Executive Summary

Sales for Macular Edema and Macular Degeneration Market

In the 7MM in this report, GlobalData valued the Macular Edema and Macular Degeneration market at $6.5 billion in 2013, and expects the market to increase to $13.3 billion in 2023, at a Compound Annual Growth Rate (CAGR) of 7.4%.

GlobalData estimates that sales within the ME market across the seven major markets (7MM) were approximately $1.5 billion in 2013, and will grow at a CAGR of 8.4% to reach approximately $3.3 billion by the end of the forecast period in 2023. The US will continue to generate more than half of the total sales during forecast period.

While in the AMD across the 7MM, GlobalData valued market worth $5.1 billion in 2013, and expected to reach $10.1 billion by the end of 2023, at a Compound Annual Growth Rate (CAGR) of 7.1%. The US contributes almost half of the total market sales in 2013.

The main drivers for the growth of ME and AMD market over the forecast period are:

- Global aging population
- Increasing diabetes prevalence and obesity rates
- Indication expansion of the marketed drugs, and new therapies entering the ME and AMD markets

The main barriers to the growth of ME and AMD market over the forecast period are:

- Healthcare budget cuts due to global austerity measures, especially in Europe
- Increased focus on the cost-effectiveness of drugs, which could be a barrier to the reimbursement and pricing of new therapies
Figure below illustrates the global sales for ME and AMD by region during the forecast period.

### Sales for ME and AMD by Region, 2013–2023

**ME**
- **Total:** $1.5bn

**2013**
- United States: 57%
- France: 4%
- Germany: 13%
- Italy: 7%
- Spain: 4%
- United Kingdom: 17%
- Japan: 9%

**2023**
- United States: 55%
- France: 5%
- Germany: 13%
- Italy: 6%
- Spain: 7%
- United Kingdom: 4%
- Japan: 10%

**Total:** $3.1bn

**AMD**
- **Total:** $5.1bn

**2013**
- United States: 49%
- France: 6%
- Germany: 15%
- Italy: 4%
- Spain: 5%
- United Kingdom: 8%
- Japan: 11%

**2023**
- United States: 55%
- France: 5%
- Germany: 13%
- Italy: 4%
- Spain: 7%
- United Kingdom: 6%
- Japan: 10%

**Total:** $10.1bn

Source: GlobalData
Executive Summary

Key Players in the ME and AMD Market
The main players in the ME and AMD markets are those with anti-vascular endothelial growth factor (anti-VEGF) drugs, which dominate these markets. Roche and Novartis market Lucentis (ranibizumab), while Regeneron and Bayer market Eylea (aflibercept), and these will remain the leading companies within this sector over the forecast period. The Eylea franchise is undergoing rapid indication expansion, essentially following in the footsteps of Lucentis, and is anticipated to enter the DME and ME-BRVO markets across the 7MM by the end of 2015.

Current Unmet Needs and Opportunities
The most pressing unmet need within the AMD market is absence of dAMD treatments. Reducing the frequency of anti-VEGF injections and increasing the efficacy of these drugs would also be a challenge. Another important need in these markets is to develop replacement of intravitreal (ITV) injections as well as to increase patient awareness and to develop home monitoring of disease progression.

These unmet needs offer substantial opportunities to gain a significant market share by developing novel therapies for dAMD, complementary therapy to anti-VEGF drugs to reduce dose frequency, and therapy with increased duration of action and improved efficacy.

Future Players and their Product Portfolios
GlobalData anticipates that seven products in the late-stage pipeline will enter the AMD and ME markets during the forecast period. These products include two DME drugs (Ampio’s Optina and Santen’s DE-102), two drugs for the treatment of dAMD (Roche’s lampalizumab and Acuela/Otsuka’s emixustat), and three wAMD drugs (Allergan’s abicipar pegol, Ophthotech’s Fovista, and Ohr’s squalamine [squalamine lactate]) with promising results in terms of safety and efficacy for the treatment of ME and AMD patients. These pipeline drugs can achieve 27% of the overall ME and AMD market share at the end of 2023.

