Clarivate™

Litigation delays the launch of Eylea biosimilars in the U.S. market

Market Trend Summary

Carolina Ruivo, Ph.D. | June 2024

The Eylea franchise capitalizes while patent disputes keep biosimilar entry at bay.

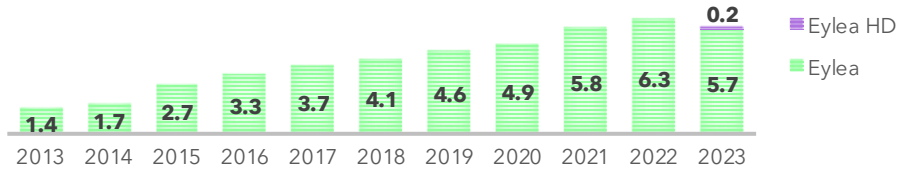
Key findings

Regeneron's blockbuster Eylea (aflibercept, 2 mg), the standard of care to treat wet AMD and DME, lost U.S. market exclusivity on May 17, 2024.

Regeneron has initiated legal battles against numerous manufacturers of Eylea biosimilars, alleging infringements to Eylea's U.S. Patent 11,084,865 B2—the common patent in all lawsuits—which is set to expire in June 2027. In December 2023, in the case against Mylan (now Viatris), the court ruled in favor of Regeneron, considering there was enough evidence supporting that Viatris infringed the '865 patent.

On May 20, 2024, the FDA approved the first interchangeable Eylea biosimilars—Biocon's Yesafili, litigated in the Regeneron vs. Mylan case, and Samsung Bioepis's Opuviz—for treating wet AMD, DME, and other retinal diseases. However, owing to ongoing litigation, their U.S. market entry date remains uncertain.

Regeneron's Eylea HD (aflibercept, 8 mg) launched in August 2023 and is gaining traction in the ophthalmology space, driven by physicians' positive perception and familiarity with aflibercept and by Eylea HD's ability to reduce the treatment burden compared with other approved drugs, while offering a favorable safety profile.



U.S. net product sales ($B)

Source: Regeneron

Clarivate's takeaways

Regeneron is fighting aggressively to protect the Eylea franchise from biosimilar competition.

Eylea remains the patient-share leader among approved therapies for wet AMD and DME in the United States. While ongoing lawsuits mitigate the biosimilar threat, Regeneron will benefit from additional time to convert patients currently on Eylea to Eylea HD prior to biosimilar launch.

Biosimilar entry in mid-2027 may exempt Eylea and Eylea HD from IRA negotiations.

Under the IRA, the CMS will select a list of Part B drugs for Medicare pricing negotiations, taking effect in 2028. One of the conditions for inclusion on the list is a lack of biosimilar competition. Thus, biosimilar entry in mid-2027 would benefit Regeneron because Eylea, and more importantly, Eylea HD, would be exempt from price negotiations because this new dose was designated as a non-new molecular entity.

With less than a year on the market, Eylea HD is already a key player in the wet AMD and DME spaces.

Clarivate's primary market research data show that Eylea HD is experiencing a rapid uptake among wet AMD and DME patients. Eylea HD's capacity to prolong dosing intervals and to offer stronger retinal drying compared with other brands are key attributes that drive its prescribing. As biosimilar competition stalls, Eylea HD will capitalize and likely win the race for the new standard of care during this decade.

Clarivate™

About the author

Carolina Ruivo, Ph.D.

Senior Healthcare Research & Data Analyst

Dr. Ruivo's 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.

