Executive Summary

Table below presents the key metrics of Orencia for Systemic Lupus Erythematosus (SLE) in the seven major pharmaceutical markets (7MM).

<table>
<thead>
<tr>
<th>Orencia: Key Metrics in Seven Major Pharmaceutical Markets for SLE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key events (2012-2022)</strong></td>
</tr>
<tr>
<td>Bristol-Myers Squibb’s Orencia approval for LN expected in 2019 in the US and 5EU</td>
</tr>
<tr>
<td>Bristol-Myers Squibb’s Orencia approval for LN expected in 2021 in Japan</td>
</tr>
<tr>
<td><strong>2022 Market Sales</strong></td>
</tr>
<tr>
<td>US</td>
</tr>
<tr>
<td>5EU</td>
</tr>
<tr>
<td>Japan</td>
</tr>
<tr>
<td><strong>Total 7MM</strong></td>
</tr>
</tbody>
</table>

Source: GlobalData.

7MM = US, France, Germany, Italy, Spain, UK and Japan; 5EU = France, Germany, Italy, Spain, UK.

Note: All sales figures are rounded to one decimal.

Table below presents the key metrics of Orencia for Lupus Nephritis (LN) in 7MM.

<table>
<thead>
<tr>
<th>Orencia: Key Metrics in Seven Major Pharmaceutical Markets for LN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key events (2012-2022)</strong></td>
</tr>
<tr>
<td>Bristol-Myers Squibb’s Orencia approval for LN expected in 2019 in the US and 5EU</td>
</tr>
<tr>
<td>Bristol-Myers Squibb’s Orencia approval for LN expected in 2021 in Japan</td>
</tr>
<tr>
<td><strong>2022 Market Sales</strong></td>
</tr>
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<td>5EU</td>
</tr>
<tr>
<td>Japan</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>

Source: GlobalData.

7MM = US, France, Germany, Italy, Spain, UK and Japan; 5EU = France, Germany, Italy, Spain, UK.

Note: All sales figures are rounded to one decimal.
Executive Summary

Sales of Orencia for SLE and LN in the 7MM

GlobalData estimates 2022 SLE drug sales to be over $98.6m across the seven major markets covered in this report: US, France, Germany, Italy, Spain, UK and Japan.

Focusing on LN, GlobalData estimates 2022 drug sales to be over $66.5m across the seven major markets covered in this report.

Key factors driving the sales of Orencia will include:

- The significant unmet need of available treatment options for the management of LN
- Rheumatologists’ familiarity with the brand and its safety profile, as it is approved for Rheumatoid Arthritis

The major barriers affecting the sales of Orencia will include:

- Weak efficacy profile to fully control the disease activity without the use of steroid and immunosuppressive therapies
- Expensive therapy
- Eminent loss of patent protection
Executive Summary

Figure below presents the sales of Orencia for SLE and LN by region in the seven major markets during the forecast period.

### Sales of Orencia for SLE and LN by Region, 2022

- **2022-SLE**
  - US: 79%
  - 5EU: 17%
  - Japan: 4%
  - Total: $98.6m

- **2022-LN**
  - US: 86%
  - 5EU: 8%
  - Japan: 6%
  - Total: $66.5m

Source: GlobalData.
Executive Summary

What Do the Physicians Think?

Physicians think that Benlysta is not a breakthrough therapy for the treatment of lupus, but they recognize that they need to gain more experience in using Benlysta in the clinic and that this product has a place in the management of patients with lupus.

“I think it [Benlysta] works for some patients. I think it mostly works in patients who have musculoskeletal or lupus cutaneous manifestations and is most helpful in patients who do not respond to more conventional therapies. I think that is probably its role and we will know in the future whether to use [Benlysta] in patients for the maintenance phase of nephritis and whether it works in other manifestations; that is, cardiovascular, pericardial, etc. We just need more time to use it and build some experience about it.”

[US] Key Opinion Leader, June 2013

The unsuccessful clinical trials of Rituxan in patients with lupus have not discouraged physicians in using this drug off-label, and they will continue to use it for the treatment of SLE and LN in the future.

“The trials are negative, but our own experiences have been good and we will continue to use it.”

[OUS] Key Opinion Leader, July 2013

The development of new drugs that are more efficacious and safer than currently available treatments remains the most pressing unmet need for the management of patients with SLE and LN.

“We need drugs that are safe, drugs that are more effective, drugs that will put patients into remission.”

