## Executive Summary

### Gout: Key Metrics in the Six Major Pharmaceutical Markets, 2013–2018

<table>
<thead>
<tr>
<th>2013 Epidemiology</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gout, diagnosed prevalent population</td>
<td>13.8 million</td>
</tr>
<tr>
<td>Total number of acute gout attacks</td>
<td>8.1 million</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2013 Market Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$893m</td>
</tr>
<tr>
<td>5EU</td>
<td>$96m</td>
</tr>
<tr>
<td>Total</td>
<td>$989m</td>
</tr>
</tbody>
</table>

### Pipeline Assessment

- Number of drugs in Phase IIb-III: Two
- Number of first-in-class drugs: One

### Most Promising Pipeline Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Peak-Year Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca's lesinurad</td>
<td>$467m</td>
</tr>
<tr>
<td>Novartis’ Ilaris (canakinumab)</td>
<td>$319m</td>
</tr>
<tr>
<td>BioCryst Pharmaceuticals’ ulodesine</td>
<td>$156m</td>
</tr>
</tbody>
</table>

### Key Events (2013–2018)

<table>
<thead>
<tr>
<th>Event</th>
<th>Level of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Launch of Krystexxa (pegloticase) in 5EU in 2013</td>
<td>↑↑</td>
</tr>
<tr>
<td>Launch of Ilaris in 5EU in 2013</td>
<td>↑↑</td>
</tr>
<tr>
<td>Launch of Ilaris in US in 2015</td>
<td>↑</td>
</tr>
<tr>
<td>Launch of lesinurad in the US and 5EU in 2015</td>
<td>↑</td>
</tr>
<tr>
<td>Launch of ulodesine in the US and 5EU in 2017</td>
<td>↑</td>
</tr>
</tbody>
</table>

### 2018 Epidemiology

<table>
<thead>
<tr>
<th>2018 Epidemiology</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gout, diagnosed prevalent population</td>
<td>15.6 million</td>
</tr>
<tr>
<td>Total number of acute gout attacks</td>
<td>9.1 million</td>
</tr>
</tbody>
</table>

### 2018 Market Sales

<table>
<thead>
<tr>
<th>2018 Market Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$2bn</td>
</tr>
<tr>
<td>5EU</td>
<td>$284m</td>
</tr>
<tr>
<td>Total</td>
<td>$2.28bn</td>
</tr>
</tbody>
</table>

Source: GlobalData

5EU = France, Germany, Italy, Spain, and UK; 6MM = US and 5EU

Above mentioned table presents the key metrics for gout in the six major pharmaceutical markets (6MM) (US, France, Germany, Italy, Spain, and UK) covered in this report during the forecast period from 2013–2018.

### Gout Market will more than Double in Size between 2013 and 2018

GlobalData estimates the 2013 sales for gout at approximately $989m across the 6MM covered in this report. The US contributed to 90% of these sales, generating an estimated $893m. The formidable dominance of the US in the gout market is a consequence of three important factors: one, the widely used gout therapy, Colcrys (colchicine), is not generically available in the US, unlike in the European countries; two, the gout prevalence is significantly higher in the US than in the 5EU; and three, the prices of branded pharmaceuticals are much higher in the US.

By the end of the forecast period in 2018, gout sales are forecast to grow to $2.28 billion at a Compound Annual Growth Rate (CAGR) of 18.2% over the five-year period. The 5EU markets will experience somewhat faster growth than the US market. This is mainly due to the fact that the 5EU is experiencing a dramatic increase in the gout prevalence, at 2.3 times with the rate seen in the US. At the end of the forecast period, the 5EU will represent 12.5% of the 6MM market.
The acute gout segment of the market will double in size over the forecast period, reaching $337m in 2018 at a CAGR of 15%. The chronic gout market, which encompasses urate-lowering and prophylactic anti-inflammatory therapies, will experience even faster growth at a CAGR of 18.8%, and it will more than double in size, reaching over 1.9 billion in 2018.

Major drivers for the growth of the gout market over the forecast period will include:

- The introduction of the novel urate-lowering agents, lesinurad and ulodesine, which will be used as add-on therapies to the current standard of care and target the treatment-failure gout population.
- The potential approval in the US of an expensive biologic, Ilaris, which is a powerful anti-inflammatory therapy targeted at chronic gout sufferers with refractory and frequent gout attacks.
- The growing number of patients suffering from difficult-to-treat gout and for whom the standard therapies are inappropriate due to the presence of comorbidities, unresponsiveness, or intolerance.
- The more aggressive approach to urate-lowering treatment, as recommended by the latest treatment guidelines, which will increase the patient pool treated with urate-lowering agents and prophylactic anti-inflammatory therapy.

