SCIENCE IN FOCUS

Xiidra® (lifitegrast ophthalmic solution 5%) for Dry Eye Disease: What Clinical Trials Reveal

Reviewing evidence from the OPUS clinical development program and emerging insights into patterns of response.

CLINICAL AREA	Dry eye disease
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PUBLICATION DETAILS	September 2026 | Approximately 4-minute read

KEY TAKEAWAYS

- Xiidra® (lifitegrast ophthalmic solution 5%) has been evaluated across OPUS, a comprehensive clinical development program involving patients with dry eye disease (DED).
- Xiidra® (lifitegrast ophthalmic solution 5%) significantly improved symptoms of eye dryness and demonstrated a generally well-characterized safety profile.
- Subgroup and post hoc analyses indicate that symptom improvement may be observed as early as two weeks after treatment initiation.
- Together, these findings contribute to a growing body of evidence supporting the use of Xiidra® (lifitegrast ophthalmic solution 5%) across diverse clinical presentations of dry eye disease.

A Recent Review Examines the Evolving Evidence Base for Xiidra® (lifitegrast ophthalmic solution 5%)

As our understanding of dry eye disease continues to evolve, so too does the evidence informing treatment decisions.

In a recently published review, experienced ophthalmologists and dry eye disease specialists Dr Eric Donnenfeld and Dr Jason Bacharach examine more than a decade of scientific evidence on Xiidra® (lifitegrast ophthalmic solution 5%) including its mechanism of action, clinical trial development program and real-world data in a diverse set of patient populations. Gathering the comprehensive body of evidence published on this treatment, this review provides a practical perspective on its potential role within contemporary dry eye management.

This first Science in Focus article highlights key insights from the review together with recent findings presented at congress communications. A companion article will examine real-world studies on Xiidra® and discuss what findings in these studies have contributed to our understanding of treatment outcomes in clinical practice.

Understanding the Role of Xiidra® (lifitegrast ophthalmic solution 5%) in Inflammatory Dry Eye Disease

Although dry eye disease can arise from a range of causes, inflammation is recognized as an important contributor to disease development and persistence. Current understanding of dry eye disease explains it as a self-perpetuating inflammatory cycle in which ocular surface stress triggers immune activation, release of inflammatory mediators and progressive ocular surface damage. As a result, anti-inflammatory approaches ranging from topical corticosteroids for short-term use to immunomodulatory agents such as cyclosporine and Xiidra® have become important components of contemporary dry eye management.

Xiidra® (lifitegrast ophthalmic solution 5%) is a lymphocyte function-associated antigen-1 (LFA-1) antagonist developed to target several key stages in this inflammatory cascade. While the precise downstream mechanism of action is not yet completely understood, it is thought that this treatment acts on pathways involved in T-cell activation, migration and retention at the ocular surface, helping to reduce the release of pro-inflammatory cytokines associated with dry eye disease.

The ability of this treatment to target inflammatory pathways associated with DED forms the mechanistic rationale underpinning the clinical program that followed.

Key Learnings from the OPUS Clinical Trial Program

The OPUS phase 3 clinical development program evaluated Xiidra® in patients with mild to severe dry eye disease. Across these studies, the treatment was associated with improvements in patient-reported symptoms of dry eye compared with vehicle, including reductions in eye dryness that were observed as early as two weeks after treatment initiation. Improvements continued throughout the study period, with additional benefits observed in ocular surface parameters such as inferior corneal fluorescein staining.

Importantly, Xiidra® was generally well tolerated across the clinical program. Most ocular treatment-emergent adverse events reported in the pivotal studies were mild or moderate in severity.

Recognizing Patterns of Response in OPUS Patients

One of the relevant developments presented at major ophthalmology congresses over the past two years has been the exploration of treatment response patterns among patients receiving Xiidra®.

Several analyses presented in 2025 and 2026 examined pooled OPUS-2 and OPUS-3 data and identified multiple distinct response trajectories among patients treated with Xiidra®. Overall, the data demonstrate that the majority of patients achieved meaningful reductions in eye dryness scores by Day 84, and more than half achieved reductions of at least 60%.

Notably, a subgroup of patients demonstrated rapid and sustained improvement beginning within the first two weeks of treatment. These patients tended to have lower symptom scores for features such as eye pain, burning, foreign body sensation and photophobia compared to other responder groups, suggesting that initiating treatment earlier in the course of DED may be beneficial for maximal responses.

While these findings remain exploratory, they provide valuable insights into treatment response and raise important questions for future research.

Extending the Evidence Base Beyond Clinical Trials

The clinical trial program provides important insights into efficacy, safety and treatment response, but it is only part of the story.

The review by Donnenfeld and Bacharach also examines evidence relating to Xiidra® use in routine clinical practice settings, including contact lens wear, cataract surgery and ocular graft-versus-host disease, and explores emerging evidence regarding how this treatment is being used across diverse patient populations in real-world practice.

In our companion Science in Focus article, “Xiidra® (lifitegrast ophthalmic solution 5%) Across Diverse Patient Populations: What Clinical Experience Has Taught Us,” we explore the registry studies, provider surveys and existing and emerging evidence underpinning use of this treatment in those cohorts.

For a comprehensive review of the evidence, readers are encouraged to consult the full article by Donnenfeld and Bacharach, as well as the work by Tichenor et al. about patterns of response, recognized as one of the top five posters presented in AOA 2026.

References

1. Donnenfeld E, Bacharach J. When to reach for XIIDRA: guidance from clinical trials and real-world evidence. *Ophthalmology 360*. 2026.
2. Tichenor AA. Patterns of response to treatment with lifitegrast ophthalmic solution in patients with dry eye disease. Scientific poster abstract presented at: Optometry’s Meeting, American Optometric Association; June 17–20, 2026; Phoenix, AZ.

Author disclosures

Authored and reviewed by Bausch and Lomb Global Medical and Scientific Affairs.

Availability statement

Xiidra® (lifitegrast ophthalmic solution 5%) is available in the US. However, it is not available worldwide. Contact us for further information about Xiidra® (lifitegrast ophthalmic solution 5%) availability.