**GlobalData** »

**PharmaPoint**

**ULCERATIVE COLITIS - US DRUG FORECAST AND MARKET ANALYSIS TO 2022**

# Executive Summary

**Sales for Ulcerative Colitis in the United States**

In 2012, GlobalData estimated that the US Ulcerative Colitis (UC) market reached $2.25 billion. By the end of the forecast period, in 2022, sales across the US will grow steadily to reach $3.49 billion, representing a Compound Annual Growth Rate (CAGR) of 4.5% over the 10-year timeframe, which includes four new market entrants and the launch of biosimilars.

Major growth drivers in the UC market over the forecast period include:

- Higher uptake of existing biologic drugs and the launch of new biologics

- Affordable Care Act (ACA)

- Eventual introduction of a biosimilar regulatory pathway

Conversely, major barriers to the growth of the UC market include:

- Pricing pressures due to US healthcare reform

- Insurance challenges and the affordability of expensive biologic therapies

- High lack of compliance

Figure below illustrates the US Ulcerative Colitis sales during the 10-year forecast period.



Sales for Ulcerative Colitis in the US by Drug Class, 2012–2022

Source: GlobalData
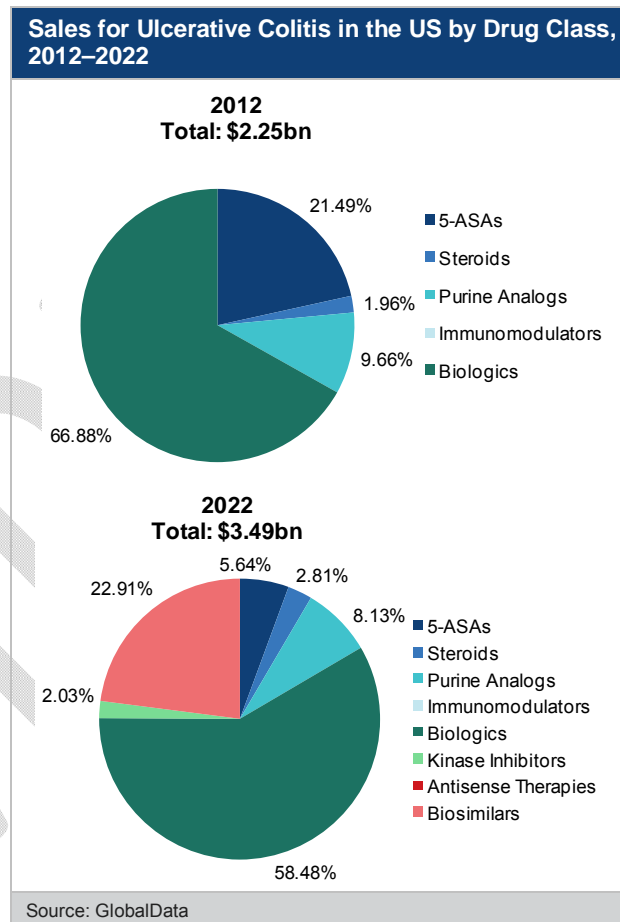
## Executive Summary

**What Do Physicians Think?**

Physicians interviewed by GlobalData expressed doubts about the use of Inflectra (an infliximab biosimilar) following its approval in Europe in September 2013.

*"I do not comprehend what the EMA based the label extrapolation upon. I would like to see data from a clinical trial of Inflectra done on UC patients. I'm afraid, though, that we [physicians] might receive pressure to prescribe this biosimilar treatment because of the healthcare funding cuts"*

*[EU] key opinion leader, October, 2013*

The physicians also underscored the need for a curative treatment for UC.

*"Essentially, there is no adequate treatment for severe UC patients. AZA [azathioprine] has an unpredictable array of adverse effects and no guaranteed efficacy. The biologics only work in 40% of the severe UC patients, and in most cases, they are underdosed. We need a curative treatment."*

*[EU] key opinion leader, October 2013*

Some KOLs expressed the opinion that UC patients should be referred to a specialist before they develop bloody diarrhea, as well as the desire for companies to develop disease severity prediction tests, which could allow for the earlier detection of UC.

*"Patients usually go to their primary care physicians and complain about chronic diarrhea, some sort of uveitis, poor quality of life, etcetera. If colonoscopy is considered necessary, and a heavy colonic inflammatory burden is observed, then the patient undergoes regular monitoring. This doesn't happen with everyone, though, and in 90% of the cases, UC is diagnosed upon the presence of bloody diarrhea. But, I think we can catch it sooner. We need a [disease] severity prediction test."*

*[US] key opinion leader, November, 2013*

## Executive Summary

The physicians also commented on the clinical positioning that they would choose for Takeda's pipeline therapy, Entyvio.