Major barriers to the growth of the gout market will include:

- The mature and highly genericized nature of the gout market (especially in Europe), which presents a stiff barrier to the entry of novel therapies.
- The enormously high prices of the recently launched biologic therapies, Krystexxa (in the US and 5EU) and Ilaris (in the 5EU), which will likely prevent reimbursement by health authorities and health insurance companies.
- Increased physician education, coupled with increased cost-consciousness, in the 6MM, which would support more proper management using the standard of care and would reduce the level of opportunity for novel agents.
- The sparsely populated gout pipeline, which will hinder the growth of the gout market.
Executive Summary

Below mentioned figure outlines the sales forecast for gout in the US and 5EU from 2013 to 2018.

Sales for Gout by Region, 2013–2018

<table>
<thead>
<tr>
<th>Year</th>
<th>US (Sales)</th>
<th>5EU (Sales)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>1,000</td>
<td>800</td>
</tr>
<tr>
<td>2014</td>
<td>1,500</td>
<td>1,200</td>
</tr>
<tr>
<td>2015</td>
<td>2,000</td>
<td>1,500</td>
</tr>
<tr>
<td>2016</td>
<td>2,500</td>
<td>2,000</td>
</tr>
<tr>
<td>2017</td>
<td>3,000</td>
<td>2,500</td>
</tr>
<tr>
<td>2018</td>
<td>3,500</td>
<td>3,000</td>
</tr>
</tbody>
</table>

CAGR (2013 – 2018): 18.2%

Source: GlobalData

5EU = France, Germany, Italy, Spain, and UK

Companies Mainly Target the Difficult-to-Treat Gout Population by Employing Diverse Research and Development Strategies

With the current standard of care for gout already encompassing very successful and cheap treatments, the bar for success in the gout market is quite high. As a result, companies are shifting the focus of their research toward more severe gout cases, trying to address the greatest unmet needs. Targeting niche patient groups that do not respond to, or are intolerant of the current standard of care, is the strongest trend in the research and development (R&D) strategies of the gout players. The mechanisms of hyperuricemia are now understood in great detail and have all been targeted. However, there is still enough space for refining the drugs in such a way that they employ a mechanism of action similar to the existing drugs (by altering or reducing the activity of enzymes required for uric acid formation), but that are more specific, more powerful, and that potentially possess fewer side effects and fewer contraindications.

The acquisition of smaller biotech companies and the formation of partnerships and licensing agreements is a very common trend among the companies that are currently in the gout market. The current leader in the gout market, Takeda Pharmaceutical Company, gained its two leading gout products through licensing and acquisition. AstraZeneca is employing a similar strategy in a bid to become a future leader in this market. The company added two novel and promising uricosurics to its pipeline by acquiring the biotech company, Ardea Biosciences. Small pharmaceutical and biotechnology companies will inevitably need to form new partnerships and licensing agreements in order to secure funding for their drug development and commercialization. However, obtaining funding or reaching acquisition and licensing agreements in the gout space may become increasingly difficult in the future, both for the early-stage and the later-stage products, if the drugs do not show a sufficient level of differentiation. Penetration into this highly genericized market has proven difficult so far.
**Executive Summary**

**Physician Education is One of the Greatest Unmet Needs in the Gout Market**

The standard treatments are effective in most gout patients, and therefore, gout is a potentially curable disease. However, there are a growing number of patients for whom the standard therapies are inappropriate. GlobalData’s interviews with key opinion leaders (KOLs) have indicated that while novel therapies for the difficult-to-treat population are needed, a greater unmet need in gout treatment is for improved physician education, as this disease is practically curable with the current standard of care. Earlier and easier access to rheumatologists is needed when gout is suspected, but this shift alone is not enough, as currently, gout management is suboptimal in both primary care and rheumatology clinics. Reasons for inadequate gout treatment include a poor patient understanding of their disease and physician failure to develop targeted treatment plans. One direct consequence of the low physician and patient awareness regarding the seriousness of the disease is the low patient compliance. Because most physicians still do not take gout seriously enough, they are passing on this attitude to their patients who are, consequently, unaware of the importance of keeping their urate levels down and are not sticking to the appropriate therapy. In turn, this leads to an increase in the difficult-to-treat patient pool.

