

Global & USA BioSimilar Market Analysis to 2021; BioBetter, Erythropoietin (EPO), Human Growth Hormone (HGH), Granulocyte Colony-Stimulating Factor (G-CSF), Anti-Tumor Necrosis Factor (Anti-TNF), Monoclonal Antibodies (MAbs), Insulins, Interferons, Product Pipelines, Trends, Key Players, Regulations and Strategic Outlook.

<https://marketpublishers.com/r/G5C928F5490EN.html>

Date: July 2015

Pages: 271

Price: US\$ 3,400.00 (Single User License)

ID: G5C928F5490EN

Abstracts

"Biosimilars are highly-similar versions of biological drugs that are indicated for cancer, kidney disorders and a wide range of autoimmune diseases. Originator biologics are the most expensive drugs in the pharmaceutical industry and many of them cost nearly \$100,000 per patient per year. These expensive biologics impose a heavy financial burden on patients and healthcare systems, limiting easy access and optimal care. Patent protection for some of the biologics has already expired and many more are to lose patent rights between now and 2020. This has given an opportunity to biotechnology companies to develop and market biosimilars with a cost benefit of about 20% to 30%.

In order to gain a slice of the \$190 billion worth of biologic's market, many biotechnology companies have ventured into the biosimilar sector bringing out less-expensive copies of reference biologics. Biosimilars have been in the E.U. market since 2006 and less-regulated markets such as China, India, and South Korea have a number of biosimilars in their domestic markets. After a long delay, finally, the FDA took a historic decision to approve the first biosimilar Zarxio from Sandoz on March 6, 2015. The coming years will witness the flooding of large number of biosimilars into the U.S., which happens to be the largest market for biopharmaceuticals.

This report provides a comprehensive overview of the size of biosimilars' market, the segmentation of the market, key players and the vast potential of therapies that are in clinical trials. On total, about 44 biosimilars are available in the global market and currently the E.U. is the major market with 19 approved biosimilars in use. A significant number of biosimilars are available in the markets of China, India, South Korea and Latin America. Biosimilars from these emerging countries are approved by a less-stringent approval pathway and therefore, the commercialization of their products is mostly confined to the domestic markets. The report describes how the long-awaited FDA approval of Zarxio from Sandoz (biosimilar for Amgen's Neupogen) in March 2015 is to transform the otherwise nascent market. The report includes:

An overview of biosimilars that includes differences between biologics; biosimilars and generics, definition of biosimilars by different agencies, barriers in developing biosimilars, cost of developing biosimilars.

A summary of regulatory pathways in various geographic regions.

Development of biosimilars in Europe, China, India, South Korea, Latin America and the sudden spurt in the development of biosimilars in the U.S.

A list of biosimilar developers in different geographic locations.

An overview of biobetters that includes regulatory considerations, differences between biosimilars and biobetters, various biobetters that are in developmental stages, and the companies with the largest biobetter pipeline.

An overview of approved biosimilars in the E.U., U.S., India, South Korea and Latin America.

The market impact of biosimilars on their reference biologics such as Epogen, Humira, Remicade, Neupogen, Neulasta, Enbrel, Rituxan, Herceptin, Avastin and Lantus through 2021.

The top ten biologics on the focus of biosimilar developers.

The five major classes of biologics and their biosimilar counterparts.

The current landscape of originators of biosimilars.

Global market for biologics by region, through 2021.

Global market for biologics by indication, through 2021.

Global market for biologics by drug class, through 2021.

Global market for biosimilars by region, through 2021.

Global market for biosimilars by indication, through 2021.

Global market for biosimilars by drug class, through 2021.

Profiles of 95 biosimilar developers, their products in the market and their product pipeline.

A newsletter in the appendix gives the latest news of biosimilar sector as of February 2015.

1.3 Key Questions Answered in This Report

How do biologics, biosimilars and generics vary from each other?

What are the different quality, safety and efficacy assessment tests for biosimilars?

How much is being spent for developing a biosimilar molecule?

How many years does a biosimilar take to reach the commercial market?

How do regulatory pathways differ from region to region?

What is the need for biosimilars?

What are the different platforms for the development of biosimilars?

What is the success rate in the development of a biosimilar when compared to a biologic and generic?

What are the most attractive target biologics for the development of biosimilars?

