IRRITABLE BOWEL SYNDROME – CURRENT AND FUTURE PLAYERS
Sales of Irritable Bowel Syndrome Market

The Irritable Bowel Syndrome (IBS) market in the 7MM (US, France, Germany, Italy, Spain, UK, and Japan) is expected to grow at a compound annual growth rate (CAGR) of 9.89% from sales of $589.6m in 2013 to $1.5 billion in 2023.

The major growth drivers in the global IBS market during the forecast period are:

- The increasing uptake of Ironwood/Actavis/Almirall/Astellas’ Linzess, and its anticipated launch in Japan in 2017
- The anticipated label expansion of Salix/Alfa Wassermann/Norgine/Bama-Geve’s Xifaxan for diarrhea-predominant IBS (IBS-D)
- The potential introduction of four late-stage pipeline products into the IBS market
- The increasing number of prevalent cases of IBS

The major growth barriers in the global IBS market during the forecast period are:

- The unsatisfactory effectiveness of IBS products
- The low diagnosis rate of IBS

The Figure below presents the sales for IBS in the 7MM by region during the forecast period.
Key Players and their Product Portfolios in the Irritable Bowel Syndrome Market

The IBS market is a naïve and underpenetrated one. Major products indicated for IBS in the 7MM are Ironwood/Actavis/Almirall/Astellas’ Linzess, which is indicated for IBS-C; Sucampo/Takeda/Abbott’s Amitiza, which is indicated for women with IBS-C only in the US; Prometheus’ Lotronex, which is indicated for women with IBS-D only in the US under a restricted prescribing program; and Astellas’ Irribow, which is indicated for men with IBS-D only in Japan. Salix/Alfa Wassermann/Norgine/Bama-Geve’s Xifaxan is another top selling product coming behind Linzess and Amitiza, used off-label in patients with IBS.

Astellas has the broadest portfolio of products. Astellas’ portfolio contains Linzess and Irribow. The global development of ASP-7147 for patients with IBS-D demonstrates the company’s strategic commitment to being a key player in the IBS market.

The four new potential therapies that have the potential to enter the IBS market during the 2013 - 2023 forecast period includes Furiex’s (Actavis’) eluxadoline and Menarini’s ibodutant for IBS-D, and Synergy’s plecanatide and AstraZeneca/Ardelyx’s tenapanor for IBS-C. In addition, Xifaxan is in development for IBS-D, and has the potential to gain a label expansion for this indication during the forecast period. The anticipated label expansion of Xifaxan will strengthen Salix’s position in the IBS market, while the potential introduction of new therapies will bring new key players into this market, such as AstraZeneca, Menarini, and Synergy.

Corporate Strategies Adopted by the Leading Players to Gain Market Share

The main corporate strategy trend in the IBS market is companies entering into partnerships; Key players are entering into partnerships for the co-development and co-marketing of products in different regions. Examples include: Ironwood/Actavis/Almirall/Astellas’ Linzess; Sucampo/Takeda/Abbott’s Amitiza; Salix/Alfa Wassermann/Norgine/Bama-Geve’s Xifaxan and AstraZeneca/Ardelyx’s tenapanor. This strategy enables companies to join efforts and resources, share the costs and risks of R&D, and maximize the commercial potential of different products in the IBS market.

Other key strategies that the players in the IBS market are pursuing include the development of a complementary portfolio of products for the treatment of different IBS subtypes, and the development of products with novel mechanisms of action.
Executive Summary

Products with Novel Mechanism of Action (MOA) to Address the Unmet Needs

The development of Furiex’s (Actavis’) eluxadoline; Menarini’s ibodutant; Synergy’s plecanatide and AstraZeneca/Ardelyx’s tenapanor are examples of players aiming to enter the IBS market with novel products. Products with a novel MOA are aiming to address some of the significant unmet needs that exist in the IBS market, which will enable future players to differentiate their products from available treatments and gain market share. With increasing knowledge of the etiology and pathophysiology of IBS, GlobalData expects that the key players will continue to pursue the development of products with novel mechanism of action in order to strengthen their foothold in this market.

The figure below provides an analysis of the company portfolio gap in irritable bowel syndrome during the forecast period.
Executive Summary

What Do Physicians Think?

The majority of KOLs interviewed by GlobalData had a positive perception of Ironwood/Actavis/Almirall/Astellas’ Linzess, which they considered the best single product for treating IBS-C.

“I think Linzess is a little bit better than Amitiza in terms of improving constipation and pain symptoms, but that is, at least, my clinical impression from treating patients over the last year-and-a-half with this medication. I seem to think that I have more patients who get some exuberant diarrhea on it, which is not a side effect; that is a known [problem related to its] mechanism of action. I often have to titrate down a little bit more than I do with Amitiza. I think if I were to have a choice and take just one or the other, I would choose Linzess.”