**The Market Entry of Novel Agents Will Improve the Treatment Landscape for the Difficult-to-Treat Gout Population**

Over the next five years, the gout market is expected to see some major changes. With the recent approval of the powerful anti-inflammatory therapy, Ilaris, and the market entry of two novel urate-lowering therapies, lesinurad and ulodesine, physicians will have more options available to tackle difficult-to-treat gout. GlobalData has assessed the promising pipeline candidates both clinically and commercially, based on the opinions generated from interviews with KOLs and secondary research. As there are currently no anti-inflammatory therapies in late-stage trials for gout, Ilaris (which has recently been approved in the EU [European Union]), was benchmarked against the older available therapies.

In the anti-inflammatory segment of the market, as illustrated in below mentioned figure, Ilaris scored high in terms of clinical attributes. Ilaris showed significantly more rapid pain relief than the corticosteroid injection; this, coupled with Ilaris’ long half-life of about four weeks, makes it a potential prophylactic therapy for very frequent and severe attacks. However, the overall clinical score of Ilaris is only slightly higher than the score for corticosteroid injections because of the lack of properly controlled clinical studies and the lack of a long-term safety profile. Ilaris scored very poorly in terms of commercial attributes, mainly because of its enormously high price, which will prevent its
reimbursement in Europe and will restrict its usage in the US. In addition, the size of the target patient pool for Ilaris is very small, as Ilaris will be restricted only to the most severe cases of frequent gout attacks that do not respond sufficiently to the standard of care.

In the urate-lowering segment of the market, the standard of care, allopurinol, has been used as the drug comparator for the two late-stage pipeline urate-lowering agents. AstraZeneca’s lesinurad and BioCryst Pharmaceuticals’ ulodesine are rated as add-on therapies to allopurinol, as this is how they will most likely be used. From a clinical perspective, it would be very hard for lesinurad and ulodesine to compete with allopurinol’s 40-year history as an effective and safe urate-lowering therapy; however, as an add-on therapy to allopurinol, both lesinurad and ulodesine scored high in terms of clinical attributes, mainly because the efficacy is substantially higher with the combination therapy than with allopurinol alone. This is an important attribute when targeting the difficult-to-treat gout population, which is unresponsive to the standard of care. However, both lesinurad and ulodesine, as an add-on therapy to allopurinol, scored more poorly than allopurinol alone in terms of commercial attributes. This is mainly due to the fact that the size of the target patient pool will be much smaller for the combination therapy than for allopurinol itself, and that the new therapies will be much more highly priced than the cheap generic alternative alone.

This may limit the uptake of the combination therapies, unless the companies confirm a substantially higher level of efficacy in the gout population that is responding insufficiently to the current standard of care.
Executive Summary

What Do the Physicians Think?

The KOLs interviewed for this report highlighted that while novel therapies are certainly needed to target the difficult-to-treat gout population, a greater unmet need in gout treatment is for improved physician education, as this disease could be treated more properly with the current standard of care than it currently is.

“Lots of patients don’t even know that it’s arthritis; they think it’s some metabolic condition and that it has nothing to do [with] damaging your joints.”

EU Key Opinion Leader, February 2014

“I think there is a need to learn to properly use the drugs that we have, because otherwise, it may happen that we continue developing drugs without realizing that we just have to learn to use what we have.”

EU Key Opinion Leader, February 2014

“Almost everyone with gout is managed in primary care, and no one in primary care reads the Annals of Rheumatic Diseases, where all the guidelines get published.”

EU Key Opinion Leader, February 2014

“The highest unmet need is patient education or public education. Well, I do not know exactly how to do it. But the reason I focus on the education is that we have medications that should be effective in 99.5% of the patients.”

US Key Opinion Leader, February 2014

Some KOLs also indicated that earlier and more aggressive urate-lowering therapy is needed.

“I think we need more urate-lowering options, and I think we need IL-1 [interleukin-1]-targeted biologics or other anti-inflammatories that really suppress the gout flares [that are induced when aggressive urate-lowering is used], and then we could treat the acute gout better, as people would stick better to the urate-lowering therapy.”