How many biosimilars are being developed for Avastin, Enbrel, Herceptin, Humira, Neulasta, and Rituxan, and what are they?

How many biosimilar MAb are being developed and what are they?

How much can the U.S. save by the introduction of biosimilars, through 2024?

Which companies are involved in developing biosimilar MAb in South Korea?

Who are the Indian players active in Indian biosimilar industry?

What are the biosimilar drugs being developed by the Indian biosimilar developers?

Name the biosimilars approved in the E.U., India, South Korea and Latin America?

What is the current utilization rate of biosimilars in the E.U. countries?

The biosimilars approved for use in Germany, Netherlands, U.K., South Korea, Japan, Latin America and India?

How far the markets of Epogen, Humira, Remicade, Neupogen, Neulasta, Enbrel, Rituxan, Herceptin, Avastin and Lantus will be affected by the entry of biosimilar counterparts?

What are the top ten biologics that have become the focus of biosimilar developers?

What are the five major classes of biologics that have attracted the attention of biosimilar developers and what are their current market shares?

What are the top ten biologic drugs from 2009 to 2014?

Which biologic drugs dominated the U.S. market, between 2010 and 2014?

How much is the Medicare Part B spending on biologics in the U.S.?

What are the top-eight biologic drugs in the E.U. market?

How many biologics maintain absolute dominance in the German market?

What is the average cost of a biologic drug in the U.S.?

How did the market for biosimilars perform between 2007 and 2014?

How small is the market for biosimilars, when compared to that of biologics?

What favorable signs are there in the industry to hope for an accelerated growth for biosimilars?

What is the projected global and regional market for biosimilars from 2014 to 2021?

What is the projected market for biosimilars by major drug classes from 2014 to 2021?

Who are the market leaders in the biosimilar sector?

What was the market for biosimilars in the major E.U. countries between 2007 and 2013?

How much is the competition between biologics and biosimilars in the German market between 2007 and 2020?

What is the potential market for biosimilars in the U.S., through 2020?

"

Contents

1 INTRODUCTION

- 1.1 Executive Summary
- 1.2 Objectives of This Report
- 1.3 Key Questions Answered in This Report

2 BIOSIMILARS: A BRIEF OVERVIEW

- 2.1 Biologic Drugs
 - 2.1.1 Development of Biologics
 - 2.1.2 Biologics vs. SMDs
- 2.2 Biosimilar Drugs
 - 2.2.1 Definition of Biosimilars by The WHO, EMA and FDA
 - 2.2.2 Quality Safety and Efficacy (QSE) Assessment of Biosimilars
 - 2.2.3 Differences between Biosimilars and Biologics
 - 2.2.4 Variations in Development Efforts for Biosimilars, Biologics and Generics
 - 2.2.5 Barriers in Developing Identical Copies of Biologics
 - 2.2.6 The Cost of Developing Biosimilars
 - 2.2.7 Roadmap to a Biosimilar
 - 2.2.8 The Emerging Role of Biosimilars
 - 2.2.9 Different Names for Biosimilars

3 REGULATIONS FOR BIOSIMILARS: AN OVERVIEW

- 3.1 Biosimilar Drug Registrations in Europe
 - 3.1.1 Rules against Automatic Substitution of Biosimilars in E.U. Member States
 - 3.1.2 Shareholders' Attitudes towards Biosimilars in Europe
- 3.2 Biosimilar Guidelines in China
- 3.3 Regulatory Pathway for the Approval of Biosimilars in India
- 3.4 Regulatory Pathway for the Approval of Biosimilars in the U.S
 - 3.4.1 U.S. Regulation on Interchangeability of Biosimilars
 - 3.4.2 Extrapolation for Biosimilars in the U.S
 - 3.4.3 Totality of Evidence Approach for Biosimilar Approval by FDA
 - 3.4.4 Evaluation of Immunogenicity in all Stages of Biosimilar Development
 - 3.4.5 Timeline of U.S. Biosimilar Guideline Evolution, 2010-2015
- 3.5 Regulations Regarding the Use of Reference Products by Country
- 3.6 Regulations Regarding Extrapolation by Country

- 3.7 Regulations Regarding Clinical Studies by Country
- 3.8 Regulations Regarding Interchangeability by Country
- 3.9 Regulations Regarding Unique Naming by Country

