

Regeneron loses first bid; Amgen's Eylea biosimilar boldly enters the U.S. market "at-risk"

Market Event Summary

Amgen triumphs against all odds and launches Pavblu “at-risk”

Key findings

- Regeneron’s Eylea, which earned an impressive \$5.7 billion in U.S. net sales in 2023, remains the SOC for wet AMD and DME in the United States.
- Regeneron has been embroiled in legal disputes with manufacturers of aflibercept biosimilars over alleged infringements of Eylea’s U.S. Patent 11,084,865, which is set to expire in June 2027. These disputes have successfully blocked the U.S. market entry of several approved biosimilars, including Biocon’s Yesafili, Samsung Bioepis’s Opuviz, Celltrion’s Eydenzelt, and Formycon’s Ahzantive.
- However, in late October 2024, following a court decision that lifted a temporary injunction, Amgen launched Pavblu without a legal settlement¹. The Northern District of West Virginia ruled that Pavblu differs from other biosimilars because it lacks a separate “buffer,” which was deemed necessary by the patent. Amgen set a list price of \$1,665 per unit, which is 10% less than that of Eylea, and the product is now available in both vial and prefilled syringe forms.
- In mid-October 2024, Pine Pharmaceuticals, the largest supplier of compounded Avastin for ophthalmic use in the United States, announced the discontinuation of its product. In response to concerns about an Avastin shortage, the American Academy of Ophthalmology and the American Society of Retina Specialists requested that large insurers halt step therapy and prior authorization requirements currently in place that require patients to first fail Avastin.

¹As of January 2024, at least 11 out of the 30 commercially available biosimilars, launched “at-risk” without substantial financial penalties, including Amgen’s Mvasi.

Clarivate’s takeaways



First-to-market advantage

Pavblu’s launch comes at a pivotal moment, following Pine Pharmaceuticals’ decision to discontinue Avastin, a major player in the wet AMD and DME markets, and ahead of more biosimilar competition. Amgen’s Pavblu is poised to seize a substantial portion of Avastin’s patient share and may stall Regeneron’s efforts to switch patients on Eylea to its 8 mg formulation, Eylea HD.



Market penetration challenges

Despite Pavblu’s well-timed launch, the adoption of biosimilars among U.S. ophthalmologists (i.e., the ranibizumab biosimilars Byooviz and Cimerli) has been low. However, setting Pavblu’s list price at a 10% discount to Eylea allows Amgen to offer significant rebates to payers to secure favorable access and to physicians under buy and bill and thus drive uptake by ophthalmologists. This strategy will be necessary to overcome Eylea’s entrenched place and Regeneron’s own rebating strategy, which Clarivate calculated ramped up in 2024 to address increased competition in the space.



Competitive landscape

Therapies like Vabysmo and Eylea HD, which offer more-convenient dosing schedules, also pose a competitive threat to Pavblu, given their comparatively favorable pricing. If step therapy using Avastin is curbed, we expect payers to implement similar cost-control measures using biosimilars, consequently increasing the use of Pavblu.

About the authors



Berta Canaleta Caballe, M.P.H.

Healthcare Research & Data Analyst

Berta Canaleta Caballé, M.P.H., is a healthcare research and data analyst on the CNS and Ophthalmology Disorders team. Before joining Clarivate, she was a clinical trial research coordinator in the obstetrics field at Sunnybrook Health Sciences Centre in Canada. Before then, she worked at the Juilliard School in New York City, where she coordinated the COVID-19 testing and surveillance program, providing data to facilitate decision-making regarding COVID-19 policies. She holds a master's degree in public health from New York University and a bachelor's degree in human nutrition and dietetics from the University of Barcelona in Spain.

Berta.CanaletaCaballe@Clarivate.com



Carolina Ruivo, Ph.D.

Senior Healthcare Research & Data Analyst

Carolina Ruivo, Ph.D., is a senior healthcare research and data analyst on the CNS and Ophthalmology Disorders team. Her focus is the ophthalmology market. Previously, she was a content specialist in Cortellis, the suite of life science intelligence solutions from Clarivate. She holds a Ph.D. in biomedical sciences from Pompeu Fabra University in Barcelona, Spain, and a B.S. in biology from the University of Aveiro in Portugal.

CarolinaRuivo.Pereira@Clarivate.com

Clarivate coverage of wet AMD products

- [Disease Landscape & Forecast | Dry and Wet Age-Related Macular Degeneration \(G7\)](#) (to be published in November 2024)
- [Current Treatment: Physician Insights | Dry and Wet Age-Related Macular Degeneration \(US\)](#) (published in 2024)
- [Treatment Algorithms: Claims Data Analysis | Wet Age-Related Macular Degeneration \(US\)](#) (published in 2024)
- [Access & Reimbursement | Age-Related Macular Degeneration \(US\)](#) (published in 2024)

Clarivate coverage of DME products

- [Disease Landscape & Forecast | Diabetic Macular Edema / Diabetic Retinopathy \(G7\)](#) (published in 2024)
- [Current Treatment: Physician Insights | Diabetic Retinopathy / Diabetic Macular Edema \(US\)](#) (published in 2024)
- [Unmet Need | Diabetic Macular Edema \(US/EU\)](#) (published in 2022)



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Have a question?

healthcare.support@clarivate.com
clarivate.com

+1 215 386 0100 (U.S.)

+44 (0) 20 7433 4000 (Europe)

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