US Key Opinion Leader, February 2014

“Urate-lowering should be started early on rather than waiting for when they’ve got tophi bursting through their skin 20 years later. So, my preference is to discuss [it] with [the] patient. At least discuss [it] with [the] patient to make them aware of what is happening to them, and also [to] let them know the urate-lowering therapy can actually cure their gout; it gets rid of pathogenic agents within a year or two.”

EU Key Opinion Leader, February 2014
Executive Summary

The KOLs also discussed the novel urate-lowering therapies, which will be used as an add-on therapy to the current standard of care.

“Novel uricosurics as add-on therapy...a very logical economic tactic, because they know they cannot compete against allopurinol, which is a very good drug, very cheap, very effective. If you continue up-titrating its dosage, you get to target almost always. Now the companies know that in practice, almost everyone just gives a fixed dose of 300mg. They don’t up-titratae; they give [a] standard 300mg. Now, in lots of people, that’s not enough. So, they know there is a big market out there and that the majority of people are on allopurinol, so rather than competing with it, they’ll say, ‘If you have tried allopurinol and you haven’t succeeded, here is our wonderful new drug; it works in a different way and the two of them combined work perfectly.’”

EU Key Opinion Leader, February 2014

“I personally don’t think that any expert would recommend the novel therapies instead of gradually increasing the dose of the xanthine oxidase [XO] inhibitor. So, I think they may have trouble even if they advertise them, if no official guidelines recommend them.”

US Key Opinion Leader, February 2014
# Table of Contents

## 1 Table of Contents

1 Table of Contents ....................................................................................................................... 9

1.1 List of Tables .................................................................................................................... 13

1.2 List of Figures .................................................................................................................. 15

## 2 Introduction

2.1 Catalyst ............................................................................................................................. 16

2.2 Related Reports ................................................................................................................ 17

2.3 Upcoming Related Reports ............................................................................................... 17

## 3 Disease Overview

3.1 Etiology and Pathophysiology ........................................................................................... 19

3.1.1 Etiology ......................................................................................................................... 19

3.1.2 Pathophysiology ............................................................................................................ 21

3.2 Symptoms ....................................................................................................................... 22

3.3 Risk Factors ...................................................................................................................... 23

3.4 Prognosis .......................................................................................................................... 23

3.5 Quality of Life .................................................................................................................... 24

## 4 Epidemiology

4.1 Risk Factors and Comorbidities ....................................................................................... 25

4.2 Global Trends ................................................................................................................... 27

4.2.1 US ................................................................................................................................. 29

4.2.2 5EU ............................................................................................................................... 29

4.3 Forecast Methodology ....................................................................................................... 30

4.3.1 Sources Used ................................................................................................................ 34

4.3.2 Sources Not Used ......................................................................................................... 38

4.3.3 Forecast Assumptions and Methods ............................................................................. 40

4.4 Epidemiological Forecast for Gout (2013–2023) ............................................................... 47

4.4.1 Diagnosed Incidence .................................................................................................... 47
# Table of Contents

4.4.2 Diagnosed Prevalence .................................................................................................. 53
4.5 Discussion ........................................................................................................................ 61
4.5.1 Epidemiological Forecast Insight ................................................................................... 61
4.5.2 Limitations of the Analysis ............................................................................................. 62
4.5.3 Strengths of the Analysis ............................................................................................... 63
5 Current Treatment Options ....................................................................................................... 64
  5.1 Overview ........................................................................................................................... 64
  5.2 Product Profiles ................................................................................................................. 67
    5.2.1 Anti-Inflammatory Therapies ......................................................................................... 67
    5.2.2 Urate-Lowering Therapies ............................................................................................. 86
6 Unmet Needs Assessment and Opportunity Analysis .................................................................. 103
  6.1 Overview ......................................................................................................................... 103
  6.2 Physician and Patient Awareness of Gout ....................................................................... 104
    6.2.1 Unmet Needs .............................................................................................................. 104
    6.2.2 Gap Analysis ............................................................................................................... 105
    6.2.3 Opportunity ................................................................................................................. 106
  6.3 Noncompliance to Gout Therapies .................................................................................. 106
    6.3.1 Unmet Needs .............................................................................................................. 106
    6.3.2 Gap Analysis ............................................................................................................... 107
    6.3.3 Opportunity ................................................................................................................. 107
  6.4 Earlier and More Accurate Diagnosis of Gout .................................................................. 107
    6.4.1 Unmet Needs .............................................................................................................. 107
    6.4.2 Gap Analysis and Opportunity ..................................................................................... 108
    6.4.3 Opportunity ................................................................................................................. 109
  6.5 Efficacious and Safe Treatment of Difficult-to-Treat Gout ................................................ 109
    6.5.1 Unmet Needs .............................................................................................................. 109
    6.5.2 Gap Analysis and Opportunity ..................................................................................... 109
# Table of Contents