4 DEVELOPMENT OF BIOSIMILARS: AN OVERVIEW

- 4.1 Unmet Need for Biosimilars
- 4.2 Stages in the Development of Biosimilars
 - 4.2.1 Developing a Highly Similar Product
 - 4.2.2 Confirming Biosimilarity
- 4.3 Biosimilar Development Stages
- 4.4 Capabilities Required for a Successful Biosimilar Developer
 - 4.4.1 Manufacturing Capabilities
 - 4.4.2 Clinical Development Experience and Regulatory Know-How
 - 4.4.3 Customized Sales and Marketing Skills
 - 4.4.4 Long-Term Biosimilar Strategy
 - 4.4.5 Upfront Capital Investment
- 4.5 Types of Firms Participating in Biosimilar Development
- 4.6 Key Markets with Biosimilar Approval Pathways
- 4.7 Success Rates in the Development of Biosimilar Drugs
- 4.8 The Most Popular Biosimilar Targets
 - 4.8.1 Total Number Biosimilars in Development for the Corresponding Biologics
 - 4.8.1.1 Biosimilars in Development for Originator Avastin (Bevacizumab)
 - 4.8.1.2 Biosimilars in Development for Originator Enbrel (Etanercept)
 - 4.8.1.3 Biosimilars in Phase III Development for Herceptin (Trastuzumab)
 - 4.8.1.4 Biosimilars in Development for Humira (Adalimumab)
 - 4.8.1.5 Biosimilars in Development for Neulasta (Pegfilgrastim)
 - 4.8.1.6 Biosimilars in Development for Rituxan (Rituximab)
- 4.9 Development of MABs
 - 4.9.1 Number of Biosimilar MABs in the Pipeline
 - 4.9.2 Development of Biosimilar MABs in South Korea
 - 4.9.3 Indian Players in Biosimilar Industry
 - 4.9.3.1 Indian Biosimilar Pipeline
- 4.10 Biosimilar Map in Table Format

5 BIOBETTERS: AN OVERVIEW

- 5.1 Regulatory Considerations for Biobetters
- 5.2 General Differences between a Biosimilar and a Biobetter

5.3 Biobetters in Development

5.3.1 Development of Biobetters by Stage

5.4 Biobetter Development in South Korea

6 THE APPROVED BIOSIMILARS: AN OVERVIEW

6.1 Authorized Biosimilars in Europe

6.1.1 Approved Biosimilars in Europe by Class

6.2 An Overview of Nineteen Biosimilars Approved in Europe

6.2.1 Abasaglar

6.2.2 Abseamed

6.2.3 Accofil

6.2.4 Bemfola

6.2.5 Binocrit

6.2.6 Biograstim

6.2.7 Epoetin Alfa Hexal

6.2.8 Filgrastim Hexal

6.2.9 Grastofil

6.2.10 Inflectra

6.2.11 Nivestim

6.2.12 Omnitrope

6.2.13 Ovaleap

6.2.14 Ratiograstim

6.2.15 Remsima

6.2.16 Retacrit

6.2.17 Silapo

6.2.18 Tevagrastim

6.2.19 Zarzio

6.3 Biosimilar Penetration in Europe

6.3.1 Biosimilar EPO Utilization in Europe

6.3.1.1 European Market Leaders for Biosimilar EPO

6.3.2 Biosimilar G-CSF in Europe

6.3.2.1 Penetration of G-CSF Biosimilars in Europe

6.3.2.2 The Three Major Biosimilar G-CSF Players in Europe

6.4 Price Differentials between Branded Neupogen, Eprex, Genotropin and their Biosimilar Counterparts in Europe

6.5 Biosimilars in Germany

6.6 Biosimilars Approved and Marketed in Netherlands

6.7 Biosimilars Available in U.K. for Myeloma

- 6.8 Biosimilars Approved and Marketed in South Korea
- 6.9 Biosimilars Approved and Marketed in Japan
- 6.10 Biosimilar MABs in Latin America
- 6.11 Biosimilars Approved in India

