US Biosimilars Market Opportunity & Clinical Pipeline Analysis

Description: Pharmaceutical companies benefited from the revolution in biotechnology that hit US market in 1980's. Some of the blockbuster biologics have been introduced in market helping pharmaceutical companies to occupy major market shares. Their presence could be felt in every disease segment as they were improved with time. Over the years, biologics lost patent giving way to biosimilars. US is late entrant and its market is largely untouched by biosimilars resulting in lots of commercialization opportunities. Now, US has become center of attraction for generating significant revenues by introducing biosimilars in different disease categories. Future prospects of US biosimilars markets have yet to be deciphered as this market is at nascent stages offering unique opportunities and challenges.

Biosimilars in US has been approved after a long-time while they have been introduced in other places over a decade ago. Late entry in US market has prevented the patients from getting benefit of biosimilars. Also, spending on healthcare could have been mitigated but absence of proper regulatory framework prevented commercialization of biosimilars in US. Number of indication under biosimilar coverage are also less, single at present, which is going to have modest effect on US market. Number of indications will increase in coming years till then US biosimilar market is expected to grow at modest rates. Slow market growth is of great concern as it is also related to cost cutting by regulators in health care spending. US biosimilars market is at nascent stage and it would take few years to become suitable niche for biosimilars.

Biologics have dominated the US market for several decades due to absence of worthy competitor in different disease segment. In coming years, this situation is expected to change as biosimilars are expected to be commercialized. Zarxio, first US biosimilar, has created lot of enthusiasm among masses but some physicians, investigators and payers have reservation against biosimilars. This scenario may cause hindrance in uptake of biosimilars in coming years. To increase acceptance rates, biosimilar developers have to produce head-to-data confirming pharmacological efficacy. Biosimilars are also expected to have higher cost-effectiveness promoting patients to switch from biologics. In this way, biosimilar developers would be able to generate more revenues by developing positive attitude towards biosimilars.

Newly developed biosimilars in US market are expected to face hard time as regulations are not in place. Both patient and payers are expected to suffer from this issue that has to be resolved as soon as possible. Implication of new rules is expected to take some time as lots of issues have to be solved. Naming of biosimilars and assigning of appropriate billing code is one of the fore most necessities. This situation is likely to deteriorate when monoclonal antibodies will be introduced in US market. Substitution and reimbursement will become easy if clear demarcation is made between which molecule belongs to which category. Regulators are likely to resolve these issues in coming years as they have just entered in biosimilars segment.

“US Biosimilars Market Opportunity & Clinical Pipeline Analysis” Report Highlight:

- US Biosimilars Market Introduction
- US Biosimilars Regulatory Scenario
- Unique Features of US Biosimilars Market
- Impact of Biosimilars in US Market
- Impact of Reimbursement Policies on US Biosimilars Market
- Zarxio: First Approved Biosimilar in US
- US Biosimilar Clinical Pipeline By Company, Indication & Phase
- US Biosimilar Clinical Pipeline: 104 Biosimilars
- Marketed Biosimilars: 1 Biosimilar

Contents:
1. US Biosimilars Market Introduction
2. US Biosimilars Regulatory Scenario
3. Unique Features of US Biosimilars Market
4. Impact of Biosimilars in US Market

5. New Biosimilar Categories with High Commercialization Potential
   5.1 High Cost-Effectiveness
   5.2 Competition
   5.3 Nature of Indication
   5.4 Nature of Biosimilars
   5.5 Cost-Effective Production
   5.6 Readily Availability of Biosimilars

6. Impact of Reimbursement Policies on US Biosimilars Market

7. Biobetters: Middle Ground between Biosimilars & Biologics

8. US Biosimilars Market Overview
   8.1 Current Market Scenario
   8.2 US Biosimilar Clinical Pipeline Overview


10. US Biosimilars Market Dynamics
    10.1 Research & Development
    10.2 Increasing Demand for Biosimilars
    10.3 Increasing Numbers Off-Patent Biologics
    10.4 Lesser Competition
    10.5 Strong Clinical Pipeline
    10.6 Large Number of Indications to be Introduced

11. US Biosimilars Commercialization Challenges

12. US Biosimilars Future Prospects

13. US Biosimilars Market Guidelines
    13.1 Scientific Considerations in Demonstration Biosimilarity to a Reference Product
    13.2 Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product
    13.3 Nonproprietary Naming of Biological Products
    13.4 Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product

14. US Biosimilar Clinical Pipeline By Company, Indication & Phase
    14.1 Research
    14.2 Preclinical
    14.3 Phase-I
    14.4 Phase-I/II
    14.5 Phase-II
    14.6 Phase-III
    14.7 Preregistration
    14.8 Registered

15. Suspended & Discontinued Biosimilars in Clinical Pipeline
    15.1 No Development Reported
    15.2 Discontinued
    15.3 Preregistration Submission Withdrawal