6.5.3 Opportunity ................................................................................................................. 110

7 Research and Development Strategies.................................................................................. 111

7.1 Overview......................................................................................................................... 111

7.1.1 Targeting Patients with Refractory Gout – Novel Uricosuric Drugs as Add-On Therapy ................................................................................................................. 111

7.1.2 Targeting Patients with Refractory Gout – PEGylation of Uricase .............................. 112

7.1.3 Small Molecules as Inhibitors of the Interleukin-1 Beta Pathway ................................. 113

7.1.4 Acquisitions and Licensing ........................................................................................ 113

7.2 Clinical Trial Design ........................................................................................................ 115

7.2.1 Current Clinical Trial Design........................................................................................ 115

7.2.2 Future Clinical Trial Designs........................................................................................ 120

8 Pipeline Assessment............................................................................................................. 122

8.1 Overview......................................................................................................................... 122

8.2 Promising Drugs in Clinical Development .................................................................... 124

8.2.1 Lesinurad (RDEA-594) .............................................................................................. 125

8.2.2 Ulodesine (BCX4208) ............................................................................................... 130

8.3 Innovative Early-Stage Approaches ................................................................................ 134

9 Pipeline Valuation Analysis.................................................................................................. 138

9.1 Clinical Benchmark of Key Pipeline Drugs ................................................................. 138

9.2 Commercial Benchmark of Key Pipeline Drugs ........................................................ 140

9.3 Competitive Assessment ............................................................................................... 141

9.4 Top-Line Five-Year Forecast ........................................................................................ 144

9.4.1 US ............................................................................................................................. 147

9.4.2 5EU .......................................................................................................................... 148

10 Appendix........................................................................................................................... 150

10.1 Bibliography .................................................................................................................. 150

10.2 Abbreviations ............................................................................................................... 164

10.3 Methodology .................................................................................................................. 168
# Table of Contents

10.4  Forecasting Methodology .................................................................................................................. 168
10.4.1 Diagnosed Gout Patients .................................................................................................................. 168
10.4.2 Percent Drug-Treated Patients ........................................................................................................ 169
10.4.3 Drugs Included in Each Therapeutic Class ................................................................................... 169
10.4.4 Launch and Patent Expiry Dates ...................................................................................................... 169
10.4.5 General Pricing Assumptions ........................................................................................................... 170
10.4.6 Individual Drug Assumptions ........................................................................................................... 171
10.4.7 Pricing of Pipeline Agents ................................................................................................................. 175
10.5  Physicians and Specialists Included in this Study ............................................................................. 176
10.6  About the Authors ................................................................................................................................ 178
10.6.1 Analyst ............................................................................................................................................... 178
10.6.2 Therapy Director – CVMD and Infectious Disease ......................................................................... 178
10.6.3 Epidemiologist ................................................................................................................................. 179
10.6.4 Global Head of Healthcare ............................................................................................................... 179
10.7  About GlobalData .................................................................................................................................. 180
10.8  Disclaimer ............................................................................................................................................. 180
1.1 List of Tables