7 THE IMPACT OF BIOSIMILARS ON ORIGINATORS: AN OVERVIEW

- 7.1 Biosimilar Impact on Epogen
 - 7.1.1 Available Biosimilars for Epogen
 - 7.1.2 Cost of Epogen Treatment
- 7.2 Impact of Biosimilars on Humira
 - 7.2.1 Biosimilars of Humira
- 7.3 Impact of Biosimilars on Remicade
 - 7.3.1 Biosimilars for Remicade
- 7.4 Impact of Biosimilars on Neupogen
 - 7.4.1 Biosimilars of Neupogen
- 7.5 The Impact of Biosimilars on Neulasta
 - 7.5.1 Biosimilars for Neulasta
- 7.6 Impact of Biosimilars on Enbrel
 - 7.6.1 Biosimilars to Enbrel
- 7.7 Impact of Biosimilars on Rituxan
 - 7.7.1 Biosimilars of Rituxan
- 7.8 Impact of Biosimilars on Herceptin
 - 7.8.1 Biosimilars of Herceptin
- 7.9 Impact of Biosimilars on Avastin
 - 7.9.1 Biosimilars of Avastin
- 7.10 Impact of Biosimilars on Lantus
 - 7.10.1 Biosimilars of Lantus

8 TOP TEN BIOLOGICS ON THE FOCUS OF BIOSIMILAR DEVELOPERS

- 8.1 Aranesp (Darbepoietin alfa)
- 8.2 Enbrel
- 8.3 Epogen/Procrit/Epex/Erypo
- 8.4 Genotropin
- 8.5 Herceptin
- 8.6 Humira
- 8.7 Neulasta
- 8.8 Neupogen

8.9 Remicade

8.10 Rituxan

9 FIVE MAJOR CLASSES OF ORIGINATOR BIOLOGICS AND THEIR MARKET PERFORMANCE

9.1 Monoclonal Antibodies (MAbs)

9.1.1 Biosimilar MAbs in Pipeline

9.2 Tumor-Necrosis-Factor Alpha (TNF-alpha)

9.2.1 Biosimilar TNF-alpha Blockers

9.2.2 Biosimilar TNF-alpha Blockers in Development

9.3 Erythropoietin (EPO)

9.3.1 Biosimilars of EPO

9.4 Insulins

9.4.1 FDA-Approved Human Insulins

9.4.2 Biosimilar Insulins

9.5 Granulocyte-Colony Stimulating Factor (G-CSF)

9.5.1 Neupogen's Biosimilars

10 THE LANDSCAPE OF THE ORIGINATORS OF BIOSIMILARS

10.1 Domination of Biologics among the Top Ten Drugs in the U.S

10.1.1 Medicare Spending on Biologics

10.1.2 U.S. Patent Expiry Dates for Best-Selling Biologics

10.2 Top Eight Biologics in European Market

10.2.1 Domination of Biologics in Germany

10.3 Distribution of Biopharmaceutical Companies

10.4 The Most Expensive Drugs

10.4.1 The Average Cost of Treatment with Biologic Drugs

10.5 Top 15 Biopharma Companies by Revenue

10.6 Projected Global Market for Top-Selling Biologics

10.7 Projected Sales of Top-Selling Biologics in the U.S. Market

10.8 Comparison of Treatment Costs of Biologics and Non-Biologics

11 A BRIEF ANALYSIS OF MARKET FOR BIOLOGICS

11.1 Global Market for Biologics: Sales and Growth Rate for the Past Six Years

11.2 Projected Market for Biologics by Geography

11.3 Top Ten Biopharmaceutical Companies

- 11.4 Top-Selling Biologics by Class
- 11.5 Five Biologics Least Affected by Biosimilars
 - 11.5.1 Sustained Growth for Humira
 - 11.5.2 Lantus Facing Imminent Competition
 - 11.5.3 Higher Growth for Xarelto
 - 11.5.4 Prenvar13: World's leading Vaccine
 - 11.5.5 Eyelea: Surpassing the Predecessors
- 11.6 Five Biologics Showing Marginal declines in Sales
 - 11.6.1 The Uncertain Revenue Base for Enbrel in the International Market
 - 11.6.2 A Small Decline in Sales for Avastin
 - 11.6.3 Difficult Patient Access to Rituxan
 - 11.6.4 The Lining up of Biosimilars against Herceptin