[US] Key Opinion Leader, August 2014

“Quite frankly, I think Linzess is probably the best single agent out there right now that is available for IBS-C.”

[US] Key Opinion Leader, August 2014

The label expansion of the currently used off-label therapy, Salix/Alfa Wassermann/Norgine/Bama-Geve’s Xifaxan, for IBS will increase its uptake, mainly due to increased use by primary care physicians (PCPs). However, Xifaxan is not expected to significantly change the treatment paradigm for IBS.

“I think Xifaxan would definitely be picked up more by local GI [gastrointestinal] doctors and by community providers, because they just do not use it [only] for IBS, and if it is FDA [Food and Drug Administration]-approved, they would be much more likely to use it. I think [the] use [of Xifaxan] will definitely go up.”

[US] Key Opinion Leader, August 2014

“I believe that this [Xifaxan] is probably not a treatment for any IBS patient. First, it is the [issue with the drug’s] efficacy, as it has been demonstrated in patients with IBS-D only, and I am not sure that any IBS-D patient is a candidate for the drug. Probably patients with small intestinal bacterial growth or abnormal microbiota could be good candidates for this drug. I believe that is a new option — a new, interesting option.”

[5EU] Key Opinion Leader, July 2014

As noted earlier, the IBS market is characterized by a number of significant unmet needs. The major unmet needs include the need for treatments with improved efficacy to control the majority of IBS symptoms, treatments for IBS-D and IBS-M patients, and an improved diagnosis rate.

“There is no one drug that is outstanding, [a drug] which is really great. Different drugs work a little bit [in improving IBS symptoms], but nothing is really fantastic.”

[5EU] Key Opinion Leader, July 2014
Executive Summary

“I think none of the drugs so far is satisfactory in controlling the IBS symptoms. There is a need for drugs, not only to control the bowel movement[s], but to also control the symptoms of pain and bloating.”

[Japan] Key Opinion Leader, August 2014

“For IBS-D, the only really agent we have is Lotronex [alosetron], which is restricted in its use, so I think there is more [unmet] need for that [subtype].”

[US] Key Opinion Leader, August 2014

“In terms of [patients with] IBS-M, we have really nothing much to offer them. That is a huge unmet need, and there is no medication approved by the FDA or the EMA [European Medicines Agency] for this condition.”

[US] Key Opinion Leader, August 2014

“We need better criteria, and what we need more [than anything] is biomarkers for the diagnosis of IBS.”

[5EU] Key Opinion Leader, August 2014

In view of the significant unmet needs in the IBS market, physicians are anticipating new products to become available for treating patients with IBS.

“I believe that any clinician is interested in new treatment options for the relief of IBS symptoms. There are several unmet needs [in this market], and any new drug is interesting.”

[5EU] Key Opinion Leader, July 2014
# Table of Contents

## 1 Table of Contents

- 1.1 List of Tables ................................................. 9
- 1.2 List of Figures .................................................. 10

## 2 Introduction .............................................. 11

- 2.1 Catalyst ....................................................... 11
- 2.2 Related Reports ............................................. 11

## 3 Market Outlook ........................................... 13

- 3.1 Global Markets ............................................ 13
- 3.1.1 Forecast ................................................... 13
- 3.1.2 Drivers and Barriers – Global Issues .................. 17

## 4 Current and Future Players ................................ 19

- 4.1 Overview ...................................................... 19
- 4.2 Trends in Corporate Strategy .............................. 21
- 4.3 Company Profiles .......................................... 22
  - 4.3.1 Actavis ................................................... 22
  - 4.3.2 Astellas .................................................. 24
  - 4.3.3 Almirall .................................................. 27
  - 4.3.4 Ironwood ................................................ 28
  - 4.3.5 Takeda .................................................... 31
  - 4.3.6 Sucampo ................................................ 33
  - 4.3.7 Prometheus ............................................. 35
# Table of Contents

4.3.8 Salix .......................................................................................................................... 37
4.3.9 Menarini ...................................................................................................................... 39
4.3.10 Synergy ..................................................................................................................... 41
4.3.11 AstraZeneca ............................................................................................................. 43

5 Appendix .......................................................................................................................... 45

5.1 Bibliography ................................................................................................................... 45
5.2 Abbreviations .................................................................................................................. 46
5.3 Methodology ................................................................................................................... 48
5.4 Forecasting Methodology ............................................................................................... 48
5.4.1 Diagnosed IBS Patients ............................................................................................. 48
5.4.2 General Pricing Assumptions .................................................................................... 49
5.4.3 Generic Erosion .......................................................................................................... 50
5.5 Primary Research – KOLs Interviewed for This Report ................................................. 51
5.6 About the Authors ......................................................................................................... 53
5.6.1 Analyst ....................................................................................................................... 53
5.6.2 Therapy Area Director ............................................................................................... 53
5.6.3 Global Head of Healthcare ........................................................................................ 54
5.7 About GlobalData ........................................................................................................... 55
5.8 Disclaimer ....................................................................................................................... 55
# Table of Contents