Table 1: Risk Factors and Comorbidities for Gout ................................................................. 26
Table 2: Summary of Reported Incidence and Prevalence of Gout in the 6MM* ..................... 28
Table 3: American College of Rheumatology Criteria for the Clinical Diagnosis of Gout .............. 31
Table 4: Sources of Gout Incidence Data in 6MM ................................................................. 32
Table 5: Sources of Gout Prevalence Data in 6MM ............................................................... 33
Table 6: Sources of Gout Flare and Tophaceous Gout Data in 6MM ........................................... 34
Table 7: 6MM, Sources Not Used in the Epidemiological Analysis of Gout ............................... 39
Table 8: 6MM, Diagnosed Incident Cases of Gout, Both Sexes, Ages ≥20 Years, N, 2013–2023 ...... 48
Table 9: 6MM, Age-Specific Diagnosed Incident Cases of Gout, Both Sexes, N (Row %), 2013 .... 49
Table 10: 6MM, Sex-Specific Diagnosed Incident Cases of Gout, Ages ≥20 Years, N (Row %), 2013 .... 51
Table 11: 6MM, Diagnosed Prevalent Cases of Gout, Both Sexes, Ages ≥20 Years, N, 2013–2023 .. 54
Table 12: 6MM, Age-Specific Diagnosed Prevalent Cases of Gout, Both Sexes, N (Row %), 2013 ... 55
Table 13: 6MM, Sex-Specific Diagnosed Prevalent Cases of Gout, Ages ≥20 Years, N (Row %), 2013 ... 57
Table 14: Leading Branded Treatments for Gout ................................................................. 66
Table 15: Nonsteroidal Anti-Inflammatory Drugs SWOT Analysis, 2013 ................................. 69
Table 16: Product Profile – Colcrys ...................................................................................... 72
Table 17: Colcrys SWOT Analysis, 2013 .................................................................................. 74
Table 18: Glucocorticoids SWOT Analysis, 2013 ................................................................. 77
Table 19: Product Profile – Ilaris ......................................................................................... 80
Table 20: Ilaris SWOT Analysis, 2013 ..................................................................................... 82
Table 21: Product Profile – Kineret ....................................................................................... 84
Table 22: Kineret SWOT Analysis, 2013 ............................................................................... 85
Table 23: Product Profile – Allopurinol ............................................................................... 87
## Table of Contents

- **Table 24:** Allopurinol SWOT Analysis, 2013 ................................ ................................ ................................ 89
- **Table 25:** Product Profile – Uloric ................................ ................................ ................................ .............. 91
- **Table 26:** Uloric SWOT Analysis, 2013 ......................................................................................... 93
- **Table 27:** Uricosuric drugs SWOT Analysis, 2013 ................................ ................................ ................ 97
- **Table 28:** Product Profile – Krystexxa ....................................................................................... 100
- **Table 29:** Krystexxa SWOT Analysis, 2013 ................................................................................. 102
- **Table 30:** Unmet Need and Opportunity in Gout ......................................................................... 104
- **Table 31:** Examples of Pivotal RCTs of Approved Treatments for Acute Gout ......................... 117
- **Table 32:** Examples of Pivotal RCTs of Approved Treatments for Chronic Gout ...................... 118
- **Table 33:** Gout – Late Stage Pipeline, 2012 ................................................................................. 124
- **Table 34:** Product Profile – Lesinurad ....................................................................................... 127
- **Table 35:** Lesinurad SWOT Analysis, 2013 ............................................................................... 129
- **Table 36:** Product Profile – Ulodesine ......................................................................................... 131
- **Table 37:** Ulodesine SWOT Analysis, 2013 ............................................................................... 133
- **Table 38:** Early-Stage Pipeline Products in Gout ......................................................................... 134
- **Table 39:** Clinical Benchmark of Key Pipeline Drugs – Anti-Inflammatory Therapies .................. 138
- **Table 40:** Clinical Benchmark of Key Pipeline Drugs – Urate-Lowering Therapies ...................... 139
- **Table 41:** Commercial Benchmark of Key Pipeline Drugs – Anti-Inflammatory Therapies .......... 140
- **Table 42:** Commercial Benchmark of Key Pipeline Drugs – Urate-Lowering Therapies ................. 141
- **Table 43:** Top Line Sales Forecasts ($m) for Gout, 2013–2018 ....................................................... 145
- **Table 44:** Key Events Impacting Sales for Gout, 2013–2018 ....................................................... 146
- **Table 45:** Gout Market – Drivers and Barriers, 2013–2018 ............................................................ 147
- **Table 46:** Key Launch Dates ......................................................................................................... 169
- **Table 47:** Key Patent Expiries ..................................................................................................... 170
# Table of Contents

