

**GlobalData»**  
**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
<b>Total</b>	<b>\$138.4m</b>
Key Events (2013–2023)	
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
<b>Total</b>	<b>\$222.2m</b>

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:

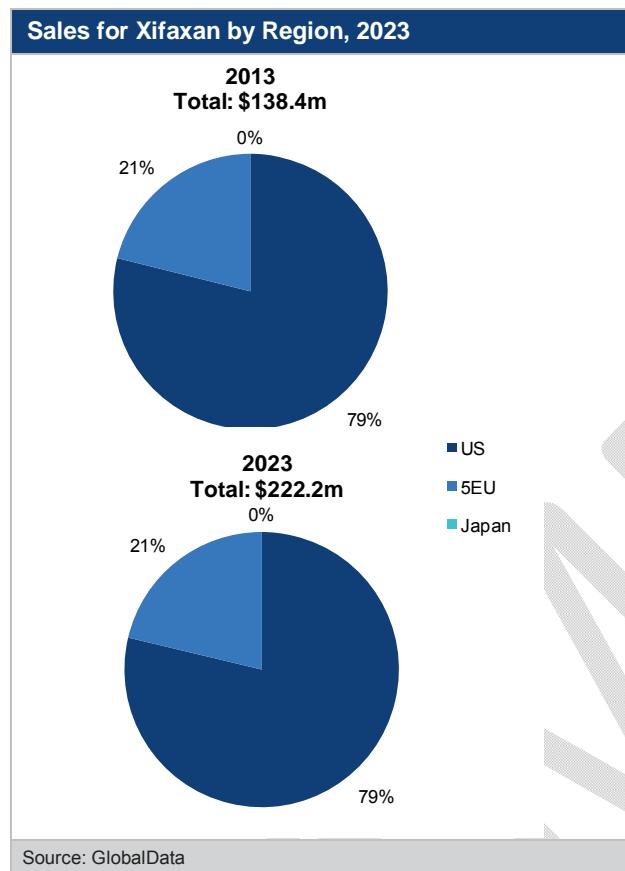
- The gastroenterologists' experience and familiarity with the product
- The increase in the prescription rate of Xifaxan by primary care physicians following its label expansion for IBS
- Its excellent safety profile

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

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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

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*"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). Ibudutant (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.

GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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