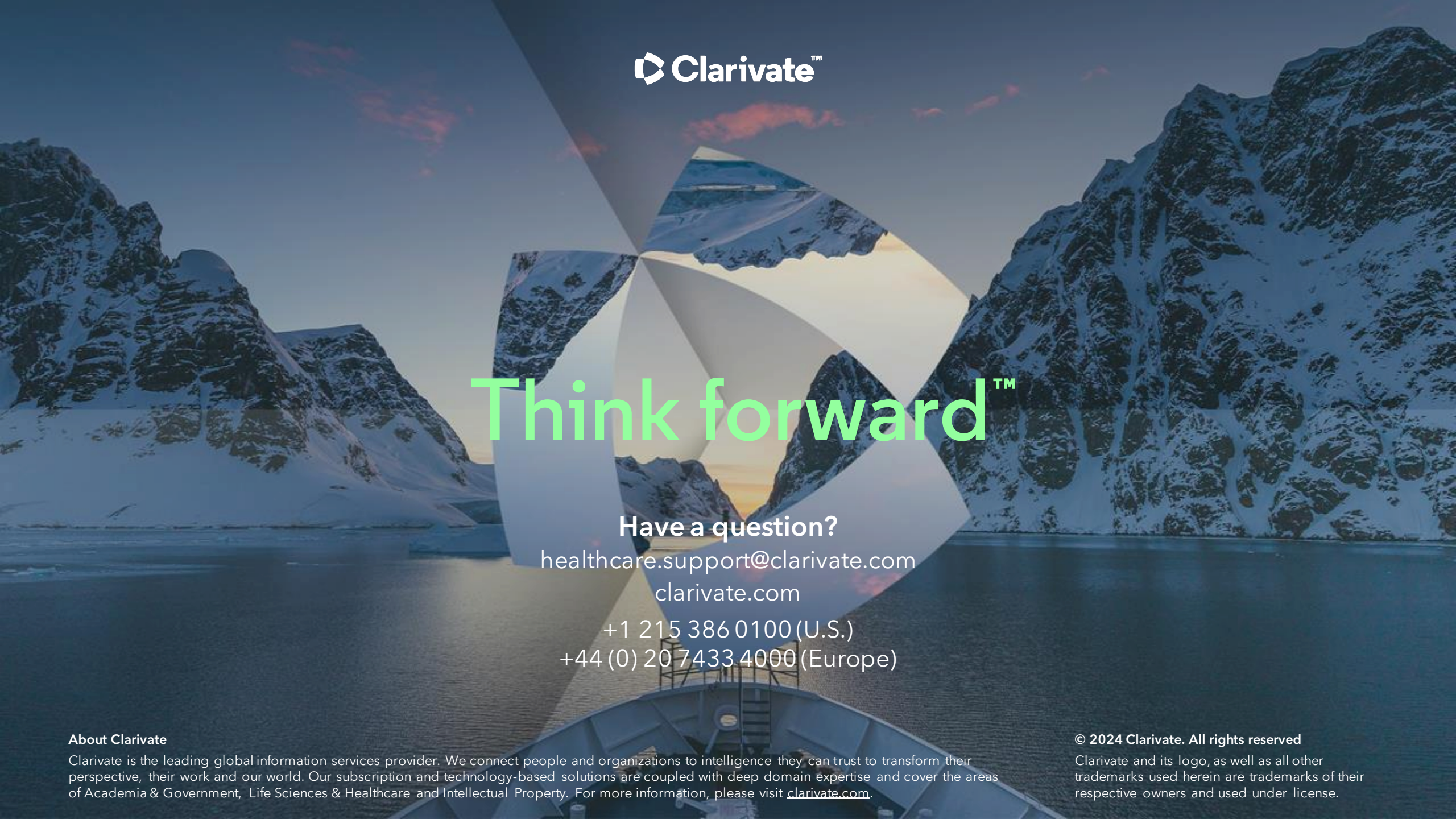
CarolinaRuivo.Pereira@Clarivate.com

Clarivate coverage of wet AMD products

- Disease Landscape & Forecast | Dry and Wet Age-Related Macular Degeneration (G7)
- Treatment Algorithms: Claims Data Analysis | Wet Age-Related Macular Degeneration (US) (published in 2024)
- Access & Reimbursement | Age-Related Macular Degeneration (US) (published in 2023)
- Unmet Need | Wet Age-Related Macular Degeneration (US/EU) (published in 2023)

Clarivate coverage of DME products

- Disease Landscape & Forecast | Diabetic Macular Edema / Diabetic Retinopathy (G7)
- Unmet Need | Diabetic Macular Edema (US/EU) (published in 2022)



Have a question?

healthcare.support@clarivate.com
clarivate.com
+1 215 386 0100 (U.S.)
+44 (0) 20 7433 4000 (Europe)

About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com.