*"I think if vedolizumab is as good as it looks, it will be [a] first- or second-line treatment in place of azathioprine. If you have a UC patient relapsing frequently, despite the use of mesalazine, vedolizumab will be an ideal candidate. I regard it as safer than azathioprine and more effective [for UC]. [However,] I would carry on using anti-TNFs for the treatment of CD."*

*[EU] key opinion leader, September 2013*

The physicians also shared their thoughts on the high risk of colorectal cancer in inflammatory bowel disease (IBD) sufferers, which includes those with UC.

*"Colorectal cancer is a huge risk in UC patients....Pharmaceutical intervention is not designed to prevent this risk. The use of immunosuppressants does not help."*

*[EU] key opinion leader, September 2013*

**Table of Contents**

# 1    Table of Contents

# Table of Contents

# Table of Contents

# Table of Contents

## 1.1 List of Tables

## Table of Contents

# Table of Contents

## 1.2    List of Figures

# Introduction

## 2 Introduction

### 2.1 Catalyst

The catalysts for this report are to:

- Assess the future of the currently marketed tumor necrosis factor (TNF)-blocking biologics, Remicade (infliximab) and Humira (adalimumab), following their loss of patent protection, the launch of new products, and the introduction of biosimilars into the market.

- Examine the impact that Entyvio's (vedolizumab's) estimated launch in 2014 will have on the management of ulcerative colitis (UC) and the competitive landscape in terms of market value.

- Evaluate the significance of the late-stage pipeline products and how their launch will shape the future treatment landscape in UC.

- Identify the remaining unmet needs in UC and highlight untapped opportunities.

The launch of new biologic drugs will increase treatment options, improve disease management, and drive growth in the UC market. Although the need for safe and effective new treatments, let alone a curative drug, is paramount for patients with UC, the products that are currently in the pipeline are expected to face challenges in gaining patient share following their entry into the UC market. These new entrants will undergo pricing and reimbursement pressures and will also face fierce competition from infliximab and adalimumab biosimilars.

### 2.2 Related Reports

- GlobalData (2013). PharmaPoint: Psoriasis – Global Drug Forecast and Market Analysis to 2022, May 2013, GDHC48PIDR

- GlobalData (2013). PharmaPoint: Rheumatoid Arthritis – Global Drug Forecast and Market Analysis Event-Driven Update, July 2013, GDHC60PIDR

- GlobalData (2014). PharmaPoint: Ulcerative Colitis – Global Drug Forecast and Market Analysis to 2022, February 2014, GDHC80PIDR

- GlobalData (2014). Ulcerative Colitis – 5EU Drug Forecast and Market Analysis to 2022, February 2014, GDHC219CFR

# Introduction

- GlobalData (2014). Ulcerative Colitis – Japan Drug Forecast and Market Analysis to 2022, February 2014, GDHC220CFR

- GlobalData (2014). Ulcerative Colitis – Canada Drug Forecast and Market Analysis to 2022, February 2014, GDHC221CFR

- GlobalData (2014). Ulcerative Colitis – China Drug Forecast and Market Analysis to 2022, February 2014, GDHC222CFR

- GlobalData (2014). Ulcerative Colitis – India Drug Forecast and Market Analysis to 2022, February 2014, GDHC223CFR

- GlobalData (2014). Entyvio (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC342DFR

- GlobalData (2014). Xeljanz (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC343DFR

- GlobalData (2014). Kappaproct (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC344DFR

- GlobalData (2014). Remicade (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC345DFR

- GlobalData (2014). Humira (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC346DFR

- GlobalData (2014). Simponi (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC347DFR

- GlobalData (2014). Apriso (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC348DFR

- GlobalData (2014). Asacol HD (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC349DFR

- GlobalData (2014). Lialda (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC350DFR

# Introduction

- GlobalData (2014). Pentasa (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC351DFR

- GlobalData (2014). Colazal & Giazo (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC352DFR

- GlobalData (2014). sfRowasa (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC353DFR

- GlobalData (2014). Uceris (Ulcerative Colitis) – Forecast and Market Analysis to 2022, February 2014, GDHC354DFR

- GlobalData (2014). Ulcerative Colitis – Current and Future Players, February 2014, GDHC1029FPR

## 2.3    Upcoming Related Reports

- GlobalData (2014). PharmaPoint: Crohn's Disease – Global Drug Forecast and Market Analysis to 2022, January 2014, GDHC77PIDR

## 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.

### 9.9    Disclaimer