



GlobalData»
PharmaPoint

**LUCENTIS
(MICROVASCULAR COMPLICATIONS OF DIABETES) -
FORECAST AND MARKET ANALYSIS TO 2022**

Executive Summary

The table below presents a summary of the key metrics for Lucentis (Microvascular Complications for Diabetes) for recombinant products in the seven major pharmaceutical markets (7MM) during the forecast period from 2012–2022.

Lucentis: Key Metrics in the Seven Major Markets (7MM)	
2012 Market Sales	
US	\$496.6m
5EU	\$292.9m
Japan	\$358.9
Total	\$1.14bn
Key Events (2012–2022)	Level of Impact
Patent expiry date in US ,5EU and Japan is 2019	↓↓↓
2022 Market Sales	
US	\$477.0m
5EU	\$294.3m
Japan	\$277.4m
Total	\$1.04bn
Source: GlobalData 5EU = France, Germany, Italy, Spain, and UK; 7MM = US, 5EU, and Japan	

Sales for Lucentis by Region, 2012–2022

The combined sales of Lucentis were estimated at \$1.14 billion in 2012 and expected to decrease to \$1.04 billion in 2022 with a negative compound annual growth rate (CAGR) of 0.9%.

Key factors driving the sales of Lucentis include:

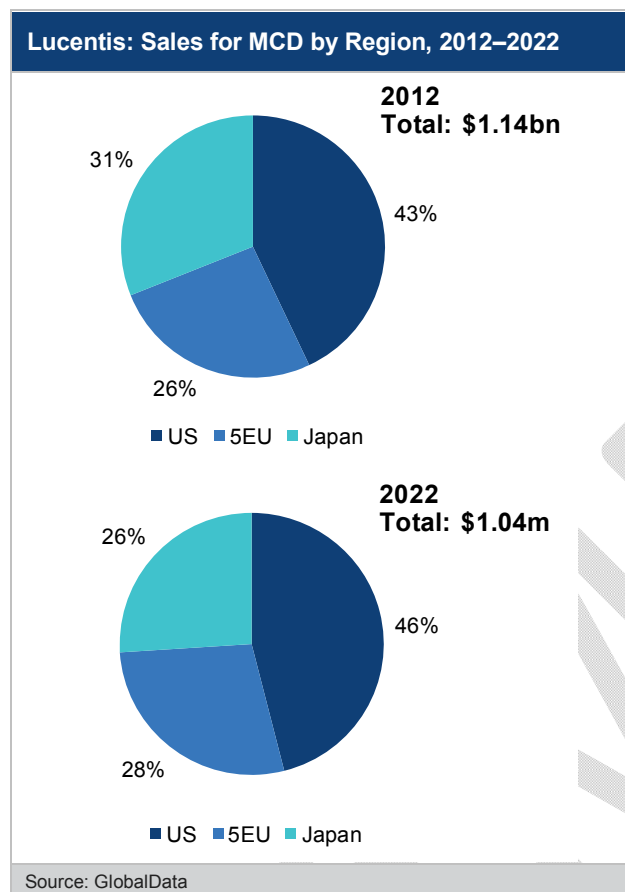
- Sole marketed therapy approved for diabetic retinopathy/DME
- Greater efficacy than laser photocoagulation
- Greater efficacy and tolerability in the treatment of DME than any of the steroid implants
- Better safety record than Avastin

Major barriers effecting the growth of Lucentis include:

- Administration by intravitreal injection makes it an unpleasant therapy for patients.
- The high cost commonly leads to the use of Avastin, which is cheaper.
- Visual acuity is never completely recovered

Executive Summary

The figure below illustrates the MCD sales for the 7MM by region during the forecast period.



What Do Physicians Think?

"The point is this. Let's say companies have found a new drug which acts on vascular tone. Then you think, okay, I know what I am doing with this drug, I'll develop this drug for hypertension. Oh, yes, 10 years ago when there would be a market for that, that's what we'd do. But now, in this stage, nobody is developing drugs for hypertension because the cost to survive is just enormous from the company's point of view (. . .). And then, oh, wow, why don't we go for other indication where vasculo-tone and vasculo-protection is important. Then they usually go to chronic heart failure or to chronic kidney failure. That's the way, so it is how the companies are thinking."

