MIGRAINE - GLOBAL DRUG FORECAST AND MARKET ANALYSIS TO 2023
Executive Summary

### Migraine: Key Metrics in the Seven Major Pharmaceutical Markets*

<table>
<thead>
<tr>
<th>Year</th>
<th>2012 Epidemiology</th>
<th>2012 Market Sales</th>
<th>Pipeline Assessment</th>
<th>Most Promising Pipeline Drugs</th>
<th>Peak-Year Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prevalent Population</td>
<td>75.7 million</td>
<td><strong>US $1,922.6m</strong></td>
<td>Number of drugs in Phase I–II</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Treated Population</td>
<td>45.3 million</td>
<td><strong>5EU $427.4m</strong></td>
<td>Number of drugs in Phase IIb–III</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>$2,490.7m</strong></td>
<td><strong>Number of drugs in Phase IIb–III</strong></td>
<td><strong>Botox (Allergan)</strong></td>
<td><strong>$706.4m</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Lasmiditan (CoLucid)</strong></td>
<td><strong>$644.3m</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>MK-1602 (Merck)</strong></td>
<td><strong>$610.7m</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Zecuity (NuPathe/Teva)</strong></td>
<td><strong>$180.5m</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Levadex (Allergan)</strong></td>
<td><strong>$162.5m</strong></td>
</tr>
</tbody>
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**Table above summarizes the key metrics for migraine in the seven major pharmaceutical markets during the forecast period from 2012–2023.**

**Moderate Growth in the Migraine Market is Expected from 2012–2023**

GlobalData estimated that the migraine market in 2012 was valued at approximately $2.5 billion in the seven major markets (7MM: US, France, Germany, Italy, Spain, UK and Japan). The migraine market is saturated with generic drugs, and the remaining branded products already on the market are expected to lose exclusivity during the next few years, with the exception of Botox for chronic migraine, which is expected to maintain its leading position in terms of sales. However, reformulations of mature products as well as new classes of therapies are anticipated to launch during the forecast period. By 2023, the migraine market will grow to $3.7 billion at a compound annual growth rate (CAGR) of 3.6%, with the US continuing to dominate the market as a result of higher drug prices and a large migraine population.

The major drivers of the migraine market over this forecast period will include:

- The continuous usage of Botox as preventive therapy for chronic migraine, which will increase sales in the US, Germany, Italy, Spain and the UK.
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- Introduction of novel acute migraine therapy classes (ditans and gepants) within the 7MM, which will address the underserved population, boosting the overall market size during the forecast period.

- The launch of combinations of drug and devices with high prices in the US.

The major barriers to growth of the migraine market during the forecast period will include:

- Patent expirations of the majority of the drugs marketed for migraine, which have resulted in generics flooding the market, and which may negatively impact revenue from branded drugs that are expected to launch in the forecast period.

- The lack of late-stage pipeline drugs as preventive treatment.

- The concerns of reducing healthcare costs as part of government austerity measures, particularly in Europe, which will impede market growth.

Figure below illustrates global migraine sales for the 7MM during the forecast period from 2012–2023.

Source: GlobalData.
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Newer Drugs with Improved Efficacy and Convenient Administration Dominate the Pipeline

The migraine market has been fairly inactive for a number of years, marked by a number of generics. The acute migraine market is dominated by the triptan class of drugs, which were introduced in the early 1990s. GlaxoSmithKline was the first to introduce a triptan, the gold-standard Imitrex (sumatriptan), and subsequently developed different formulations of this flagship brand, as well as drug combinations (e.g., Treximet) to expand its franchise. Other companies, such as AstraZeneca and Merck, have followed this strategy, aiming to expand and protect their mature product offering. The majority of the triptan class of drugs has now been exposed to severe sales erosion from generic competitors. Further jeopardizing the position of these mature brands is the presence of a number of late-stage pipeline triptans in development that consist of reformulations of these off-patent therapies, which aim to improve the efficacy of the existing formulations. Further to this is the development of these reformulations in combination with new devices. These include Zogenix’s Sumavel DosePro (needle-free delivery), Teva and NuPathe’s Zecuity (transdermal patch), Allergan’s Levadex (inhaler), OptiNose’s AVP-825 (breath-powered bi-directional nasal drug delivery device) and SUDA’s SUD-001 (oral mist).

Besides triptans, an exciting era is foreseeable in the near future. Merck has aimed to maintain its share of the migraine market in anticipation of the patent expiry of its triptan, Maxalt, by developing novel drugs for a new class of acute migraine therapy. This strategy has also been taken by a new company to the migraine market, CoLucid, which is developing a first-in-class ditan. The launch and rapid uptake of these new therapies, which have an advantage over current acute therapy classes, triptans and ergots, will have notable commercial potential.

In the preventive market, Allergan’s Botox will remain the market leader and sole player as preventive medication for chronic migraine. The other preventive migraine therapy classes (beta blockers, anti-epileptics, antidepressants and calcium channel antagonists) are expected to remain relatively stable as this arena stays genericized.
A Minority of the Pipeline Drugs Target the Unmet Needs of the Migraine Market

The choice of therapies in both the acute and preventive therapy markets has remained stable over the years and the majority of these are now easily accessible to patients, as most are available as inexpensive generics. For this reason the existing unmet needs within the migraine market have remained the same for some time. The classes of acute treatments currently available are contraindicated in patients with, or at risk of, cardiovascular disorders; in addition, not all patients respond to the available acute therapies.

On the other hand, all preventive treatments were not originally approved for migraine use and not all are well tolerated, which points to the need for more effective and safer medication. More importantly, the absence of diagnostic tools for identifying migraines has led to a major challenge for physicians to make a correct diagnosis. This suggests there is a need for greater awareness and understanding of the indication by physicians that would allow for a more effective treatment approach. Overall, GlobalData's research indicates that the level of unmet needs in the migraine market is within the moderate-to-high range.

Of the drugs that are in the late stages of development, only two are likely to address the clinical unmet needs. CoLucid's lasmiditan has shown encouraging results from its Phase IIb trials that it does not cause vasoconstrictive effects and is safe to use in patients with, or at risk of, cardiovascular disorders. Merck's drug, MK-1602, is also anticipated to be safe to use for this population; however, clinical trials have yet to show this and at the time of the publication of this report, Merck had not yet publically disclosed the results of its two Phase IIb trials. Both of these first-in-class drugs, with estimated launches in 2017, will additionally provide alternative classes of acute therapies for patients where the triptans and ergot alkaloids are not effective.
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Market Opportunities for New Entrants

By 2023, the migraine market will be even more crowded with generics. Nevertheless, while the new classes of therapies, ditans and gepants, will already be established, there will still be a ready market for further acute treatment choices. However, from a commercial perspective, ditans and gepants will need to show significant overall efficacy benefits compared with their competitors while maintaining or improving the safety and side-effects profile, in order to launch successfully.

Additionally, there is no preventive migraine therapy on the market or in late-stage clinical trials that was specially developed for migraine pain. This is a prime need that would be revolutionary if addressed, both from a clinical and commercial perspective. It presents a significant opportunity for investment by drug developers.

New Therapy Classes with Novel Mechanisms will Revitalize the Migraine Drug Landscape

CoLucid’s lasmiditan and Merck’s MK-1602, the first-in-class drugs for the ditans and gepants, respectively, will be the new classes of acute therapy to be launched in the next 10 years. The market entrances of both of these drugs in the US (2017), 5EU (2018) and Japan (2023) are set to boost the overall market size during the forecast period.

Both classes of drugs have the potential to steal shares from the existing triptans and ergot alkaloids, in addition to gaining shares from patients who are unresponsive to these existing medications. GlobalData forecasts that their combined sales will reached approximately $1.3 billion by 2023.

In addition, Teva and NuPathe’s Zecuity, the first and only iontophoretic transdermal system (patch) for migraine, will prove to be popular among the migraine population that require or prefer an alternative route of administration over the existing formulations (tablets, injections and nasal sprays) of acute treatments. The novel product is estimated to gain sales of approximately $180.5m by 2023. A drawback for Zecuity’s market potential is that concerns with contact dermatitis may limit its adoption in clinical practice.

Competitive Assessment of Late-Stage Pipeline Agents in Migraine, 2012–2023

Please note: Bubble size represents approximate peak-year sales of pipeline drug

Source: GlobalData.
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What do the physicians think?

Physicians interviewed by GlobalData acknowledged that members of the new classes of acute migraine therapy, lasmiditan and MK-1602, will be promising for the underserved migraine population. They would also be easier medications for physicians to prescribe, reducing the time required to take patient histories for comorbidities that are contraindicated with the use of triptans and ergot alkaloids. However, some physicians did express concerns about the safety of both drugs and also the cost associated with them.

“I have seen some of the early studies on lasmiditan. You know, it looks pretty good... what I like about it is it’s not supposed to constrict blood vessels because it’s [a] 5-HT$_{1F}$ receptor. I have no experience with it, but it was evaluated and looked at it again … [for] cardiac problems, and they didn’t find any problem there… There aren’t too many adverse events; this could also be another good drug and it is [a] totally new way of treating… You never had a drug like this, so that makes it exciting.”

[US] Key Opinion Leader, October 2013

“I would suppose those class of compounds [ditans and gepants] don’t have direct constriction activities on blood vessels, so that they would both … meet an immediate unmet need, that is for the group of people we are just talked about, [with] cardiovascular, cerebrovascular problems, and in general terms make therapy easier for primary care physicians to initiate.”

