivotal phase 3 VISIONARY study
- Up to 47.2%, 58.8% and 62.0% UPCR reduction (2, 4 and 8 mg/kg) at 12 months vs 20.0% with placebo (phase 2 trial); eGFR decline markedly attenuated (least-squares mean changes: −2.7, +0.2 and −1.5 ml/min/1.73 m² vs −7.4 ml/min/1.73 m² with placebo)
- 51.2% 24-hour placebo-adjusted UPCR reduction at 9 months (VISIONARY trial); lower rates of TEAEs (76.3% vs 84.5%) and serious TEAEs (3.9% vs 5.4%) vs placebo

Learn more

Disease Landscape & Forecast

Shows that VOYXACT is aligned with the KDIGO's dual-action approach, expanding the eligible IgAN population by moving treatment upstream and enabling combination strategies for patients.

- ~527,000 diagnosed IgAN cases in the G7 markets as of 2025
- IgAN market likely to expand as KDIGO 2025 guidelines drive dual-pathway treatment (pathogenesis + nephron loss), increasing use of targeted agents earlier in disease
- $955m sales forecast in the G7 markets by 2031, driven by early-line adoption, combination use and expansion of the treated population

Learn more

Epidemiology Intelligence

Identifies how VOYXACT could benefit from a growing pool of eligible patients given the large, under-treated, high-risk IgAN subpopulation and guideline-endorsed immune targeting.

- Progressive IgAN a leading cause of end-stage kidney disease, with many patients progressing despite blood pressure and proteinuria control using standard care
- IgAN reframed into two therapeutic axes (immune drivers vs nephron loss) by KDIGO 2025, creating a defined role for agents like VOYXACT that target immunopathology
- Monthly, self-administered subcutaneous dosing that offers an at-home option that avoids the infusion-center burden associated with some emerging competitors

Learn more

Summary of impact

VOYXACT

VOYXACT's targeted approach can shift IgAN treatment from "slowing damage" to "changing trajectory." Leading phase 3 proteinuria reduction with promising potential for long-term renal preservation support earlier-line use, combination with RAAS/SGLT2 backbones and potential expansion into adjacent immune kidney diseases.

Ready to see if your drug is one to watch?

Contact us to learn how integrating intelligence from multiple Clarivate products, powered by AI, drives confident predictions of the potential competitive impact of your drug on the market and patients' lives.

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