



## NEW HORIZONS IN EYE CARE: 2023'S FDA-APPROVED OPHTHALMOLOGY BREAKTHROUGHS.

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### ABSTRACT

The US Food and Drug Administration (FDA) routinely approves new drugs, new indications for old drugs, same drug with different vehicle and drug delivery system. In 2023 FDA has approved 12 new drugs, these drugs offer new treatment options for various eye conditions such as Geographic atrophy secondary to age related macular degeneration and Demodex blepharitis, some new drug delivery methods like Optejet dispenser spray. They demonstrate the ongoing innovation in ophthalmic drug development, providing hope for improved vision and quality of life of patients. This article highlights the notable approvals, exploring their mechanisms, benefits, and impact on patient outcomes.

**KEYWORDS :** Optejet, demodex, mydcombi, presbyopia

In ophthalmology, 2023 proved as a big year with 12 approvals by FDA. There are thousands of drugs in market but there are always more drugs needed to be approved, a key goal is the recognition of new molecular entities that may be of value in the treatment of diseases that qualify as presenting unmet medical needs. Some drugs are approved with different drug delivery method reducing overdosing, adverse effects and exposure to drug and preservatives improving the effectiveness of the drug.

This article describes recently FDA approved drugs in ophthalmology (in the year 2023). The year started off with breakthrough approval of first and only drug for Geographic atrophy secondary to age related macular degeneration Apellis Pharmaceuticals' Syfovre (pegcetacoplan) which is C3 inhibitor and 6 months later second drug for geographical atrophy was approved Iveric Bio received FDA approval for Izervay (avacincaptad pegol intravitreal solution) which is a complement protein C5 inhibitor, both the drugs slows the progression of GA and does not cure it.<sup>[1]</sup>

Regeneron Pharmaceuticals revealed that the FDA approved the use of EYLEA® (aflibercept) Injection to treat preterm infants with retinopathy of prematurity (ROP). Following this first paediatric approval, EYLEA is now indicated to treat five retinal conditions caused by ocular angiogenesis.<sup>[2]</sup>

Regeneron secured FDA approval for Eylea HD (aflibercept 8 mg), prolonging dosing intervals for patients dealing with retinal diseases such as wet age-related macular degeneration (AMD), diabetic macular oedema (DME), and diabetic retinopathy (DR).<sup>[3]</sup> It is a higher-dose, longer-acting injectable form of aflibercept that only needs to be given once every 2 to 4 months after an initial dosing period. This allows patients to receive less frequent injections for similar visual gains, and anatomic improvements, without an increased risk of side effects.

Allergan announced that the FDA approved the use of Vuity (pilocarpine HCl ophthalmic solution) 1.25% twice a day for adults experiencing presbyopia, earlier VUITY was approved for once daily dosing in October 2021.<sup>[4]</sup> Similarly, lower concentration, near neutral pH and preservative-free Orasis Pharmaceuticals, Qlosi (pilocarpine hydrochloride ophthalmic solution) 0.4% has also been approved for presbyopia.<sup>[5]</sup> Given Qlosi's lower concentration, it will be curious to see whether it results in fewer adverse effects than Vuity. Another potential plus: the formulation is preservative-free.<sup>[6]</sup>

With three new therapies recently approved by the FDA, we now have more targeted options for patients than ever.

FDA has approved for Novaliq's VEVE™ (cyclosporine ophthalmic solution) 0.1% in treating signs and symptoms of dry eye disease. VEVE™, previously known as CyclASol®. It is an anti-inflammatory drug for dry eye disease. It contains the same active ingredient — an anti-inflammatory called cyclosporine — as Restasis (cyclosporine ophthalmic emulsion) 0.05% and CEQUA (cyclosporine - ophthalmic solution) 0.09%. But VEVE contains a slightly higher concentration of the drug and uses a different delivery method.<sup>[7]</sup>

Second drug, Miebo a collaboration between Bausch & Lomb and Novaliq, received FDA approval for Miebo (perfluorohexyl octane ophthalmic solution; formerly NOV03) for dry eye disease due to meibomian gland dysfunction with objective of reducing tear evaporation on ocular surface.<sup>[8]</sup> As the first and currently the only prescription treatment approved directly addressing the pathophysiology of excessive tear evaporation, perfluorohexyl octane ophthalmic solution is a valuable emerging option for the management of DED.<sup>[9]</sup>

Tarsus Pharmaceuticals obtained FDA approval for XDEMZY™ (lotilaner ophthalmic solution) 0.25%, the first and the only treatment against Demodex mites causing Demodex blepharitis to effectively and safely target, paralyze, and kill Demodex mites.<sup>[10]</sup>

Eyenovia got FDA approval of MydCombi, the first ophthalmic spray designed for mydriasis. Mydcombi is a micro-dose ophthalmic spray containing tropicamide 1% and phenylephrine 2.5%, using Optejet dispenser which administers an easier, more accurate and appropriate dose directly where it is needed in the eye.<sup>[11]</sup> Ophthalmic solution administered with the Optejet is less than 20% of that delivered using conventional eyedroppers, thus reducing overdosing and exposure to drug and preservatives.<sup>[12]</sup>

Ocuphire Pharma and Viatrix jointly announced the FDA approval for Ryzumvi (phentolamine ophthalmic solution) 0.75% a nonselective alpha-1 and alpha-2 adrenergic antagonist has now been approved for the treatment of pharmacologically induced mydriasis mydriasis caused by adrenergic agonists (such as phenylephrine) or parasympatholytic agents (like tropicamide).<sup>[13]</sup>

FDA has approved for Genentech's Vabysmo (faricimab-svoa)

6mg prefilled syring and macular oedema following retinal vein occlusion (RVO), first and only bispecific antibody acts by inhibiting VEGF-A and Angiopoietin-2.<sup>[14]</sup> It was already approved for the treatment of wet age-related macular degeneration (nAMD) and diabetic macular oedema (DME).

The FDA approvals of these top 12 ophthalmic drugs in 2023 signify a transformative era in eyecare, offering diverse and advanced treatment options for various eye conditions.

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