12 MARKET FOR BIOSIMILARS: AN OVERVIEW

- 12.1 Past Seven Years of Market Performance by Biosimilars
- 12.2 Loss of Patent Protection for Biologics: The Major Driver of Biosimilars' Market
- 12.3 Relatively Small Size of Biosimilars' Market Compared to Biologics'
- 12.4 Favorable Signs for Increased Uptake of Biosimilars
- 12.5 Recent Events in Biosimilars' Market
- 12.6 Future of Biosimilars
- 12.7 Market for Biosimilars by Geography
- 12.8 Global Market for Biosimilars by Drug Class
- 12.9 Biosimilar Market Leaders
- 12.10 Distribution of Biosimilar Companies by Geography
 - 12.10.1 The Largest Markets for Biosimilars in Europe
 - 12.10.1.1 Biosimilars' Market in Germany
 - 12.10.1.2 Norway's Efforts to Achieve Larger Biosimilar Uptake
- 12.11 The Market Potential for Biosimilars in the U.S
 - 12.11.1 Optimistic Predictions for the Growth of Biosimilars' Market in the U.S
 - 12.11.2 Viability of Biosimilars in the U.S
 - 12.11.3 Projected Savings with Biosimilars in the U.S
 - 12.11.4 Multiple Challenges for Biosimilars' Entry into the U.S. Market
 - 12.11.5 Break-Even Analysis for Biosimilars in the U.S
 - 12.11.6 Biosimilars About to Enter the U.S. Market
- 12.12 SWOT Analysis
 - 12.12.1 Strengths
 - 12.12.2 Weaknesses
 - 12.12.3 Opportunities

- 12.12.4 Threats
- 12.12.5 Market Drivers
- 12.12.6 Barriers

13 SELECTED COMPANY PROFILES

- 13.1 3SBio Inc
 - 13.1.1 Biosimilars from 3SBio
- 13.2 Abzena
- 13.3 Actavis plc
 - 13.3.1 Actavis' Biosimilars
- 13.4 AET BioTech
 - 13.4.1 Distribution Agreement for Adalimumab
 - 13.4.2 Codevelopment of Adalimumab
- 13.5 Alvogen Inc
- 13.6 Amega Biotech
- 13.7 Amgen Inc
- 13.8 Anhui Anke Biotechnology (Group) Co., Ltd
- 13.9 Apotex Inc
 - 13.9.1 Biosimilars from Apotex
- 13.10 Avesthagen Ltd
 - 13.10.1 Agreement with Elpen
 - 13.10.2 Alliance with Kemwell Biopharma
- 13.11 Baxter International Inc
 - 13.11.1 Collaboration with Coherus
 - 13.11.2 Collaboration with Momenta
- 13.12 Beijing Four Rings Biopharmaceutical Co., Ltd
- 13.13 Bharat Biotech International Ltd
 - 13.13.1 Regen-D
 - 13.13.2 Regen-D
- 13.14 Biocon Ltd
 - 13.14.1 Human Insulin
 - 13.14.2 Insulin Glargine
 - 13.14.3 Insulin Lispro
 - 13.14.4 Insulin Aspart
 - 13.14.5 Erythropoietin (EPO)
 - 13.14.6 Filgrastim (GCSF)
 - 13.14.7 Streptokinase
 - 13.14.8 Monoclonal Antibodies (MAbs)

- 13.14.9 Contract Manufacturing
- 13.14.10 Research Services
- 13.15 Biogen Inc
 - 13.15.1 Joint Venture with Samsung
- 13.16 Bionovis SA
 - 13.16.1 Bionovis' Product Pipeline
- 13.17 Biopartners GmbH
 - 13.17.1 Somatropin
- 13.18 Biosidus S.A
- 13.19 Bioton Spółka Akcyjna
 - 13.19.1 Agreement with Medipolis
 - 13.19.2 Agreement with Actavis
- 13.20 Bioviz Technologies Pvt., Ltd
- 13.21 BioXpress Therapeutics SA
 - 13.21.1 Future Programs
- 13.22 Biotechnol AS
 - 13.22.1 Tb535
 - 13.22.2 Tb434
- 13.23 Boehringer Ingelheim GmbH
 - 13.23.1 Boehringer's Biosimilar Efforts
- 13.24 Bolder BioTechnology Inc
- 13.25 Cadilla Pharmaceuticals Ltd
 - 13.25.1 Exemptia
- 13.26 Celltrion Inc
 - 13.26.1 Remsima
 - 13.26.2 Product Candidates
 - 13.26.2.1 CT-P6
 - 13.26.2.2 CT-P10
- 13.27 Cerbios-Pharma S.A
 - 13.27.1 Biological Services
 - 13.27.2 Biotechnology Services
 - 13.27.3 Recombinant Urokinase
 - 13.27.4 Recombinant G-CSF
- 13.28 Cipla Ltd
 - 13.28.1 Etaccept
 - 13.28.2 Actorise
- 13.29 CJSC Biocad
 - 13.29.1 AcellBia
- 13.30 Ckd Bio Corp

