ABILIFY (MAJOR DEPRESSIVE DISORDER) - FORECAST AND MARKET ANALYSIS TO 2023
Executive Summary

Table below presents the key metrics for Abilify in the seven major pharmaceutical markets (7MM) (US, France, Germany, Italy, Spain, UK, and Japan). In addition, Australia is covered in this report, for a total of eight markets during the forecast period from 2013–2023.

### Abilify: Key Metrics in the 7MM and Australia Major Depressive Disorder Markets, 2013–2023

<table>
<thead>
<tr>
<th>2013 Market Sales</th>
<th>2023 Market Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US</strong></td>
<td>$1,769.9m</td>
</tr>
<tr>
<td><strong>5EU</strong></td>
<td>$171.7m</td>
</tr>
<tr>
<td><strong>Japan</strong></td>
<td>$67.3m</td>
</tr>
<tr>
<td><strong>Australia</strong></td>
<td>$10.4m</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$2.0bn</td>
</tr>
</tbody>
</table>

**Key Events (2013–2023)**

- Otsuka/BMS' Abilify patent expiries in 7MM and Australia

<table>
<thead>
<tr>
<th>Level of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>↓↓↓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2023 Market Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US</strong></td>
<td>$268.0m</td>
</tr>
<tr>
<td><strong>5EU</strong></td>
<td>$77.7m</td>
</tr>
<tr>
<td><strong>Japan</strong></td>
<td>$48.1m</td>
</tr>
<tr>
<td><strong>Australia</strong></td>
<td>$5.4m</td>
</tr>
<tr>
<td><strong>Global</strong>*</td>
<td>$0.4bn</td>
</tr>
</tbody>
</table>

7MM = US, France, Germany, Italy, Spain, UK and Japan
5EU = France, Germany, Italy, Spain, UK
*For the purpose of this report, Global = US, France, Germany, Italy, Spain, UK, Japan, and Australia; N/A = Not Available

Source: GlobalData

### Sales for Abilify in the Major Depressive Disorder (MDD) Market

Abilify sales are expected to decrease from $2.0 billion in 2013 to $0.4 billion in 2023 with a negative Compound Annual Growth Rate (CAGR) of 14.96%.

Major growth drivers for Abilify in the MDD market during the forecast period include:

- Oral administration.
- As an adjunctive therapy, Abilify can be used in combination with other antidepressant therapies.
- Psychiatrists have gained extensive experience with Abilify.

Conversely, major barriers to the growth of Abilify in the MDD market include:

- Imminent patent expiries.
- Patients with MDD have a negative view towards antipsychotics.
- Undesirable safety profile.
- Modest antidepressant effects.
- Slow onset of therapeutic effect.
Executive Summary

Figure below illustrates the global Abilify sales by region during the forecast period.

**Sales for Abilify by Region, 2013-2023**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales</th>
<th>US</th>
<th>EU</th>
<th>Japan</th>
<th>Australia</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$2.0bn</td>
<td>87.6%</td>
<td>8.5%</td>
<td>3.3%</td>
<td>0.5%</td>
</tr>
<tr>
<td>2023</td>
<td>$0.4bn</td>
<td>19.5%</td>
<td>12.0%</td>
<td>1.4%</td>
<td>67.1%</td>
</tr>
</tbody>
</table>

What Do the Physicians Think?

Selective serotonin reuptake inhibitors (SSRIs) are the fist-line treatment choice in the MDD market.

“My general opinion for SSRIs is that they are the standard of first-line care, so you cannot hope for something in a more exulted position than that. They have limitations however, that is why we have unmet needs. I think they are slightly less effective as a class than the SNRIs [serotonin-norepinephrine reuptake inhibitors], but they are somewhat better tolerated as a class, so, the overall advantage goes to the SSRIs.”


“SSRIs are available generically now, they are inexpensive, they are the safest antidepressants, work reasonably well, are easy to prescribe, and relevantly easy to take. So, low cost, good tolerability, decent-great safety, and adequate efficacy make these products first-line treatments.”


Physicians need to gain experience with Lundbeck/Takeda’s Brintellix in clinical practice in order to become convinced about the added benefits of this product in treating patients with depression.
Executive Summary

“\textit{I think Brintellix has more than an SSRI. The question is how big the advantage over SSRIs in terms of tolerability and efficacy is. There are some studies showing promising results, but we have to see how it works in clinical practice.}”

[OUS] Key Opinion Leader, February 2014

“\textit{Brintellix may have some advantages, but it is not a first-line drug in my mind, it is not the first thing I would prescribe. It is [a] brand new product and unproven in the real world. Although the registration trials demonstrated safety, tolerability, and efficacy, it is not the same thing as the drugs that are being around for years.}”


The most pressing unmet need in the depression market is for the development of drugs with improved efficacy, according to the physicians interviewed by GlobalData.

