

Seeing Beyond Sight: New Frontiers in AMD Treatment-Gene Therapy and Biosimilars Take Center Stage | CI Intelligence

Pioneering AMD therapies-gene therapy, biosimilars, long acting biologicspromise durable vision gains and reduced injection burden for aging populations.

AUSTIN, TX, UNITED STATES, June 19, 2025 /EINPresswire.com/ --Revolutionizing AMD Care: From Monthly Injections to One-Time Gene Therapies

In a watershed moment for retinal health, the <u>Age-Related Macular</u>



<u>Degeneration (AMD)</u> therapeutics market is poised for transformation. A new wave of innovative treatments—from gene therapy to long-acting anti-VEGF biologics and biosimilars—is reshaping care protocols and expanding access for millions worldwide. With the global burden of AMD projected to surpass 300 million by 2040, the urgency to reduce injection frequency, slow disease

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AMD treatment is entering a transformative era, where precision gene therapy and extended-duration biologics are redefining care. The market is poised to benefit both patients and healthcare systems." DataM Intelligence progression, and improve affordability has never been more critical.

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 Market Snapshot: AMD Therapeutics Poised for Growth
The global AMD therapeutics market was valued at approximately \$14.24 billion in 2024, with expectations to reach \$24.22 billion by 2033, registering a 6–8% CAGR over the forecast period.

- North America remains the leading market due to high disease prevalence and early access to biologics, while Asia-Pacific is emerging rapidly with aging populations and increasing healthcare access.

- Biosimilar competition, reimbursement reforms, and gene therapy innovations are key drivers shaping this growth trajectory.

Disease Overview: AMD at a Glance

Age-related macular degeneration affects the macula—the central portion of the retina responsible for sharp, straight-ahead vision. It is the leading cause of irreversible vision loss in people aged 50 and older.

Two Forms of AMD:

- Dry AMD (Atrophic): The most common form, accounting for about 80% of cases. Characterized by thinning of the macula and drusen deposits.

- Wet AMD (Neovascular): Less common but more severe. Marked by abnormal blood vessel growth beneath the retina, leading to leakage, scarring, and rapid vision loss.

I Current Therapies: Anti-VEGF Dominates, But GA Drugs Rising

Wet AMD: Approved Therapies

- Eylea (Aflibercept): VEGF and PIGF inhibitor, long-standing market leader.
- Lucentis (Ranibizumab): Anti-VEGF monoclonal antibody fragment, widely adopted globally.
- Beovu (Brolucizumab): Longer dosing intervals, though safety remains under scrutiny.
- Vabysmo (Faricimab): Dual inhibition of VEGF-A and Ang-2; allows for 16-week dosing intervals.
- Off-label Avastin (Bevacizumab): Economical alternative, frequently used off-label.

Recent Developments:

Biosimilars: Byooviz (ranibizumab-nuna), Yesafili, and Opuviz (aflibercept biosimilars) are now FDA-approved, offering cost-effective alternatives with similar efficacy.

Dry AMD / Geographic Atrophy (GA):

- Syfovre (Pegcetacoplan): First FDA-approved therapy for GA, slows disease progression by up to 36% by inhibiting complement C3.

- Izervay (Avacincaptad Pegol): Approved in 2023; targets complement C5 to reduce retinal degeneration in GA.

- AREDS2 Supplements and Photobiomodulation Therapy offer supportive care for early or intermediate dry AMD.

D Emerging Therapies and Pipeline Highlights

The AMD pipeline is robust, focusing on durable solutions and novel mechanisms of action.

For Dry AMD (GA):

- ALK-001 (Alkeus Pharmaceuticals): A modified vitamin A derivative in Phase II/III trials aimed at slowing photoreceptor degeneration.

- Tinlarebant (Belite Bio): Oral therapy reducing retinal vitamin A buildup to slow GA progression (Phase III).

For Wet AMD:

 ABBV-RGX-314 (REGENXBIO/AbbVie): Gene therapy delivering anti-VEGF via subretinal or suprachoroidal injection. Phase III underway, with potential to eliminate frequent injections.
4D-150 (4D Molecular Therapeutics): Intravitreal gene therapy targeting VEGF-A and VEGF-C for sustained delivery—Phase III trials are ongoing.

Other Novel Agents:

- UBX1325 (Unity Biotechnology): Senolytic targeting aging retinal cells to improve vision in AMD and DME.

- Complement Inhibitors in Development: Aimed at upstream and downstream components (e.g., CFB, CFD, FD inhibitors).

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I Market Opportunities & Forecasting

- The wet AMD market continues to dominate revenue, but geographic atrophy (GA) is a growing segment due to newly approved treatments and expanding patient population.

- Gene therapy and biosimilars are expected to drive a paradigm shift by improving durability and lowering long-term costs.

- Market revenue is projected to grow from \$14.24 billion (2024) to \$24.22 billion by 2033, largely fueled by treatment innovation and the rising global prevalence of AMD.

Unmet Needs: The Next Frontier in AMD Care

Despite progress, critical gaps remain:

- Treatment Burden: Monthly injections are unsustainable for many elderly patients. Gene therapies and extended-interval dosing are key solutions.
- Lack of Cure for Dry AMD: GA treatments slow degeneration but cannot reverse damage.
- Global Access & Cost: High biologic prices remain a barrier in low- and middle-income countries. Biosimilars and oral agents offer scalable alternatives.

- Delayed Detection: Early AMD often goes undiagnosed. Greater emphasis on screening and Alenabled imaging is needed.

- Personalized Medicine: Genotype-based AMD therapies remain underdeveloped, despite promising biomarker research.

Competitive Landscape and Strategic Positioning Key Players in Wet AMD:

- Regeneron: Market leader with Eylea/Eylea HD. Facing competition from biosimilars and Roche's Vabysmo.

- Roche/Genentech: Innovator with Vabysmo and sustained delivery devices.

- Novartis: With Beovu, pursuing longer dosing intervals.

Leading in Dry AMD:

- Apellis (Syfovre) and Astellas/Iveric Bio (Izervay) have pioneered complement-targeted approaches.

Emerging Innovators:

- REGENXBIO and Adverum Biotech: Leading the charge in gene therapy, aiming to provide onetime, durable treatment solutions.

- Samsung Bioepis, Biocon, Polpharma: Disrupting the pricing landscape with Lucentis and Eylea biosimilars.

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□ Target Opportunity Profile (TOP): Strategic Drug Benchmarking Ideal Drug Profile:

- Wet AMD: ORR > 90%, injection frequency ≤ every 16 weeks, subcutaneous/gene therapy option.

- GA: ≥30% reduction in lesion growth, good safety profile, ideally oral or less invasive.
- Gene Therapy: One-time treatment, durable for 2–5+ years, minimal side effects.

Benchmarking Snapshot:

- Eylea HD: 12–16 week interval; market leader.
- Vabysmo: Dual-target; fast-growing market share.
- Syfovre & Izervay: First-movers in GA.
- RGX-314 & 4D-150: Future disruptors with one-time treatment potential.
- Yesafili, Opuviz: Cost-effective alternatives, expanding access.

Conclusion: A Clearer Vision for Millions

The Age-Related Macular Degeneration (AMD) landscape is evolving from high-frequency, highcost injection therapies toward smarter, longer-lasting, and more accessible treatments. From breakthrough gene therapies to affordable biosimilars and the first-ever drugs for geographic atrophy, this is an era defined by innovation and opportunity.

As the AMD patient population swells worldwide, driven by aging demographics, these advancements are not just medically vital—they're a necessity for sustainable and equitable eye care.

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