Trends in Corporate Strategy
Companies in retinal disease space are using similar type of strategies, companies first penetrate in the single therapeutic market and then expand their market to other indications by using this as a platform. wAMD is most targeted market by these companies as it is most lucrative and having large patient pool make it easier to conduct a clinical trials. While on the other hand smaller companies struggle with the financial burden involved in the clinical development and have to wait for a longer period of time to generate revenue.
Executive Summary

For these reasons, acquisitions, collaborations, and licensing agreements are very common in the ophthalmic market. For example, agreement between Ophthotech and Novartis for Fovista and the co-development of emixustat by Acucela and Otsuka.

Figure below provides an analysis of the company portfolio gap in ME and AMD during the forecast period.

![Company Portfolio Gap Analysis in ME and AMD, 2013–2023](image)

Source: GlobalData

What Do Physicians Think?

The recent approval of Eylea in the US and in the EU, will have a significant impact on the DME market. As such, key opinion leaders (KOLs) interviewed by GlobalData highlighted the advantages of Eylea over Lucentis and Avastin, which are due to Eylea’s less frequent dosing regimen and anticipate that this drug will gain a significant share of the DME market.

“I think Eylea will probably do better [than Lucentis] because it has less frequent injections that seem to...be more and more attractive….We don’t have any problem with [Lucentis]. I think that [it] will be nice to have that [choice].”

OUS Key Opinion Leader

“My gut feeling is that for high-VEGF diseases like RVOs [retinal vein occlusions] and DME, more VEGF blockade is better than less VEGF blockade, and…my feeling is that if they [patients] are insufficiently responding to Avastin [bevacizumab], they will still probably have a better response to Eylea. And so,..., Eylea will likely just take over the DME market very quickly.”

US Key Opinion Leader

“[Eylea] is not FDA [Food and Drug Administration]-approved in the US [for DME], and therefore, it is not covered by insurance....And so, that’s the present obstacle for my using Eylea for diabetic macular edema. So, once there is financial coverage for patients, I fully anticipate using Eylea, in addition to Lucentis, for DME.”

US Key Opinion Leader

KOLs also highlighted the need for drugs to treat the geographic atrophy (GA) associated with progressive dAMD, and recognized this as the most urgent unmet need within the ME and AMD markets.
Executive Summary

“I think the new market [is] really in dry AMD, [which is] considered a big clinical unmet need.”

OUS Key Opinion Leader

“The huge unmet need [is in] geographic atrophy, and that, by far, is, no question, the biggest, because we have so many patients, well, [who are] treated [for] wet macular degeneration, with huge [numbers of] patients [with] geographic atrophy, and there is growing evidence that suggest[s] that anti-VEGF treatment compromises all the circulation and contributes to geographic atrophy. And so,...that is the one unmet need all around.”

US Key Opinion Leader

KOLs also showed optimism about a new device in the early stages of commercialization, called ForeseeHome, which allows AMD patients to monitor their disease progression at home, thereby relieving the burden of having regular eye check-ups, while offering the benefit of detecting any changes in visual deterioration at the earliest stage.

“There is this home device that can be used by some, not all, but some patients with dry macular degeneration as a means to monitor their vision and give them a heads up when something may have changed that suggest[s] wet macular degeneration has developed. That will prompt them to go in for an examination, and when this works correctly, they are then identified with an earlier onset [of] disease.”

US Key Opinion Leader

“The ForeseeHome device, for people who can afford it, is a way to monitor for new [vision] distortion at home, and potentially diagnose wet macular degeneration sooner. But this is very much for patients who have the wherewithal and [the] finances to afford that device.”

US Key Opinion Leader

Numerous late-stage pipeline products were viewed favorably by KOLs, and are expected to make a significant impact on the market. However, they viewed other pipeline products with some skepticism.

