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PharmaPoint

**LIDODERM/VERSATIS (NEUROPATHIC PAIN) -
FORECAST AND MARKET ANALYSIS TO 2022**

Executive Summary

Table below provides a summary of the key metrics for Lidoderm/Versatis in the 7MM neuropathic pain markets during the forecast period from 2012–2022.

Lidoderm/Versatis: Key Metrics in the 7 MM Neuropathic Pain Markets	
2012 Market Sales	
US	\$340.8m
5EU	\$89.5m
Japan	N/A
Total	\$430.3m
Key events (2011–2019)	Level of Impact
Lidoderm patent expiry in 2014 in the US	↓↓
Versatis exclusivity ends in 2017 in 5EU	↓↓
2022 Market Sales for NP	
US	\$100.2m
5EU	\$58.4m
Japan	N/A
Total	\$158.6m
Source: GlobalData: N/A= not available	
5EU = France, Germany, Italy, Spain, and UK	
7MM = US, 5EU and Japan	

Sales for Lidoderm/Versatis in the Neuropathic Pain (NP) Market

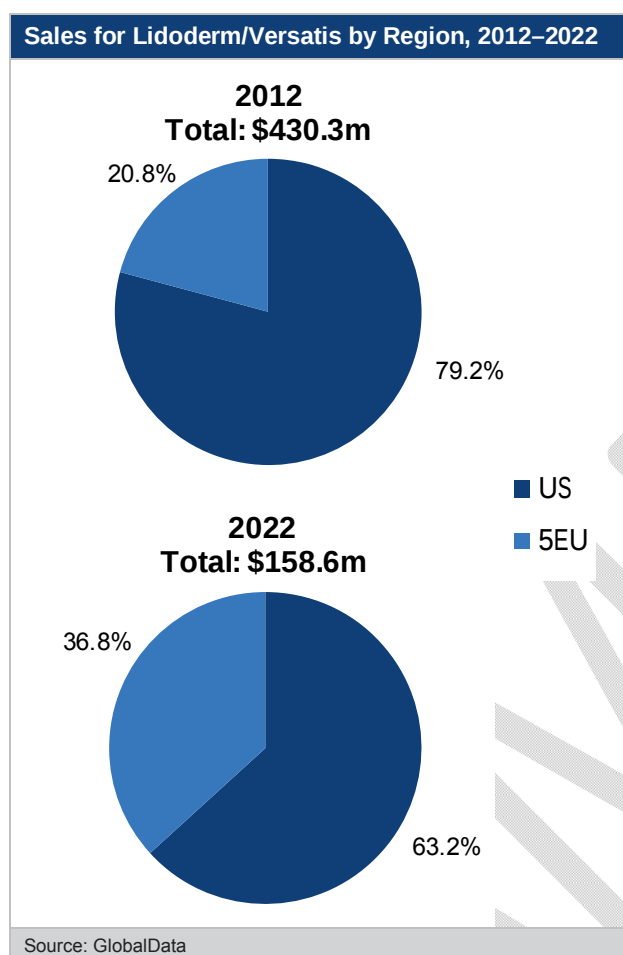
The combined sales of Lidoderm/Versatis were estimated at \$430.3 million in 2012. By 2022, we project Lidoderm/Versatis sales to fall to \$158.6 million, with a negative Compound Annual Growth Rate (CAGR) of 9.5% over the course of the decade. These estimates cover the sales in the seven countries included in this report: the US, France, Germany, Italy, Spain, the UK and Japan.

Major growth drivers for Lidoderm/Versatis in the NP market over the forecast period include:

- Good efficacy in terms of pain relief; one study showed comparable efficacy to Lyrica.
- Excellent tolerability; low risk of systemic side effects, since it is a topical treatment.
- Advantageous for elderly patients, who are the demographic at highest risk for PHN, due to its strong safety profile and ease of administration.
- Good for combination therapy with oral medications, since it has very low systemic absorption and a low drug interaction risk.
- Major barriers of growth for Lidoderm/Versatis in the NP market over the forecast period include:
 - Lidoderm patent expiry in 2014.
 - As a topical treatment, efficacy is limited to NP, which presents peripherally in a localized manner.
 - Inconvenient daily application of multiple patches compared with the capsaicin patch, which is only applied once every three months.

Executive Summary

Figure below illustrates Global Lidoderm/Versatis sales by region during the forecast period.



What Do Physicians Think?

When queried about the most challenging aspects of treating patients with NP, key opinion leaders (KOLs) were in agreement, citing efficacy and safety as the key issues.

"Well, I think the efficacy and safety of the drugs we have available, because with the given monotherapy, we can have only 50% of the patients [responding]. And many patients also stop treatment due to side effects, especially central nervous system adverse event[s] like dizziness, nausea, somnolence, and concentration difficulties."

[EU] KOL, October 2013

"If you look at all the clinical trials — Lyrica, duloxetine, opioids, Qutenza — you name it. So, what is the outcome? Forty percent [of] patients get 30% pain relief. So, what it means is that 60% of patients got no pain relief, and even those who get 30% of pain relief still have plenty of pain. So, if you have a pain [score] of eight, and your pain is down to five, you are still in a lot of pain. So, [when] all [is] said and done, it's pretty pathetic."

[US] KOL, September 2013

Another major challenge observed in clinical practice is the underdosing of key medications.

Executive Summary

"These drugs are notoriously underdosed. So, they come in with 600[mg] or 900[mg] gabapentin, or 75mg pregabalin, per day, which have not been shown to be effective in those trials. But, I would not rule out that there are certain patients who are doing well on low doses, which may not be placebo, also. But these are all assumptions, because it has never been demonstrated in clinical trials that 75mg of pregabalin are effective. Even 150mg are not."

