ENTYVIO (ULCERATIVE COLITIS) - FORECAST AND MARKET ANALYSIS TO 2022
Executive Summary

Table below provides a summary of the key metrics for Entyvio in the 8MM Ulcerative Colitis (UC) markets in 2022:

<table>
<thead>
<tr>
<th>Key Events (2012–2022)</th>
<th>Level of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entyvio entering the US and EU in 2014</td>
<td>↑↑↑</td>
</tr>
</tbody>
</table>

**2022 Market Sales**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$839.8m</td>
</tr>
<tr>
<td>5EU</td>
<td>$483.1m</td>
</tr>
<tr>
<td>Japan</td>
<td>$17.5m</td>
</tr>
<tr>
<td>Canada</td>
<td>$86.7m</td>
</tr>
<tr>
<td>Global*</td>
<td>$1.4bn</td>
</tr>
</tbody>
</table>

Global* = US, France, Germany, Italy, Spain, UK, Japan, Canada, China, and India
5EU = France, Germany, Italy, Spain, and UK; 8MM = US, 5EU, Japan, and Canada
Source: GlobalData

**Sales for Entyvio in Global Ulcerative Colitis Market, 2022**

Takeda will launch Entyvio in the US market in 2014. In its first year, sales of Entyvio in the Ulcerative Colitis market are projected to reach $0.2 billion. By 2022, we project its sales to increase up to $1.4 billion in the Ulcerative Colitis market. Key factors affecting the sales of Entyvio will include:

- Major growth drivers for Entyvio in the UC market over the forecast period include:
  - Takeda is a company that focuses on GI treatments and has already helped gastroenterologists around the world become aware of vedolizumab.
  - Antibodies to α4β7 do not inhibit lymphocyte homing in tissues outside the GI tract.
  - Has shown remarkable results in the induction of remission in severe UC patients, with better results than Remicade.
  - Novel MOA compared with the other biologics approved for UC
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  - Novel MOA compared with the other biologics approved for UC

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

- IV injections are not pleasant, and therefore, patients tend not to prefer them.
- Not known if it is suitable for chronic use.
Executive Summary

Figure below illustrates the global Entyvio sales by region in 2022.

<table>
<thead>
<tr>
<th>Sales for Entyvio by Region, 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
</tr>
<tr>
<td>Total: $1.4bn</td>
</tr>
<tr>
<td>US 58.85%</td>
</tr>
<tr>
<td>5EU 33.85%</td>
</tr>
<tr>
<td>Japan 1.23%</td>
</tr>
<tr>
<td>Canada 6.07%</td>
</tr>
</tbody>
</table>

Source: GlobalData

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

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.
# Table of Contents

## 1 Table of Contents

1. **Table of Contents**....................................................................................................................... 5
   1.1 List of Tables ...................................................................................................................... 8
   1.2 List of Figures ..................................................................................................................... 9

## 2 Introduction............................................................................................................................... 10

2.1 Catalyst ..................................................................................................................................... 10
2.2 Related Reports ................................................................................................................ 10
2.3 Upcoming Related Reports ............................................................................................... 12

## 3 Disease Overview..................................................................................................................... 13

3.1 Etiology and Pathophysiology ........................................................................................... 13
   3.1.1 Etiology ......................................................................................................................... 13
   3.1.2 Pathophysiology ............................................................................................................ 15
3.2 Symptoms ............................................................................................................................... 16
   3.2.1 Quality of Life ................................................................................................................ 17

## 4 Disease Management............................................................................................................... 19

4.1 Diagnosis and Treatment Overview .................................................................................. 19
   4.1.1 Diagnosis ...................................................................................................................... 19
   4.1.2 Treatment Guidelines and Leading Prescribed Drugs ................................................... 22
   4.1.3 Clinical Practice ............................................................................................................. 24

## 5 Competitive Assessment .......................................................................................................... 28

5.1 Overview............................................................................................................................... 28
5.2 Strategic Competitor Assessment ........................................................................................ 29
# Table of Contents

## 6 Opportunity and Unmet Need

6.1 Overview .................................................................................................................. 31

6.2 Unmet Needs .............................................................................................................. 32

6.2.1 Curative Therapy for Severe UC Patients ............................................................... 32

6.2.2 Diagnostic Markers for Disease Severity ............................................................... 32

6.2.3 Personalized Therapy ............................................................................................ 33