“I am also aware of Iluvien [being] on the horizon..., but I don’t know exactly where it is in terms of approval, but I think [it] is to be coming through fairly soon. That would be very exciting.”

OUS Key Opinion Leader

“I think that the Phase II trial for this drug [Fovista] was quite good, and if they can replicate that in the Phase III [studies], then it will be approved. It can be a little bit difficult, you know. Sometimes when you go to Phase III, you might lose [a] little bit of ground, and if that’s the case, it may not get approved. But I think [there is] at least a 50-50 chance that it will [be approved].”

US Key Opinion Leader
Executive Summary

“I think there is some encouraging Phase I clinical result with an anti-factor D antibody [lampalizumab]. I think the clinical trial that showed these results required monthly injections, and that’s just not feasible in the healthcare system. So, over the long term, in terms of a [target].”

OUS Key Opinion Leader

“I will be very skeptical [about squalamine] because thus far, no eye drop has succeeded. You know several have tried, and [one of] the most recent ones, pazopanib, got into mouse eyes very well and had efficacy in mice, but no efficacy in humans. So, until we see a success with eye drops, I am going to be quite skeptical.”

US Key Opinion Leader
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# Introduction

Macular edema (ME) is a condition where fluid and protein deposits accumulate on the macula, causing it to swell, leading to vision deterioration and loss. There are three main types of ME that warrant pharmacological treatment: diabetic macular edema (DME), macular edema following branch retinal vein occlusion (ME-BRVO), and macular edema following central retinal vein occlusion (ME-CRVO). The main therapy for all three of these indications is anti-vascular endothelial growth factor (VEGF) therapy; corticosteroids are often used as a second-line therapy.

The ME market is expected to grow significantly over the next decade, and will be driven by indication expansions of anti-VEGF drugs, Eylea (aflibercept) and Ozurdex (dexamethasone), in addition to an increasing prevalence in diabetes and its associated complication of DME.

Age-related macular degeneration (AMD) is the leading cause of vision loss among persons ages 50 years and over in the developed world. There are two main types of this retinal disease: wet and dry AMD. Dry age-related macular degeneration (dAMD) accounts for most patients with this retinal disease but there are no treatments currently available; however, the more severe type of AMD, wet age-related macular degeneration (wAMD), is treatable, predominantly with anti-VEGF therapy.

The AMD market is about to enter an exciting phase with the arrival of two novel therapies for dAMD, as well as the launch of two promising adjunctive therapies for wAMD over the next decade. The global population is aging rapidly, which is a driver for significant growth in both the ME and AMD markets.

The catalysts and objectives for this report are to:

- Assess the impact Eylea (aflibercept) will have on Lucentis’ (ranibizumab) global and national market shares for ME and AMD
- Evaluate the role that corticosteroid implants will have within the DME market
- Assess the significance of the late-stage pipeline products entering the ME and AMD markets, and evaluate how these products will impact the future treatment landscape
- Highlight the significant unmet needs in the ME and AMD markets
- Identify any remaining opportunities in the ME and AMD markets
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2.1 Related Reports

- GlobalData (2014). Lucentis (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC480DFR
- GlobalData (2014). Avastin (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC481DFR
- GlobalData (2014). Eylea (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC482DFR
- GlobalData (2014). Visudyne (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC483DFR
- GlobalData (2014). Corticosteroid Implants (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC484DFR
- GlobalData (2014). Abicipar pegol (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC485DFR
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- GlobalData (2014). Fovista (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC486DFR
- GlobalData (2014). Squalamine (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC487DFR
- GlobalData (2014). Lampalizumab (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC488DFR
- GlobalData (2014). Emixustat (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC489DFR
- GlobalData (2014). Optina (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC490DFR
- GlobalData (2014). DE-102 (Macular Edema and Macular Degeneration) – Forecast and Market Analysis to 2023, October 2014, GDHC491DFR
5.8 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research, and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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