## 1.1 List of Tables

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Global Sales Forecasts ($m) for IBS, 2013–2023</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td>Global IBS Market – Drivers and Barriers, 2013–2023</td>
<td>17</td>
</tr>
<tr>
<td>3</td>
<td>Key Companies in the IBS Market in the 7MM, 2014</td>
<td>20</td>
</tr>
<tr>
<td>4</td>
<td>Actavis’ IBS Portfolio Assessment, 2014</td>
<td>23</td>
</tr>
<tr>
<td>5</td>
<td>Astellas’ IBS Portfolio Assessment, 2014</td>
<td>25</td>
</tr>
<tr>
<td>6</td>
<td>Almirall’s IBS Portfolio Assessment, 2014</td>
<td>27</td>
</tr>
<tr>
<td>7</td>
<td>Ironwood’s IBS Portfolio Assessment, 2014</td>
<td>29</td>
</tr>
<tr>
<td>8</td>
<td>Takeda’s IBS Portfolio Assessment, 2014</td>
<td>31</td>
</tr>
<tr>
<td>9</td>
<td>Sucampo’s IBS Portfolio Assessment, 2014</td>
<td>33</td>
</tr>
<tr>
<td>10</td>
<td>Prometheus’ IBS Portfolio Assessment, 2014</td>
<td>35</td>
</tr>
<tr>
<td>11</td>
<td>Salix’s IBS Portfolio Assessment, 2014</td>
<td>37</td>
</tr>
<tr>
<td>12</td>
<td>Menarini’s IBS Portfolio Assessment, 2014</td>
<td>39</td>
</tr>
<tr>
<td>13</td>
<td>Synergy’s IBS Portfolio Assessment, 2014</td>
<td>41</td>
</tr>
<tr>
<td>14</td>
<td>AstraZeneca’s IBS Portfolio Assessment, 2014</td>
<td>43</td>
</tr>
</tbody>
</table>
# Table of Contents

## 1.2 List of Figures

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>Global Sales for IBS by Region, 2013–2023</td>
<td>16</td>
</tr>
<tr>
<td>Figure 2</td>
<td>Company Portfolio Gap Analysis in IBS, 2013–2023</td>
<td>21</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Actavis’ SWOT Analysis in IBS, 2013–2023</td>
<td>24</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Astellas’ SWOT Analysis in IBS, 2013–2023</td>
<td>26</td>
</tr>
<tr>
<td>Figure 5</td>
<td>Almirall’s SWOT Analysis in IBS, 2013–2023</td>
<td>28</td>
</tr>
<tr>
<td>Figure 6</td>
<td>Ironwood's SWOT Analysis in IBS, 2013–2023</td>
<td>30</td>
</tr>
<tr>
<td>Figure 7</td>
<td>Takeda's SWOT Analysis in IBS, 2013–2023</td>
<td>32</td>
</tr>
<tr>
<td>Figure 8</td>
<td>Sucampo’s SWOT Analysis in IBS, 2013–2023</td>
<td>34</td>
</tr>
<tr>
<td>Figure 9</td>
<td>Prometheus’ SWOT Analysis in IBS, 2013–2023</td>
<td>36</td>
</tr>
<tr>
<td>Figure 10</td>
<td>Salix’s SWOT Analysis in IBS, 2013–2023</td>
<td>38</td>
</tr>
<tr>
<td>Figure 11</td>
<td>Menarini’s SWOT Analysis in IBS, 2013–2023</td>
<td>40</td>
</tr>
<tr>
<td>Figure 12</td>
<td>Synergy’s SWOT Analysis in IBS, 2013–2023</td>
<td>42</td>
</tr>
<tr>
<td>Figure 13</td>
<td>AstraZeneca’s SWOT Analysis in IBS, 2013–2023</td>
<td>44</td>
</tr>
</tbody>
</table>
2 Introduction

2.1 Catalyst

Irritable Bowel Syndrome (IBS) is a common disorder characterized by abdominal discomfort associated with altered bowel function. Although IBS is not a life-threatening disorder, it has a considerable effect on patients’ quality of life (QOL). In terms of volume, the IBS market is a large, albeit naïve, one, with only a small number of pharmacotherapies indicated for the treatment of the disorder, and it is also characterized by significant unmet needs. The catalysts and objectives for this report are to:

- Evaluate the impact of Ironwood/Actavis/Almirall/Astellas’ Linzess (linaclotide) on the IBS market following its launch in 2012 in the US and in 2013 in the 5EU region
- Evaluate the significance of the late-phase pipeline agents for IBS, and how the potential launch of these products will shape the future IBS market
- Highlight the significant unmet needs in the IBS market
- Identify the remaining opportunities in the IBS market

2.2 Related Reports

Introduction

5.7 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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