- 13.30.1 Phase I Study of Darbepoietin alfa Biosimilar
- 13.31 Claris Lifesciences Ltd
 - 13.31.1 Fegrast
- 13.32 Coherus Biosciences Inc
 - 13.32.1 The Pipeline
- 13.33 CT Arzneimittel GmbH
 - 13.33.1 Biograstim
- 13.34 Dawoong Pharmaceutical Co. Ltd
- 13.35 Dong-A Socio Holdings Co., Ltd
- 13.36 Dr. Reddy's Laboratories Ltd
 - 13.36.1 Grafeel
 - 13.36.2 Reditux
 - 13.36.3 Cresp
 - 13.36.4 Peg-Grafeel
- 13.37 Eli Lilly & Co
 - 13.37.1 Abasria
 - 13.37.2 Basalgar
- 13.38 Emcure Pharmaceuticals Ltd
 - 13.38.1 Biosimilar for Herceptin
- 13.39 Epirus Biopharmaceuticals Inc
 - 13.39.1 Epirus' Programs
- 13.40 Finox AG
 - 13.40.1 Bemfola r-FSH
- 13.41 Fujifilm Diosynth Biotechnologies
 - 13.41.1 Joint Venture with Kyowa
- 13.42 Gan & Lee Pharmaceuticals Ltd
- 13.43 GeneScience Pharmaceuticals Co., Ltd
- 13.44 Genexine Co. Ltd
- 13.45 Genova Biopharmaceuticals Ltd
 - 13.45.1 Genova's Biosimilar
- 13.46 Genor BioPharma Co., Ltd
 - 13.46.1 Genor's Pipeline
- 13.47 Glenmark Pharmaceuticals Ltd
 - 13.47.1 GBR
 - 13.47.2 GBR
 - 13.47.3 GBR
- 13.48 Glycotope GmbH
 - 13.48.1 Glycotope's Pipeline
- 13.49 Green Cross Corp

- 13.50 HanAll BioPharma Co., Ltd
- 13.51 Hanwha Chemical Corp
 - 13.51.1 HD203
- 13.52 Harvest Moon Pharmaceuticals USA Inc
 - 13.52.1 Stable Cell Lines for Biosimilar Development
- 13.53 Hetero Drugs Ltd
 - 13.53.1 Darbepoetin alfa
- 13.54 Hexal AG
 - 13.54.1 EPO-alfa Hexal
 - 13.54.2 Filgrastim Hexal
- 13.55 Hospira Inc
 - 13.55.1 Retacrit
 - 13.55.2 Nivestim
 - 13.55.3 Inflectra
- 13.56 Innovent Biologics Inc
 - 13.56.1 IB1301
 - 13.56.2 IB1302
 - 13.56.3 IB1303
 - 13.56.4 IB1305
 - 13.56.5 IB1306
 - 13.56.6 IB1308
- 13.57 Intas Pharmaceuticals Ltd
- 13.58 ISU Abxis Co. Ltd
 - 13.58.1 Clotinab
 - 13.58.2 ISU101
 - 13.58.3 ISU302 &
 - 13.58.4 ISU201
- 13.59 Kyowa Hakko Kirin Pharma Inc
- 13.60 LG Life Sciences Co., Ltd
 - 13.60.1 Adalimumab Biosimilar
- 13.61 Lupin Ltd
 - 13.61.1 Lupin's Biosimilar
- 13.62 Mabion SA
 - 13.62.1 Phase III for Rituximab Biosimilar
- 13.63 mAbxience S.A
 - 13.63.1 mAbxience's Biosimilars
- 13.64 MacroGenics Inc
 - 13.64.1 Collaboration with Janssen
 - 13.64.2 Collaboration with Gilead