## 1.2 List of Figures

| Figure 1: | Overview of Purine Metabolism, Leading to Uric Acid Formation | 20 |
| Figure 2: | Stages of Gout | 22 |
| Figure 3: | 6MM, Diagnosed Incident Cases of Gout, Both Sexes, Ages ≥20 Years, N, 2013–2023 | 48 |
| Figure 4: | 6MM, Age-Specific Diagnosed Incident Cases of Gout, Both Sexes, N, 2013 | 50 |
| Figure 5: | 6MM, Sex-Specific Diagnosed Incident Cases of Gout, Ages ≥20 Years, N, 2013 | 51 |
| Figure 6: | 6MM, Age-Standardized Diagnosed Incidence of Gout (Cases per 100,000 Population), Ages ≥20 Years, by Sex, 2013 | 53 |
| Figure 7: | 6MM, Diagnosed Prevalent Cases of Gout, Both Sexes, Ages ≥20 Years, N, 2013–2023 | 54 |
| Figure 8: | 6MM, Age-Specific Diagnosed Prevalent Cases of Gout, Both Sexes, N, 2013 | 56 |
| Figure 9: | 6MM, Sex-Specific Diagnosed Prevalent Cases of Gout, Ages ≥20 Years, N, 2013 | 57 |
| Figure 10: | 6MM, Age-Standardized Diagnosed Prevalence (%) of Gout, Ages ≥20 Years, by Sex, 2013 | 59 |
| Figure 11: | 6MM, Number of Gout Flares in the Diagnosed Prevalent Population of Gout, Both Sexes, Ages ≥20 Years, N, 2013 and 2023 | 60 |
| Figure 12: | 6MM, Tophaceous Gout Cases in the Diagnosed Prevalent Population of Gout, Both Sexes, Ages ≥20 Years, N, 2013 and 2023 | 61 |
| Figure 13: | Mechanisms Targeted by Marketed and Late-Stage Pipeline Drugs | 124 |
| Figure 14: | Competitive Assessment of the Novel Anti-Inflammatory Agent for Gout, 2013–2018 | 143 |
| Figure 15: | Competitive Assessment of the Late-Stage Pipeline Urate-Lowering Agents for Gout, 2013–2018 | 144 |
| Figure 16: | Sales for the Gout Market, US and 5EU (2013–2018) | 146 |
2 Introduction

2.1 Catalyst

The global gout market is very mature, highly genericized, and characterized by a sparsely populated pipeline. Nevertheless, GlobalData expects this market to undergo substantial growth between 2013 and 2018, more than doubling over this period. The main drivers of this large expansion will be: the growing number of patients who are suffering from difficult-to-treat gout, for whom the standard therapies are inappropriate; the introduction of two novel branded therapies; and the more aggressive approach to urate-lowering therapy, as recommended by the latest treatment guidelines.

The first-line treatment for acute gout attacks is dominated by generic drugs from the class of nonsteroidal anti-inflammatory drugs (NSAIDs), while the first-line urate-lowering therapy is allopurinol, a generic drug that has been used for almost 40 years in the majority of chronic gout sufferers. The dominating treatment for anti-inflammatory prophylaxis is Colcrys (available generically as colchicine in Europe). Despite the fact that the standard treatments for gout are cheap and effective in most patients, there is an increasing population of patients for whom these standard therapies are inappropriate due to unresponsiveness, intolerance, or the presence of comorbidities. The need for alternative treatment options for difficult-to-treat patients has been recognized, and the pharmaceutical industry has responded with the development of new therapies that offer hope to these patients. Two novel urate-lowering agents, AstraZeneca’s lesinurad and BioCryst Pharmaceuticals’ ulodesine, will be used individually as add-on therapies to the current standard of care and target the treatment-failure gout population. The low cost of allopurinol, combined with its established position in the treatment of chronic gout, presents a stiff barrier to the entry of the novel urate-lowering therapies. However, the testing of these new drugs as a combination therapy for use with the standard of care in patients who are inadequate responders or treatment-refractory allows not only a higher efficacy in this patient population, but also makes more commercial sense, as the drug developers will not have to compete with allopurinol.
Introduction

2.2 Related Reports

- GlobalData (2013). Type 2 Diabetes – Global Drug Forecast and Market Analysis to 2022, July 2013, GDHC55PIDR
- GlobalData (2013). Obesity – Global Drug Forecast and Market Analysis to 2022, November 2013, GDHC50PIDR

2.3 Upcoming Related Reports

- GlobalData (2013). Dyslipidemia – Global Drug Forecast and Market Analysis to 2022, June 2014, GDHC46PIDR
10.7 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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