Executive Summary

Actemra: Key Metrics in Rheumatoid Arthritis Markets

<table>
<thead>
<tr>
<th>2012 Actemra Sales</th>
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<tr>
<td>Total 7 MM</td>
<td>$355m</td>
</tr>
<tr>
<td>Total Global*</td>
<td>$412m</td>
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Key events (2011-2022)

<table>
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<th>Level of Impact</th>
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New oral therapy targeting JAK kinase potentially coming onto market in Q1 2013


<table>
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<tr>
<th>2022 Actemra Sales</th>
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<tbody>
<tr>
<td>Total 7 MM</td>
<td>$270m</td>
</tr>
<tr>
<td>Total Global*</td>
<td>$419m</td>
</tr>
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7 MM = US, Japan, UK, France, Germany, Spain, Italy. 5EU = UK, France, Germany, Spain, Italy.

*For the purposes of this report, Global = US, Japan, UK, France, Germany, Spain, Italy, India, China and Australia.

Source: GlobalData

Sales for Actemra in Rheumatoid Arthritis by Region

We estimate 2012 Rheumatoid Arthritis (RA) drug sales for Actemra to be $412m across the nine markets covered in this report: US, UK, France, Germany, Italy, Spain, Japan, India and Australia. By the end of the forecast period, sales will decline to $419m with a CAGR of 1.3%. This increase will largely be driven by growth in India, while sales in the 7 MM will decrease. This decline will be driven by:

- The patent expiration of Actemra in the US, EU and Japan in 2015, 2017 and 2015 respectively.
- New oral therapy targeting JAK kinase potentially coming onto market in Q1 2013
- Competition from other biologics such as Orencia which offer novel MOAs and two delivery methods for patients that are refractory to TNF inhibitors
- The launch of novel products, such as Pfizer’s JAK3 inhibitor, tofacitinib, Eli Lilly’s anti-BAFF, tabalumab and Rigel/AstraZeneca’s SYK inhibitor, fostamatinib

However, Actemra has a novel MOA and will be available in two delivery methods, directly competing with Orencia which also touts the same values. Actemra has potential to be used ahead of TNF inhibitors in the treatment paradigm.
What do the Physicians Think?

- Experts have mixed feelings about the emergence of biosimilars. Generally, there is hope that such drugs will be equally safe and efficacious at a reduced cost. This optimism is tempered by a cautious attitude that these attributes will need to be verified.

  “If they have the same efficacy and side-effect profile of the generic drug and significantly cheaper which we’ve been led to believe, they should really become the drug of choice. I would use biosimilars quickly…”

  [UK] key opinion leader, July 2012

- Despite the activity in RA research and development, experts believe that treatment will remain static for the foreseeable future.

  “I feel my paradigm, algorithm will be MTX, anti-TNF, and then other drugs before I pro-actively say ‘I’ll try you on this’…”

  [US] key opinion leader, July 2012
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2 Introduction

2.1 Catalyst

The RA market is currently very dynamic, with novel oral therapies awaiting approval such as:

- Eli Lilly’s anti-BAFF, tabalumab and JAK1,2 inhibitor, baricitinib
- Rigel/AZ’s SYK inhibitor, fostamatinib

These compounds will challenge the current biologics in the attempt to dislodge the stronghold of the TNF inhibitors, if their safety and efficacy profiles are proven once they enter the market.

The impending patent cliff will allow for the emergence of generics and biosimilars. Patent expiries begin in 2012 for current market leaders such as:

- Roche’s Actemra/RoActemra
- Amgen’s Enbrel
- J&J’s Remicade

The emergence of biosimilars will provide alternatives to the current biologics, hopefully at a lower cost. With more drugs in the treatment paradigm, the market will be overcrowded by the end of the forecast due to the approval of such biosimilars as:

- Enbrel (etanercept)
- Remicade (infliximab)
- Orecina (abatacept)

The drivers for market growth will also include the treatment of the increasing 55+ population throughout the world as well as the push for earlier diagnosis. India and China will also contribute to market growth as their populations obtain increasing access to RA pharmacotherapy. The challenges will be the crowded marketplace, comprising highly diversified field of therapies, with individual drugs struggling to distinguish themselves.

2.2 Related Reports

- GlobalData (2012). Enbrel (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1001DFR
- GlobalData (2012). Humira (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1002DFR
• GlobalData (2012). Remicade (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1003DFR
• GlobalData (2012). Simponi (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1004DFR
• GlobalData (2012). Cimzia (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1005DFR
• GlobalData (2012). Ocrevus (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1006DFR
• GlobalData (2012). Xeljanz (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1007DFR
• GlobalData (2012). Tabalumab (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1008DFR
• GlobalData (2012). Fostamatinib (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1009DFR
• GlobalData (2012). Secukinumab (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1010DFR
• GlobalData (2012). Masitinib (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1011DFR
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• GlobalData (2012). Sirukumab (Rheumatoid Arthritis) - Forecast and Market Analysis. GDHC1014DFR
• GlobalData (2012). Rheumatoid Arthritis - United States Drug Forecast and Market Analysis. GDHC1015DFR
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- GlobalData (2012). Rheumatoid Arthritis - Australia Drug Forecast and Market Analysis. GDHC1010CFR
- GlobalData (2012). Rheumatoid Arthritis - Current and Future Players. GDHC1001FPR
7.8 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.

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