6.2.4 A Replacement for Steroids .................................................................................. 33

6.2.5 Novel Oral Drug Formulations ............................................................................. 34

6.2.6 Preventative Medicine for Lowering the Associated Colorectal Cancer Risk ........ 35

6.2.7 Improved Management of Infectious Adverse Events .......................................... 35

6.3 Unmet Needs Gap Analysis ...................................................................................... 36

6.4 Disease Severity and Colorectal Cancer Biomarker-Based Prognostic Tools .......... 37

6.5 Predictors of Medically-Refractory Disease ............................................................. 38

## 7 Pipeline Assessment

7.1 Overview .................................................................................................................... 39

7.2 Promising Drugs in Clinical Development ............................................................... 39

## 8 Entyvio (vedolizumab)

8.1 Overview .................................................................................................................... 41

8.2 Efficacy ....................................................................................................................... 43

8.3 Safety .......................................................................................................................... 45

8.4 Dosing and Formulation ........................................................................................... 47

8.5 Potential Clinical Positioning ..................................................................................... 47

8.6 Potential Commercial Positioning .............................................................................. 48
# Table of Contents

8.7 Pricing and Reimbursement ........................................................................................................... 49  
8.8 SWOT Analysis .................................................................................................................................. 50  
8.9 Forecast ........................................................................................................................................... 50  

9 Appendix ............................................................................................................................................. 52  
9.1 Bibliography ....................................................................................................................................... 52  
9.2 Abbreviations ....................................................................................................................................... 54  
9.3 Methodology ......................................................................................................................................... 58  
9.4 Forecasting Methodology ..................................................................................................................... 58  
9.4.1 Diagnosed UC Patients .................................................................................................................... 58  
9.4.2 Percent Drug-Treated Patients ........................................................................................................ 59  
9.4.3 General Pricing Assumptions .......................................................................................................... 59  
9.4.4 Generic Erosion .............................................................................................................................. 60  
9.4.5 Pricing of Pipeline Agents .............................................................................................................. 60  
9.5 Physicians and Specialists Included in This Study ........................................................................... 61  
9.6 Primary Research – Prescriber Survey ............................................................................................... 63  
9.7 About the Authors ............................................................................................................................. 64  
9.7.1 Author ........................................................................................................................................... 64  
9.8 About GlobalData ............................................................................................................................. 65  
9.9 Disclaimer ........................................................................................................................................... 65
1.1 List of Tables

Table 1: Genetic Factors That Confer a Predisposition to UC ................................................................. 15
Table 2: Typical Symptoms of UC ........................................................................................................... 17
Table 3: Truelove and Witts UC Severity Index ....................................................................................... 21
Table 4: UCDAI ....................................................................................................................................... 22
Table 5: Treatment Guidelines for UC Used in the 10MM .................................................................... 23
Table 6: Most Commonly Prescribed Drugs for UC by Class in the 10MM, 2013 ................................. 24
Table 7: Leading Treatments for UC, 2014 ............................................................................................. 30
Table 8: Overall Unmet Needs – Current Level of Attainment ............................................................... 31
Table 9: Corticosteroid Long-Term Side Effects ..................................................................................... 34
Table 10: Clinical Unmet Needs in UC – Gap Analysis, 2013 ................................................................. 37
Table 11: Prognostic Markers in UC ....................................................................................................... 38
Table 12: UC – Pre-Registration and Phase III Pipeline, 2014 ............................................................... 39
Table 13: Comparison of Therapeutic Classes in Development for UC, 2014 ....................................... 40
Table 14: Product Profile – Entyvio ......................................................................................................... 43
Table 15: Results of the GEMINI I Trial, Efficacy of Vedolizumab in the Induction of Remission in UC ...... 44
Table 16: Results of the GEMINI I Trial, Efficacy of Vedolizumab in the Maintenance of Remission in UC ..... 45
Table 17: Most Common Adverse Events with Vedolizumab in the GEMINI I Study.............................. 46
Table 18: Entyvio SWOT Analysis, 2014 ............................................................................................... 50
Table 19: Global Sales Forecasts ($m) for Entyvio, 2012–2022 ............................................................... 51
Table 20: Physicians Surveyed, By Country ......................................................................................... 63
1.2 List of Figures

Figure 1: Cellular Mechanisms Involved in the Pathogenesis of UC ................................................................. 16
Figure 2: UC Disease Management Flowchart .................................................................................................. 27
Figure 3: Competitive Assessment of Late-Stage Pipeline Agents UC, 2012–2022 ........................................ 40
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

Introduction

- 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
Introduction

- 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
- 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

2.3 Upcoming Related Reports

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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