Below table provides a summary of the key metrics for Cyclokat in the major pharmaceuticals markets.

<table>
<thead>
<tr>
<th>Cyclokat: Key Metrics in the Major Pharmaceutical Markets, 2012 - 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2022 Market Sales</strong></td>
</tr>
<tr>
<td>US $87.6m</td>
</tr>
<tr>
<td>5EU $518.0m</td>
</tr>
<tr>
<td><strong>Total Global</strong> $605.6m</td>
</tr>
<tr>
<td><strong>Key events (2012-2022)</strong></td>
</tr>
<tr>
<td>Cyclokat launch in the US in 2016 ↑</td>
</tr>
<tr>
<td>Cyclokat launch in the 5EU in 2014 ↑↑</td>
</tr>
</tbody>
</table>

*For the purposes of this report, Global = US, France, Germany, Italy, Spain, UK
Source: GlobalData
NA: Not Applicable

Sales of Cyclokat in the Global Dry Eye Syndrome Market

GlobalData expects Cyclokat to launch in the US market in 2016 and in 2014 in the EU. We estimate that 2022 sales of Cyclokat will reach $605.6m across these markets.

Key factors affecting the uptake of Cyclokat will include:

- Cyclokat is likely to be the first prescription drug to enter the DES market in Europe, which will give it a huge advantage.
- Many physicians are well-acquainted with using CsA and trust in its safety, so Cyclokat will capture share more quickly in these markets.
- The strong late-stage pipeline is set to offer a strong competition to Cyclokat.
- Potential generic Restasis will prove detrimental to Cyclokat uptake in the US, since they both have the same active ingredient.

Below figure illustrates Cyclokat sales during the forecast period.
Executive Summary

What do the physicians think?

Our experts believe the DES market will increase significantly in the forecast period

“I would expect an increase in dry eye population especially with ageing of population, more frequent use of computers and contact lenses, refractive laser surgery. Probably by 2020 the dry eye population is going to double because the population 65 years old and older is going to double by 2020.”

US KOL

“Dry eye is going to increase significantly in the next ten years. It’s age-dependent and the population is aging. Its also nutritionally dependent and a move away from omega-3s to omega-6s is contributing to the epidemic.”

US KOL

“DES is much more common in an elderly population so yes, prevalence will increase. According to the government estimate, our current elderly population is about 23% of the general population so 1 out of 5 individuals will be over the age of 65. And we are expecting this figure to increase a little above 30% beyond 2025 so about 1 out 3 individuals will be elderly very soon within 10 years.”

Asian KOL

Improvement in diagnosis is the biggest unmet need in DES

“The biggest unmet need in terms of effectively treating DES is actually diagnosis. There are a lot of tests out there but its hard to determine why the patient has dry eye. Managing an ADE patient versus an EDE patient is very difficult so defining the root cause early on is very important.”

US KOL

“Even with the diagnostic tests we have on the market today such as the Schirmer test, unless there is an indication going on in the mind of the ophthalmologist, physicians will not standardly run this test. So with increasing awareness in the coming few years or decade, the diagnostic tests may become more routine and rates will greatly increase.”

Asian KOL
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2 Introduction

2.1 Catalyst

Dry eye syndrome (DES), or keratoconjunctivitis sicca, is a multifactorial disease of the eye caused by dryness, decreased tear production, or increased tear film evaporation. DES, which is often referred to simply as dry eye, is the most prevalent form of ocular discomfort and irritation. The most common symptoms of DES are ocular irritation and discomfort, foreign body sensation, fatigue, and visual disturbances, which interfere with daily activities. In the elderly population, it is the most common reason for seeking eye care, and this is expected to increase exponentially with an aging demographic. In addition to becoming increasingly common in patients over the age of 50, DES is also increasing in mild to moderate forms due to external stimuli, such as computer usage. As the developed world expands, the market for more mild treatments will also grow.

This report provides a thorough analysis of the current and future landscape of DES therapeutics. For this report, the global coverage includes the seven major markets (7MM), US, UK, Germany, France, Italy, Spain, UK, and Japan, as well as the emerging markets of China and India. Artificial tears are the mainstay of therapy for the treatment of dry eye, regardless of severity of the disease, along with other pharmacologic treatment options, including Restasis (cyclosporine 0.05% ophthalmic emulsion), Diquas (diquafosol tetrasodium), and Mucosta (2% rebamipide ophthalmic suspension). The DES pipeline is strong, with 49 molecules in various phases of development. More notably, the late-stage pipeline has three products with novel mechanisms of action to treat the inflammation associated with the disease.

Since the last GlobalData DES report, in addition to a consistently growing patient population as a result of aging baby boomers and lifestyle changes associated with increased industrialization, two new entrants have emerged in the DES market: Diquas and Mucosta. Both have been launched in Japan and are contributing significantly to the treatment paradigm and will continue to capture market share.
2.2 Related Reports

- GlobalData (2013). Dry Eye Syndrome – United Kingdom Drug Forecast and Market Analysis to 2022. GDHC1120CFR.
- GlobalData (2013). Dry Eye Syndrome – France Drug Forecast and Market Analysis to 2022. GDHC1116CFR.
- GlobalData (2013). Dry Eye Syndrome – Germany Drug Forecast and Market Analysis to 2022. GDHC1117CFR.
- GlobalData (2013). Dry Eye Syndrome – Italy Drug Forecast and Market Analysis to 2022. GDHC1118CFR.
- GlobalData (2013). Dry Eye Syndrome – Spain Drug Forecast and Market Analysis to 2022. GDHC1119CFR.
- GlobalData (2013). Dry Eye Syndrome – Japan Drug Forecast and Market Analysis to 2022. GDHC1121CFR.
- GlobalData (2013). Dry Eye Syndrome – China Drug Forecast and Market Analysis to 2022. GDHC1122CFR.
- GlobalData (2013). Dry Eye Syndrome – India Drug Forecast and Market Analysis to 2022. GDHC1123CFR.
- GlobalData (2013). Restasis (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC186DFR.
- GlobalData (2013). Diquas (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC187DFR.
- GlobalData (2013). Mucosta (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC188DFR.
- GlobalData (2013). Lifitegrast (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC189DFR.
• GlobalData (2013). CF101 (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC190DFR.

• GlobalData (2013). EGP-437 (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC192DFR.

• GlobalData (2013). RX-10045 (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC193DFR.

• GlobalData (2013). MIM-D3 (Dry Eye Syndrome) – Forecast and Market Analysis to 2022. GDHC194DFR.

• GlobalData (2013). Dry Eye Syndrome – Current and Future Players. GDHC1016FPR.
9.7 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, Boston, London, India and Singapore.

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