Analysis of USFDA’s Approval of Biosimilars - Case in Focus: Zarxio (Biosimilar of Amgen's Neupogen)

Description: Report Highlights:

- Regulations around approval biosimilars in the US
- An overview of global biosimilar market
- Case study on the US approval of Zarxio (Biosimilar of Amgen's Neupogen)
- Measures taken by biotech focused companies to protect competitive advantage

A must buy for:

professional from the pharmaceutical, biotech, medical device and diagnostics industries with responsibilities or involvement in the following areas:

- Competitive Intelligence
- Business Intelligence
- Information Specialist
- Commercial/Customer Insights
- Strategic Planning
- Market/Marketing Research
- Decision Analysis/Decision Support
- Business Analytics
- New Product Planning/Development
- Forecasting
- Librarian
- Brand Management/Product Management
- Marketing
- Business Portfolio Planning
- Strategic/Business Analysis
- Business Development
- Licensing
- Technical Analysis
- Portfolio Management/Planning
- Project Management
- Risk Management
- Research Planning
- Research & Development
- Regulatory
- Scientist
- Legal/Regulatory
- Outsourcing
- Manufacturing

Contents:

1. Executive Summary

2. Overview:
- Definition: Biological Product
- Definition: Biosimilars
- The Biologics Price Competition and Innovation Act of 2009 (BPCI Act)
- Purple Book
- First Biosimilars Approved in Key Regions

3. Case Study: US Approval of Zarxio (Biosimilar of Amgen's Neupogen)
- Overview:
- What is Zarxio
- What is Zarzio
- What is Filgrastim
- Approved Indications for Zarxio
- Clinical Evidence: Zarxio
- Why not Generic
- Will it be Cheaper?
- Cost Comparison of Various Regimens of Neupogen, Neulasta, and Zarzio across 14 days (in EUR)
- Comparative Costs (in EUR) of Zarzio, Neupogen, and Neulasta Associated with the Estimates of Treatment across Three Tumor Types

4. Biosimilar Applications Pending/Under Review with USFDA

5. Global Biosimilars Market
   - Global Biosimilars Market Overview
   - Impact on Industry Competition
   - Novartis: The First to Market

6. Mergers and Acquisitions: To Enhance Biosimilar Capabilities

7. Measures Taken by Biotech Focused Companies to Protect Competitive Advantage

8. Biosimilars: Expected to Reduce Prices and Thus Enabling Healthcare Savings

9. Ancillary Services (Temperature Controlled Logistics, Lyophilization): Expected to Increase in the Wake of Biosimilars Approval

10. KOL Comments: Analysis of Statements from Various KOLs

Ordering:

Order Online - [http://www.researchandmarkets.com/reports/3341608/](http://www.researchandmarkets.com/reports/3341608/)

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct.

Product Name: Analysis of USFDA's Approval of Biosimilars - Case in Focus: Zarxio (Biosimilar of Amgen's Neupogen)
Web Address: http://www.researchandmarkets.com/reports/3341608/
Office Code: SC

Product Format
Please select the product format and quantity you require:

<table>
<thead>
<tr>
<th>Quantity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF) - Single User:</td>
<td>USD 1000</td>
</tr>
</tbody>
</table>

* The price quoted above is only valid for 30 days. Please submit your order within that time frame to avail of this price as all prices are subject to change.

Contact Information
Please enter all the information below in BLOCK CAPITALS

Title: Mr □ Mrs □ Dr □ Miss □ Ms □ Prof □
First Name: ___________________________ Last Name: ___________________________
Email Address: * ___________________________
Job Title: ___________________________
Organisation: ___________________________
Address: ___________________________
City: ___________________________
Postal / Zip Code: ___________________________
Country: ___________________________
Phone Number: ___________________________
Fax Number: ___________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:
Account number 833 130 83
Sort code 98-53-30
Swift code ULSBIE2D
IBAN number IE78ULSB98533083313083
Bank Address Ulster Bank,
27-35 Main Street,
Blackrock,
Co. Dublin,
Ireland.

If you have a Marketing Code please enter it below:

Marketing Code: _______________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:
(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World