\textit{\textquotedblleft The major unmet need still is efficacy. It is the most pressing one.\textquotedblright} \\

[OUS] Key Opinion Leader, March 2014

\textit{\textquotedblleft The biggest unmet need is that we do not have good treatments. The remission and response rates are low, and we have not found new, more effective agents.\textquotedblright} \\


Physicians acknowledge that Alkermes’s ALKS-5461 is one of the most promising products in the pipeline for MDD.

\textit{\textquotedblleft It [ALKS-5461] is [a] very intriguing product. It has a different mechanism of action, so if it really does work, then, I think it has really good potential for adoption. I would see ALKS-5461 as being preferred as an augmenter over second generation antipsychotics.\textquotedblright} \\


\textit{\textquotedblleft We have lots of things that are just the same, but this [ALKS-5461] looks a bit different and is exciting. There is a story about buprenorphine and depression anyway, and if this is a mu [opioid receptor]-blocker it might take some of the problematic aspects, such as dependence.\textquotedblright} \\

[OUS] Key Opinion Leader, February 2014

Products that demonstrate better efficacy, improved safety, and rapid antidepressant effects will move to the forefront of the treatment line.

\textit{\textquotedblleft Something has to be tangibly better, not tangibly different, [but] tangibly better to become a first-line antidepressant.\textquotedblright} \\


\textit{\textquotedblleft If a new compound has better efficacy, [can] show rapid action and low metabolic impact, for me, it will be a first-line treatment.\textquotedblright} \\

[OUS] Key Opinion Leader, February 2014
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Introduction

2 Introduction

2.1 Catalyst

Major depressive disorder (MDD) is one of the most common psychiatric diseases worldwide. The MDD market is a crowded and competitive market, with more than 30 marketed products available for the treatment of patients with MDD. The depression market is about to enter a dynamic phase with imminent patent expiries for top selling products, such as Eli Lilly’s Cymbalta, and Otsuka/BMS’s Abilify, along with the recent launch of the multimodal antidepressant, Lundbeck/Takeda’s Brintellix, in January 2014, and the potential introduction of seven promising late-stage pipeline products into the market during the forecast period. The catalysts and objectives for this report are:

- To assess the impact of imminent patent expiries for Cymbalta and Abilify in the MDD market.
- To evaluate the impact of Brintellix’s 2014 launch in the MDD market.
- To evaluate the significance of late-phase pipeline products, and to show how their launch will shape the future treatment landscape of the MDD market.
- To identify the significant unmet needs in the MDD market.
- To highlight the remaining opportunities in the MDD market.

2.2 Related Reports

Introduction

- GlobalData (2014). PharmaPoint: Lexapro (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC415DFR
- GlobalData (2014). PharmaPoint: Viibryd (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC416DFR
- GlobalData (2014). PharmaPoint: Effexor (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC417DFR
- GlobalData (2014). PharmaPoint: Cymbalta (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC418DFR
- GlobalData (2014). PharmaPoint: Pristiq (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC419DFR
- GlobalData (2014). PharmaPoint: Fetzima (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC420DFR
- GlobalData (2014). PharmaPoint: Savella (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC421DFR
- GlobalData (2014). PharmaPoint: Brintellix (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC422DFR
- GlobalData (2014). PharmaPoint: Seroquel XR (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC424DFR
- GlobalData (2014). PharmaPoint: Brexiprazole (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC425DFR
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- GlobalData (2014). PharmaPoint: Cariprazine (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC426DFR
- GlobalData (2014). PharmaPoint: ALKS-5461 (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC427DFR
- GlobalData (2014). PharmaPoint: Amitifadine (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC428DFR
- GlobalData (2014). PharmaPoint: GLYX-13 (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC429DFR
- GlobalData (2014). PharmaPoint: Tedatioxetine (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC430DFR
- GlobalData (2014). PharmaPoint: ETS6103 (Major Depressive Disorder) – Forecast and Market Analysis to 2023, May 2014, GDHC431DFR

2.3 Upcoming Related Reports

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, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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