Key Opinion Leader, October 2013

Executive Summary

"I am not certain how much interest there's going to be in developing new drugs for the diabetic neuropathic pain, because of gabapentin going generic and Cymbalta going generic. Why would they want to bring out another class of agent for 500 million dollars and then compete in the generic market place? The problem here in the US, may be the same in Europe, is that prescribing is so much controlled by the pharmacy formularies. The pharmacy formulary is giving a terrible time when you are competing with the generic manufacturers because the formularies just won't pay for it. I wouldn't try to develop another agent competing with Cymbalta which is going to be generic next year; I would be hesitant to do it."

Key Opinion Leader, October 2013

If we go for the health economics point of view, the highest unmet need is to bring the patients to target with respect to risk factors – diabetes, blood pressure, and lipids. If you control these three, you don't have a problem with diabetic complications so much. But, it is so difficult, people will not tolerate it, they are incontinent, don't want to sacrifice too much, to eat low salts, to eat low fats, to control their sugar levels. And then we have the complications."

Key Opinion Leader, October 2013

"The approval of anti-VEGF agents was a very big thing forward, and so the use of laser for macular edema will decline significantly."

Key Opinion Leader, September 2013

"The thing is that there is no specific treatment for neuropathy. In retinopathy they have now the VEGF antagonists for the macular edema which looks good. Nephropathy, they have at least the ARB's and they have ACE inhibitors, but still I feel that there is need for further treatment. The highest unmet need is for neuropathy actually. Because apart from controlling blood sugar, and we don't know whether that works either, there is virtually nothing. So, we need drugs which need to slow down the progression of neuropathy and thereby improve the prognosis, and also have an influence on the hard end points. We need drugs that address several mechanisms of action, not just one."

Key Opinion Leader, October 2013

"There is a high risk in the diabetes neuropathy market because there are many big companies who lost a lot of money by developing several drugs, but on other hand, it's a high-value market. So, if one drug comes through, then it's worth the risk as it's a highend scenario. In the same time, it's a high risk, because you need to spend hundreds [of] millions of dollars for a study like this. It's relatively easier to do studies for neuropathic pain, but even there the market is drying up because no new studies come in, and no new drugs."

Key Opinion Leader, October 2013

Executive Summary

"Preventive therapies are always needed [for diabetic nephropathy], and this may be one of the reasons that atrasentan is not targeting preventive therapies. It's more likely to be expensive and have some adverse effects, and for those things, it is totally reasonable to apply them to the high-risk population with high-risk of progression – for the advanced kidney disease group. For preventive therapies, you'd rather want something that's not expensive and is safe."

Key Opinion Leader, October 2013

"Lucentis is the best at the moment [for DME], but Eylea will become a serious competitor since it is less frequently administered (. . .). In fact, the dosing is not that much different overall, but physicians and patients may believe it is."

Key Opinion Leader, September 2013

"In diabetic retinopathy, of course they think diabetes control is important, but apparently only 11% of the risk for the development of the retinopathy is reduced through the medical treatment for diabetes. It means that in many patients, diabetic retinopathy moves and progresses and its course is somewhat independent of the control of diabetes. It's a memory kind of situation, if you had diabetes for a long time, the damage is already done and it's too late to control it."

Key Opinion Leader, September 2013

"I am using what is generally recommended by the guidelines [for diabetic neuropathic pain], so that means first-line is either the anti-epileptics, such as gabapentin or pregabalin, or antidepressants, such as duloxetine or amitriptyline (. . .). These are the drugs that are used usually as a first line of treatment in these patients; there are many, but they are all the same in terms of efficacy, it just depends on what better suits a particular patient in terms of side effects, but also the price."

Key Opinion Leader, October 2013

"I never prescribed opioids. There is a lot of prescribing of opioids going on in United States, it's a huge problem, and the problem with giving an opioid in any kind of long-term pain situation is that patients will be hooked on it. I would get hooked on it. You would be hooked on it. Everybody would. You have madness of drug addiction now all over the US, and all these people who would go and say that they have a back pain, get opioids and they chew them up and sell them and all that, so now they are trying to undo 20 years of mistakes. So, I would never give an opioid for a long-term situation unless it's a fatal disease like cancer."