- 13.64.3 Collaboration with Boehringer Ingelheim
- 13.64.4 Collaboration with Green Cross
- 13.64.5 Collaboration with Takeda
- 13.64.6 Collaboration with Pfizer
- 13.64.7 MacroGenic's Pipeline
 - 13.64.7.1 Margetuximab
 - 13.64.7.2 MGA271
 - 13.64.7.3 MGD006
 - 13.64.7.4 MGD007
 - 13.64.7.5 MGD001
 - 13.64.7.6 MGD010
 - 13.64.7.7 Teplizumab
- 13.65 Medice Arzneimittel Putter GmbH & Co. KG
 - 13.65.1 Abseamed
- 13.66 Merck Serono
 - 13.66.1 Serono's Biosimilar Programs
- 13.67 Merck & Co., Inc
 - 13.67.1 Biosimilar Development and Commercialization Agreement with Samsung Bioepis
- 13.68 MJ Biopharm Pvt. Ltd
- 13.69 Mochida Pharmaceutical Co. Ltd
 - 13.69.1 LBEC0101 Trial
 - 13.69.2 Collaboration with LG Life Sciences
- 13.70 Momenta Pharmaceuticals Inc
 - 13.70.1 Momenta's Biosimilars Program
- 13.71 Mycenax Biotech Inc
 - 13.71.1 TuNEX
- 13.72 Mylan NV
 - 13.72.1 First Trastuzumab Biosimilar
 - 13.72.2 Two U.S. Phase III Clinical Trials for Insulin Glargine
 - 13.72.3 Partnership with Biocon
- 13.73 Nippon Kayaku Co. Ltd
 - 13.73.1 Nippon's Biosimilars
- 13.74 Oncobiologics Inc
- 13.75 Pfizer Inc
- 13.76 Pharma Praxis
- 13.77 PlantForm Corporation
- 13.78 Polpharma SA
 - 13.78.1 Polpharma's Collaboration for Biosimilars

- 13.79 Probiomed S.A. de C.V
- 13.80 Protalix BioTherapeutics Inc
 - 13.80.1 Biobetters from Protalix
 - 13.80.1.1 PRX-102
 - 13.80.1.2 Oral Anti-TNF
 - 13.80.1.3 AIR DNase
 - 13.80.1.4 Oral GCD
- 13.81 Ranbaxy Laboratories Ltd. (Sun Pharmaceutical Industries Ltd.)
 - 13.81.1 Infimab
- 13.82 Ratiopharm GmbH
 - 13.82.1 Ratiograstim
- 13.83 Reliance Life Sciences Pvt. Ltd
 - 13.83.1 ReliFeron
 - 13.83.2 ReliPoietin
 - 13.83.3 ReliGrast
 - 13.83.4 MIReI
 - 13.83.5 FostiRel
 - 13.83.6 ReliBeta
 - 13.83.7 ChorioRel
 - 13.83.8 AbcixiRel
- 13.84 Samsung Bioepis Co., Ltd
- 13.85 Sandoz Inc
 - 13.85.1 Sandoz's Biosimilars
 - 13.85.2 Sandoz's Biosimilar Clinical Trials
- 13.86 Shanghai CP Guojian Pharmaceutical Co., Ltd
- 13.87 Shantha Biotechnics Ltd
 - 13.87.1 Shanpoietin
- 13.89 Stada Arzneimittel AG
 - 13.89.1 Biosimilars from Stada
- 13.90 Synthon BV
 - 13.90.1 SYD985
 - 13.90.2 Antibody Discovery Agreement
 - 13.90.3 Global License Agreement for Biosimilar Trastuzumab
- 13.91 Teva Pharmaceutical Industries Ltd
 - 13.91.1 TevaGrastim
 - 13.91.2 Ovaleap
- 13.92 USV Ltd
 - 13.92.1 PEG-Filgrastim
 - 13.92.2 Teriparatide Injection

- 13.92.3 Somatropin
- 13.92.4 Filgrastim Injection
- 13.93 Wockhardt Ltd
 - 13.93.1 Glaritus
 - 13.93.2 Wepox
- 13.94 Xencor Inc
- 13.95 Xiamen Amoytop Biotech Co., Ltd
 - 13.95.1 Filgrastim (rHuG-CSF)
 - 13.95.2 Oprelvekin (rHuIL-11)
 - 13.95.3 Molgramostim (rHuGM-CSF)