[EU] KOL, October 2013

"If the drug is difficult to titrate, it's usually that they [physicians] start treatment, and then they just...I do not know, they forget titrating. For them, it's much easier to handle drugs which actually you don't have to titrate that much. So, if you look at duloxetine, for example, there you don't have this danger, because they start usually with 30[mg], and then they go to 60[mg], and that's it. But, with gabapentin, especially, and also with pregabalin, you need to titrate for longer periods of time. And maybe that's too cumbersome for them, inconvenient. So, it's much better to have a drug which doesn't need that much of a titration."

[EU] KOL, October 2013

Physicians also raised concerns about the lack of guidance on combination therapies, which are frequently necessary in the treatment of NP.

"So, I guess my concern is that this in the real world, we treat medical illness, including chronic pain, with multi-drug approaches, and then the data that we get typically from studies seeking FDA approval or otherwise is based upon patients who are being compared with placebo in a single therapy, and we don't get guidance about how to take care of people in the real world. And we also don't get the benefit of knowing how these drugs combine together, [how they] work with each other, and I think that's the shame. It is a big obstacle, because you know the providers of care don't have enough studies to support their use of multiple types of medications at one time — safe or not safe, what's likely to help, what's not likely to help."

[US] KOL, July 2013

Although physicians indicated a need for novel therapies, they also pointed out that there are sometimes financial pressures to prescribe less expensive drugs first, even though they may be poorly tolerated by the patient.

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"There are two drugs that are approved in the United States for the management of peripheral neuropathy: one is duloxetine, and the other one is pregabalin....Now if you, in the United States, want to prescribe duloxetine or pregabalin, the third-party payer or the insurer will refuse to pay for it. [They say] you should use a simpler drug...you should use a drug like [a] tricyclic [antidepressant] first. So, if you use a drug like amitriptyline first, what happens is the patients hate you. You know? They become constipated, they get erectile dysfunction, and they get urinary retention. They get [low] blood pressure, they get a dry mouth — they hate you for that."

[US] KOL, August 2013

"Now, what are we doing in clinical practice, we use a drug like gabapentin [be]cause it is very cheap today."

[US] KOL, August 2013

In terms of promising pipeline drugs, Daiichi-Sankyo's DS-5565 was highlighted by physicians as being most promising.

"The Daiichi Sankyo compound, for example, the calcium [channel] alpha-2-delta [ligand], which...of course — it's not a new mechanism, but [it] could be that this is something which maybe is more effective than pregabalin, or maybe more safe, theoretically. They will need to prove this....So, I think, among the systemically-administered drugs in the pipelines, I think the Daiichi compound has the best chance. But it's nothing new. Not [a] new mechanism or so."

[EU] KOL, October 2013

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Introduction

2 Introduction

2.1 Catalyst

The entire neuropathic pain (NP) market is characterized by a high level of unmet need across all indications, and across the seven major markets (7MM) (US, France, Germany, Italy, Spain, UK, and Japan). The market, however, is anticipated to grow during the forecast period, from \$2.58 billion in 2012 to \$3.53 billion in 2022, at a Compound Annual Growth Rate (CAGR) of 3.19%.

During this time, the NP market will be characterized by the following key events, drivers, and barriers:

- Growth in the global market will be driven by the growing incidence of NP as a result of the increasing elderly population, the increasing prevalence of type 2 diabetes and the resultant rise in painful diabetic neuropathy (PDN) cases, as well as the market entry of seven pipeline drugs (DS-5565, eslicarbazepine, cebranopadol, topical clonidine, Eladur, CNV-2197944, and CNV-1014802).
- The fastest-growing market will be Japan, which will end the forecast period accounting for 14% of the market, with projected sales of \$491m and a CAGR of 6.38%. This higher-than-average growth in Japan will be driven by the fact that its population is aging at a faster rate than any of the other countries in the 7MM, as well as by the delayed launches and continued growth of Lyrica (pregabalin) and Cymbalta (duloxetine) in Japan.
- However, growth in the rest of the 6MM will be greatly impacted by the patent expirations and subsequent generic erosion of the key leading brands, Lyrica, Cymbalta, and Lidoderm (lidocaine patch 5%).

2.2 Related Reports

- GlobalData (2014). PharmaPoint: Neuropathic Pain – Global Drug Forecast and Market Analysis to 2022, April 2014, GDHC70PIDR
- GlobalData (2014). Neuropathic Pain – US Drug Forecast and Market Analysis to 2022, April 2014, GDHC239CFR
- GlobalData (2014). Neuropathic Pain – 5EU Drug Forecast and Market Analysis to 2022, April 2014, GDHC240CFR

Introduction

- GlobalData (2014). Neuropathic Pain – Japan Drug Forecast and Market Analysis to 2022, April 2014, GDHC241CFR
- GlobalData (2014). Lyrica (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC403DFR
- GlobalData (2014). Cymbalta (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC404DFR
- GlobalData (2014). Nucynta ER/Palexia SR (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC405DFR
- GlobalData (2014). Qutenza (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC407DFR
- GlobalData (2014). Eslicarbazepine acetate (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC408DFR
- GlobalData (2014). DS5565 (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC409DFR
- GlobalData (2014). Eladur (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC410DFR
- GlobalData (2014). Topical clonidine (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC411DFR
- GlobalData (2014). Cebranopadol (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC412DFR
- GlobalData (2014). CNV-2197944 (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC413DFR
- GlobalData (2014). CNV-1014802 (Neuropathic Pain) - Forecast and Market Analysis to 2022, April 2014, GDHC414DFR
- GlobalData (2014). Neuropathic Pain – Current and Future Players, April 2014, GDHC1034FPR

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.

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