Key Opinion Leader, October 2013

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Introduction

2 Introduction

2.1 Catalyst

The entire market for microvascular complications of diabetes (MCD) — diabetic nephropathy, retinopathy, and neuropathy — is facing an extremely high level of unmet need across the seven major markets (7MM) (US, France, Germany, Italy, Spain, UK, and Japan). With the exception of the diabetic retinopathy segment of the market, which has recently seen a rapid uptake of novel anti-VEGF therapies, the MCD market has been slowly overtaken by generic drugs. During the 2012–2022 forecast period, the MCD market will be characterized by the following key trends:

- The major global barrier for all microvascular complications is the sparsely populated pipeline, with the diabetic neuropathy and nephropathy segments facing the additional barrier of an increasing number of generic competitors.
- The entire anti-VEGF (vascular endothelial growth factor) class, used for the treatment of diabetic macular edema (DME), will experience steady growth over the forecast period and will be further stimulated by the entry of Regeneron/Bayer's Eylea (aflibercept), an anti-VEGF therapy with a less-frequent mode of administration.
- The market entry of AbbVie's atrasentan, the first novel, branded diabetic nephropathy drug to enter the market in more than 10 years, is expected to noticeably enhance the overall market size during the forecast period. This, of course, will depend on the outcome of the long and risky Phase III trial for atrasentan, which is highly uncertain, as trials in this space are marked by a very high rate of failure.
- The growth of the diabetic neuropathy segment will be restricted the most over the forecast period due to the lack of novel therapies, and due to the loss of patent exclusivity for the two major branded drugs, Eli Lilly's Cymbalta (duloxetine) and Pfizer's Lyrica (pregabalin), used for the treatment of diabetic neuropathic pain.

Whether branded or generic, none of the current therapies for diabetic microvascular complications are able to alter their progressive natural course: therefore, the market will remain underserved and a large opportunity for drug developers will persist.

The major global barrier for all microvascular complications is the sparsely populated pipeline, while the diabetic neuropathy and nephropathy segments also face the barrier in an increasing number of generic competitors

Introduction

2.2 Related Reports

- GlobalData (2013). Diabetic Foot Ulcers – Opportunity Analysis and Forecast to 2017, October 2013, GDHC005POA
- GlobalData (2013) Avastin (Microvascular Complications of Diabetes) - Forecast and Market Analysis to 2022, December 2013, GDHC318DFR
- GlobalData (2013) Eylea (Microvascular Complications of Diabetes) - Forecast and Market Analysis to 2022, December 2013, GDHC319DFR
- GlobalData (2013) Optina (Microvascular Complications of Diabetes) - Forecast and Market Analysis to 2022, December 2013, GDHC320DFR
- GlobalData (2013) Atrasentan (Microvascular Complications of Diabetes) - Forecast and Market Analysis to 2022, December 2013, GDHC321DFR
- GlobalData (2013) Ranirestat (Microvascular Complications of Diabetes) - Forecast and Market Analysis to 2022, December 2013, GDHC322DFR
- GlobalData (2013) (Microvascular Complications of Diabetes) - US Drug Forecast and Market Analysis to 2022, December 2013, GDHC201CFR
- GlobalData (2013) (Microvascular Complications of Diabetes) - France Drug Forecast and Market Analysis to 2022, December 2013, GDHC202CFR
- GlobalData (2013) (Microvascular Complications of Diabetes) - Germany Drug Forecast and Market Analysis to 2022, December 2013, GDHC203CFR

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- GlobalData (2013) (Microvascular Complications of Diabetes) - Italy Drug Forecast and Market Analysis to 2022, December 2013, GDHC204CFR
- GlobalData (2013) (Microvascular Complications of Diabetes) - Spain Drug Forecast and Market Analysis to 2022, December 2013, GDHC205CFR
- GlobalData (2013) (Microvascular Complications of Diabetes) - UK Drug Forecast and Market Analysis to 2022, December 2013, GDHC206CFR
- GlobalData (2013) (Microvascular Complications of Diabetes) - Japan Drug Forecast and Market Analysis to 2022, December 2013, GDHC207CFR
- GlobalData (2013). Microvascular Complications of Diabetes – Current and Future Players, December 2013, GDHC1026FPR

Appendix

7.7 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, Boston, London, India and Singapore.

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