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PharmaPoint

**XIFAXAN (IRRITABLE BOWEL SYNDROME) –
FORECAST AND MARKET ANALYSIS TO 2023**

Executive Summary

The Table below presents the key metrics of Salix/Alfa Wassermann/Norgine/Bama-Geve's Xifaxan for Irritable Bowel Syndrome (IBS) in the seven major pharmaceutical markets (US, France, Germany, Italy, Spain, UK, and Japan) covered in this report during the 2013–2023 forecast period.

Xifaxan: Key Metrics in the 7 Major Pharmaceutical Markets	
2013 Market Sales	
US	\$109.2m
5EU	\$29.2m
Japan	N/A
Total	\$138.4m
Key Events (2013–2023)	Level of Impact
Salix/Alfa Wassermann/Norgine/Bama-Geve's Xifaxan label expansion for IBS-D expected in the US in 2016 and the 5EU in 2017	↑↑
2023 Market Sales	
US	\$174.9m
5EU	\$47.2m
Japan	N/A
Total	\$222.2m
Source: GlobalData	
7MM = US, France, Germany, Italy, Spain, UK, Japan	
5EU = France, Germany, Italy, Spain, and UK	
N/A = Not Available	

Sales for Xifaxan in the IBS Market

GlobalData estimates that the Xifaxan off-label sales for IBS in 2013 were approximately \$138.4m across the seven major markets (7MM) covered in this report. By the end of the forecast period in 2023, Xifaxan sales will increase approximately to \$222.2m, at a Compound Annual Growth Rate (CAGR) of 4.84%.

The major drivers of growth for Xifaxan in the IBS market during the forecast period include:

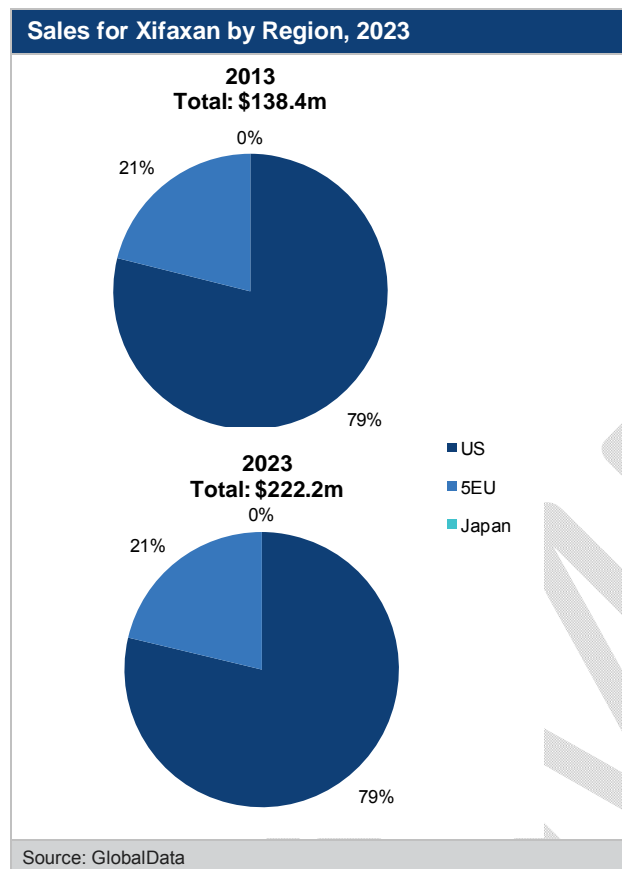
- The gastroenterologists' experience and familiarity with the product
- The increase in the prescription rate of Xifaxan by primary care physicians following its label expansion for IBS
- Its excellent safety profile

The major barriers of growth for Xifaxan in the IBS market during the forecast period include:

- Its modest efficacy
- The physicians' concerns about the long-term use of antibiotics

Executive Summary

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



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

Executive Summary

“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

“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

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Introduction

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 Salix/Alfa Wassermann/Norgine/Bama-Geve's Xifaxan on the IBS market
- 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

- GlobalData (2014). EpiCast Report: Irritable Bowel Syndrome – Epidemiology Forecast to 2023, October 2014, GDHCER068-14
- GlobalData (2014). OpportunityAnalyzer: Celiac Disease – Opportunity Analysis and Forecast to 2018, November 2014, GDHC036POA
- GlobalData (2014). PharmaPoint: Ulcerative Colitis – Global Drug Forecast and Market Analysis to 2022 – Event-Driven Update, September 2014, GDHC005EPIDR
- GlobalData (2014). PharmaPoint: Crohn's Disease – Global Drug Forecast and Market Analysis to 2022, January 2014, GDHC77PIDR
- GlobalData (2014). PharmaPoint: Irritable Bowel Syndrome – Global Drug Forecast and Market Analysis to 2023, December 2014, GDHC97PIDR

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- GlobalData (2014). Irritable Bowel Syndrome – US Drug Forecast and Market Analysis to 2023, December 2014, GDHC270CFR.
- GlobalData (2014). Irritable Bowel Syndrome – 5EU Drug Forecast and Market Analysis to 2023, December 2014, GDHC271CFR
- GlobalData (2014). Irritable Bowel Syndrome – Japan Drug Forecast and Market Analysis to 2023, December 2014, GDHC272CFR
- GlobalData (2014). Amitiza (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC517DFR
- GlobalData (2014). Linzess (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC518DFR
- GlobalData (2014). Lotronex (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC519DFR
- GlobalData (2014). Irribow (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC520DFR
- GlobalData (2014). Eluxadoline (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC521DFR
- GlobalData (2014). Ibodutant (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC522DFR
- GlobalData (2014). Plecanatide (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC524DFR
- GlobalData (2014). Tenapanor (Irritable Bowel Syndrome) – Forecast and Market Analysis to 2023, December 2014, GDHC525DFR
- GlobalData (2014). Irritable Bowel Syndrome – Current and Future Players, December 2014, GDHC1042FPR

Appendix

9.8 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.

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