14 BIOSIMILAR MARKET PARTICIPANTS AND THEIR FOCUSED PRODUCTS

List Of Figures

LIST OF FIGURES

- Figure 2.1: Size Comparison of Small Molecule Drugs (SMD) and Biologics
- Figure 2.2: Reasons for the Differences in Biologics of the Same Class by Different Manufacturers
- Figure 2.3: Roadmap to a Biosimilar
- Figure 3.1: Scientific Justification to Support Extrapolation to Indications not clinically Studied
- Figure 3.2: Totality of Evidence Approach for Biosimilar Approval by FDA
- Figure 3.3: Evaluation of Immunogenicity in all Stages of Biosimilar Development
- Figure 4.1: Development Timeline for Biologics and Biosimilars Compared
- Figure 4.2: Success Rates in the Development of Biosimilar Drugs
- Figure 4.3: The Anticipated 2017 Peak in Revenues for Humira and Decline Thereafter
- Figure 5.1: Number of Biobetters in Development by Stage
- Figure 5.2: Number of Biobetters in Development by Region/Country
- Figure 5.3: Companies with the Largest Pipeline of Biosimilars/BioBettters
- Figure 6.1: Share of HGH, EPO and G-CSF Biosimilars Utilization in European Market
- Figure 6.2: Approved Biosimilars in Europe by Class
- Figure 6.3: Biosimilar Penetration in Austria, Belgium and Bulgaria
- Figure 6.4: Biosimilar Penetration in Croatia, Czech Republic and Denmark
- Figure 6.5: Biosimilar Penetration in Finland France and Germany
- Figure 6.6: Biosimilar Penetration in Hungary, Ireland and Italy
- Figure 6.7: Biosimilar Penetration in Norway, Poland and Portugal
- Figure 6.8: Biosimilar Penetration in Romania, Slovakia and Slovenia
- Figure 6.9: Biosimilar Penetration in Spain, Sweden, Switzerland and U.K
- Figure 6.10: Top Ten E.U. Countries in Biosimilar Penetration
- Figure 6.11: The Steady Increase in Biosimilar EPO Utilization in Europe
- Figure 6.12: The Four European Market Leaders for Biosimilar EPO
- Figure 6.13: Volume Uptake of Biosimilar G-CSF in Standard Units vs. Daily G-CSF Available Market Products (%) in E.U. Countries
- Figure 6.14: The Three Major Biosimilar G-CSF Players in Europe
- Figure 6.15: Price Differential between Branded Neupogen and their Biosimilars in E.U.
- Figure 6.16: Price Differential between Branded Eprex and Biosimilars in E.U.
- Figure 6.17: Price Differential between Branded Genotropin and its Biosimilars in France, Germany, Spain and U.K
- Figure 7.1: Decline of Sales Revenue for Epogen due to Biosimilars, Through 2020
- Figure 7.2: Epogen Treatment Cost for Three Major Indications

- Figure 7.3: Revenue Generated by Epogen for Amgen, 2009-2014
- Figure 7.4: Marginal Decline of Sales Revenues for Humira, Through 2020
- Figure 7.5: Humira's Revenue Generation, 2010-2014
- Figure 7.6: Decline of Sales Revenues for Remicade due to Biosimilars, Through 2020
- Figure 7.7: Steady and Steep Decline of Revenues for Neupogen, Through 2020
- Figure 7.8: Impact of Biosimilars on Neulasta's Sales, Through 2020
- Figure 7.9: Marginal Decline in Sales Revenue for Enbrel due to Biosimilars, Through 2020
- Figure 7.10: The Estimated Market for Rituxan after Biosimilar Competition, Through 2020
- Figure 7.11: Impact of Biosimilars on Herceptin, Through 2020
- Figure 7.12: Impact of Biosimilars on Avastin's Revenues, Through 2020
- Figure 7.13: Impact of Biosimilars on Lantus, Through 2020
- Figure 8.1: U.S. Sales Data for Aranesp
- Figure 8.2: U.S. Sales Data for Enbrel
- Figure 8.3: U.S. Sales Data for Epogen/Procrit/Eporex/Erypo
- Figure 8.4: U.S. Sales Data for Herceptin
- