Executive Summary

Botox: Key Metrics in the 7MM* for Migraine, 2012-2023

<table>
<thead>
<tr>
<th>Year</th>
<th>US 2012</th>
<th>5 EU 2012</th>
<th>Japan 2012</th>
<th>Total 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>$434.3m</td>
<td>$68.3m</td>
<td>N/A</td>
<td>$502.6m</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>US 2023</th>
<th>5 EU 2023</th>
<th>Japan 2023</th>
<th>Total 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>2023</td>
<td>$615.1m</td>
<td>$91.3m</td>
<td>N/A</td>
<td>$706.4m</td>
</tr>
</tbody>
</table>

Table above summarizes the key metrics for Botox in the seven major pharmaceutical markets during the forecast period from 2012–2023.

Botox Sales By Region, 2012–2023

- The sales of Botox were estimated at $502.6 million in 2012. By 2023, GlobalData projects these sales to increase to $706.4 million at a compound annual growth rate (CAGR) of 3.1%. These estimates cover the sales in the seven major markets (7MM) included in this report: the US, France, Germany, Italy, Spain, the UK, and Japan. We believe that the following parameters will drive expansion in these markets:
  - First member of the neurotoxins class for preventive migraine treatment
  - Positive efficacy profile
  - Few side effects
  - Treatment is once every 12 weeks
  - The following factors will hinder the growth of these drugs:
    - The distant spread of toxin effect from injection site
    - Administration requires a total of 31 injections across 7 head/neck muscles
    - Administration requires a headache specialist

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

Sales for Botox by Region, 2012–2023

- 2012: Total $502.6m
- 2023: Total $706.4m

Source: GlobalData.

*7MM = US, 5 EU (France, Germany, Italy, Spain, UK), and Japan
For the purposes of this report, Global = US, France, Germany, Italy, Spain, UK and Japan, N/A = not applicable
Executive Summary

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
Executive Summary

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

“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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Introduction

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

Introduction

- GlobalData (2014). Ergot Alkaloids (Migraine) – Forecast and Market Analysis to 2023, March 2014, GDHC373DFR
Introduction


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.
7.8 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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