

US Biosimilars Market Opportunity & Clinical Pipeline Analysis

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Abstracts

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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

9. ZARXIO: FIRST APPROVED BIOSIMILAR IN US

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 & DISCONTUED BIOSIMILARS IN CLINICAL PIPELINE

15.1 No Development Reported

15.2 Discountinued

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

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

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
- Table 6-1: Categories of Medicare Plan
- Table 6-2: Estimated Reimbursement of Zarxio according to Medicare B
- Table 7-1: Few Examples of Biologics, Biosimilars and Biobetters
- Table 8-1: Biosimilars with High Commercialization Potential in US, 2013-2024
- Table 8-2: Companies Involved in Marketing of Rituximab
- Table 8-3: Categories with High Potential for Biosimilar Revenue Generation
- Table 16-1: Celltrion Clinical Pipeline

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