16. Competitive Landscape
    16.1 Amgen
    16.2 Apotex
    16.3 Boehringer Ingelheim
    16.4 Celltrion
    16.5 Coherus BioSciences
    16.6 Eli Lilly
    16.7 EPIRUS Biopharmaceuticals
16.8 Finox Biotech
16.9 Harvest Moon Pharmaceuticals
16.10 Hospira
16.11 Intas Biopharmaceuticals
16.12 Juno Therapeutics (Opus Bio)
16.13 Merck
16.14 Momenta Pharmaceuticals
16.15 Mylan
16.16 Nora Therapeutics
16.17 Novartis
16.18 Oncobiologics
16.19 Pfenex
16.20 Pfizer
16.21 Sandoz
16.22 Wockhardt

List of Figures:
Figure 1-1: Benefits of Biosimilar Introduction in US
Figure 1-2: Present Limitations of Biosimilars in US
Figure 1-3: FDA's Requirements for Biosimilar Products
Figure 2-1: Criterias for Similarity Formulated by Food and Drug Administration (FDA)
Figure 4-1: Global Sales of Neupogen/Neulasta (USD Million), 2012-2014
Figure 4-2: Global Sales of Epogen (USD Million), 2012-2014
Figure 4-3: Global Sales of Neulasta (USD Million), 2012-2014
Figure 4-4: Shares of Amgen Products Exposed to Biosimilars Competition (USD Million), 2014
Figure 5-1: Factors Responsible for Significant Revenue Generation
Figure 7-1: Properties of Biobetters
Figure 7-2: Few Advantages of Biobetters
Figure 7-3: Disadvantages of Biobetters
Figure 8-1: US- Estimated Humira Sales (USD Million), 2012-2014
Figure 8-2: Global Remicade Sales (USD Million), 2012-2014
Figure 8-3: US- MabThera/Rituxan Quarterly Constant Exchange Rate Sales Growth (USD Million), Q3 2014-Q3 2015
Figure 8-4: US- Herceptin Quarterly Constant Exchange Rate Sales Growth (USD Million), Q3 2014- Q3 2015
Figure 8-5: Global Herceptin Quarterly Constant Exchange Rate Sales Growth (USD Million), Q3 2014-Q3 2015
Figure 8-6: Estimated Global Aranesp Sales (USD Million), 2012-2014
Figure 8-7: US- Estimated Aranesp Sales (USD Million), 2012-2017
Figure 8-8: Estimated Sales of Selected Biologics Exposed to Biosimilars Competition, 2014 (USD Million)
Figure 8-9: Estimated Shares of Selected Biologics Exposed to Biosimilars Competition (USD Million), 2014
Figure 8-10: Rank of US among Different Diabetes Prone Countries
Figure 8-11: US Biosimilar Pipeline by Phase (%),2016
Figure 8-12: US Biosimilar Pipeline by Phase (Number),2016
Figure 8-13: No Development Reported US Biosimilar All Pipeline by Phase (%),2016
Figure 8-14: No Development Reported US Biosimilar All Pipeline by Phase (Number),2016
Figure 8-15: Discontinued US Biosimilar All Pipeline by Phase (%),2016
Figure 8-16: Discontinued US Biosimilar All Pipeline by Phase (Numbers),2016
Figure 16-1: Amgen Clinical Pipeline
Figure 16-2: Coherus Bioscience Clinical Pipeline
Figure 16-3: EPIRUS Biopharmaceuticals- Clinical Pipeline
Figure 16-4: Merck Clinical Pipeline
Figure 16-5: Novartis Clinical Pipeline
Figure 16-6: Oncobiologics-Clinical Pipeline
Figure 16-7: Pfenex Clinical Pipeline
Figure 16-8: Sandoz Clinical Pipeline

List of Tables:
Table 2-1: Major Regulatory Differences Related to Biosimilars in US & EU
Table 2-2: Differences between Biosimilars Applications & Biologics License Applications
Table 4-1: Comparison of Neupogen vs. Zarxio Cost
Table 4-2: Competition to Neupogen
Table 4-3: Amgen's Biosimilar Competitors in US
Table 4-4: Categories with Potential to Generate Significant Revenues in US Market
Table 5-1: Biosimilars under Food and Drug Administration (FDA) Review
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 and select the format(s) you require.

Product Name: US Biosimilars Market Opportunity & Clinical Pipeline Analysis
Web Address: http://www.researchandmarkets.com/reports/3610903/
Office Code: SCPLHPJE

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Format</th>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF)</td>
<td>□</td>
<td>USD 2400</td>
</tr>
<tr>
<td>Single User</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hard Copy</td>
<td>□</td>
<td>USD 3600 + USD 57</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shipping/Handling</td>
</tr>
<tr>
<td>CD-ROM</td>
<td>□</td>
<td>USD 3600 + USD 57</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shipping/Handling</td>
</tr>
<tr>
<td>Electronic (PDF)</td>
<td>□</td>
<td>USD 6000</td>
</tr>
<tr>
<td>Enterprisewide</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Shipping/Handling is only charged once per order.

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