[US] Key Opinion Leader, October 2013

“With lasmiditan, we talked before, a new drug, a new approach, would be interesting to have in the market because some of the patients could improve; even in the future we could prescribe this drug with a combination, perhaps with a triptan, perhaps with [an NSAID].”

[EU] Key Opinion Leader, October 2013

“Lasmiditan, the problem is it causes dizziness and tiredness in higher dosage, and patients don’t want to be tired.”

[EU] Key Opinion Leader, October 2013

“The difficulty is that it’s going to be a branded drug [lasmiditan] and that’s not currently on the market, and so that’s going to be expensive.”

[EU] Key Opinion Leader, November 2013
“And all of the CGRP receptors and antagonist were failures, not because of efficacy but all had safety problems irrespective of from which company… as soon as they were used frequently, whichever drug it was, it caused liver problems. So, it most probably is a class effect.”

[EU] Key Opinion Leader, October 2013

In contrast, physicians were unsure of the beneficial effects that reformulations of off-patent triptans would provide to the migraine population.

“I am not excited about the rizatriptan as a film without seeing more data, because rizatriptan was not absorbed from the mouth as a melt tablet that I am aware of, and so if this film is totally absorbable and it gets in very quickly and because of that it works faster than the nasal spray or shot, which I doubt will be the case… they now have a tremendous heads-up on everybody else. My guess is it will work fine but it won’t be that much faster or work that much better than a tablet, so the only advantage may end up being that you don’t have to swallow the pill.”

[US] Key Opinion Leader, October 2013

“[I] think that the rizatriptan film could be interesting for some patients. Even that we have the formulation which is very similar to this formulation, but perhaps in some cases could be interesting, but the results in clinical effect will be the same exactly as that formulation of the rizatriptan.”

[EU] Key Opinion Leader, October 2013

Key opinion leaders are also optimistic about the new combinations of drugs and devices entering the market, but there are concerns associated with each.

“A company came along and made a lontophoretic patch where they drive it across the skin using a battery and a computer and that seems to work pretty well, but it doesn’t work as well as some of the other forms, and that’s about to be released in the next few months.”

[US] Key Opinion Leader, October 2013

“My second most favorite drug would be one I know a little bit about, that is the OptiNose. It’s not just a drug, it’s also a device, [which is] little bit unusual and the biggest problem with this is it is unusual. It’s always difficult to get doctors and patients to do things that are unusual but it’s [a] standard drug, sumatriptan, it is very well absorbed.”

[US] Key Opinion Leader, October 2013

Physicians have stressed the need for more effective drugs to treat the migraine population, in particular that there is a lack of preventive therapies.

“We will definitely need drugs that work in people who do not respond to triptans, and even more we need more effective drugs for preventive therapy.”

[EU] Key Opinion Leader, October 2013
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“We have very few preventive treatments which have made it to clinical trials in migraine… we need, for the future, new preventive drugs. In some patients, we cannot improve them with the treatments that we have at this moment.”

[EU] Key Opinion Leader, October 2013
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2 Introduction

2.1 Catalyst

The migraine market is divided into acute and preventive segments, which are largely saturated with generic drugs. Over the next few years, the remaining branded products in the acute market, Axert, Frova and Relpax, are expected to lose patent protection, allowing more generics to enter the market. However, the acute migraine therapeutics market is set to change and become more competitive with late-stage pipeline products consisting of combinations of off-patent reformulations and devices such as NuPathe’s transdermal patch and OptiNose’s breath-powered bi-directional device, which aim to provide improvements in efficacy and convenience of drug delivery. The challenge for these new products is the crowded marketplace, which is saturated with inexpensive generics. New products will have to be reasonably priced and distinguish themselves in terms of efficacy. Furthermore, the potential launches of new acute therapy classes, ditans and gepants, are set to revolutionize the migraine market by targeting the underserved migraine population. These new classes are set to escalate patients’ therapy choices and will experience rapid uptake during the forecast period, which will noticeably enhance the overall market size.

Aside from new market entries, the preventive migraine segment is unlikely to see any change in the development of new treatments. However, Allergan’s Botox, as the only preventive treatment for chronic migraine in the market, is expected to continue to drive market growth during the forecast period, and will continue to be the market leader in terms of sales.

2.2 Related Reports


2.3 Upcoming Related Reports

- GlobalData (2014). Neuropathic Pain - Global Drug Forecast and Market Analysis to 2023, April 2014, GDHC003PIDR.

- GlobalData (2014). Depression - Global Drug Forecast and Market Analysis to 2023, April 2014, GDHC003PIDR.
Appendix

11.8 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, Boston, London, India and Singapore.

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