[US] Key Opinion Leader, July 2013

With high R&D activity in lupus therapeutics, physicians are looking forward to pipeline products becoming available in the market, which will enable them to improve patients’ treatment.

“We are hopefully at the edge of getting new drugs available for treating our lupus patients and hopefully this will become true not only in the pipeline, but also in reality, and then we need to identify the best strategies on how we put all these available drugs in clinical practice.”

[OUS] Key Opinion Leader, July 2013

UCB’s epratuzumab is the most promising drug in the pipeline for patients with lupus.

“That is the one [epratuzumab] that has most excitement going on and certainly I hope it delivers. Everybody in the world is very excited about this one.”

[US] Key Opinion Leader, July 2013
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# Introduction

## 2.1 Catalyst

The approval of GlaxoSmithKline’s Benlysta in 2011, the first product to gain marketing approval for patients with SLE in more than 50 years, has paved the way for the introduction of new disease-modifying therapies and reignited the interest of pharmaceutical developers in this therapy area. The catalysts for this report are:

- To assess the impact Benlysta has had on the lupus therapeutics market following its approval in 2011 and re-evaluate its future outlook within this market.
- To examine the impact Rituxan’s failed Phase III trials in LN had on the lupus market and assess its off-label use during the 10-year forecast period from 2012–2022.
- To evaluate the significance of late-phase pipeline products and how their launch will shape the future treatment landscape in SLE and LN.
- To identify remaining unmet needs and highlight opportunities.
- To determine the remaining opportunities within the SLE and LN markets.

The launch of new biologic drugs will increase treatment options, improve treatment management and drive growth in the SLE and LN markets. Although the need for safe and effective new treatments is paramount for patients with lupus, products in the pipeline are expected to face many challenges in gaining patient share following their entry into the lupus market. New entrants will be required to demonstrate their clinical benefits to gain physicians’ and patients’ confidence for their use, overcome reimbursement challenges and face increasing competition from competing biologic products and inexpensive, potent immunosuppressive and steroid therapies.

## 2.2 Related Reports

Introduction

- GlobalData (2013). Systemic Lupus Erythematosus and Lupus Nephritis - France Drug Forecast and Market Analysis to 2022, GDHC161CFR.
- GlobalData (2013). Systemic Lupus Erythematosus and Lupus Nephritis - Germany Drug Forecast and Market Analysis to 2022, GDHC162CFR.
- GlobalData (2013). Systemic Lupus Erythematosus and Lupus Nephritis - Italy Drug Forecast and Market Analysis to 2022, GDHC163CFR.
- GlobalData (2013). Systemic Lupus Erythematosus and Lupus Nephritis - Spain Drug Forecast and Market Analysis to 2022, GDHC164CFR.
- GlobalData (2013). Systemic Lupus Erythematosus and Lupus Nephritis - UK Drug Forecast and Market Analysis to 2022, GDHC165CFR.
- GlobalData (2013). Systemic Lupus Erythematosus and Lupus Nephritis - Japan Drug Forecast and Market Analysis to 2022, GDHC166CFR.
- GlobalData (2013). Benlysta (Systemic Lupus Erythematosus and Lupus Nephritis) - Forecast and Market Analysis to 2022, GDHC273DFR.
- GlobalData (2013). Rituxan (Systemic Lupus Erythematosus and Lupus Nephritis) - Forecast and Market Analysis to 2022, GDHC274DFR.
- GlobalData (2013). Blisibimod (Systemic Lupus Erythematosus and Lupus Nephritis) - Forecast and Market Analysis to 202, GDHC275DFR.
- GlobalData (2013). Tabalumab (Systemic Lupus Erythematosus and Lupus Nephritis) - Forecast and Market Analysis to 2022, GDHC276DFR.
- GlobalData (2013). Atacicept (Systemic Lupus Erythematosus and Lupus Nephritis) - Forecast and Market Analysis to 2022, July 2013, GDHC277DFR.
Introduction

- GlobalData (2013). Epratuzumab (Systemic Lupus Erythematosus and Lupus Nephritis) - Forecast and Market Analysis to 2022, July 2013, GDHC278DFR.
- GlobalData (2013). Lupuzor (Systemic Lupus Erythematosus and Lupus Nephritis) - Forecast and Market Analysis to 2022, GDHC279DFR.
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, Boston, London, India and Singapore.

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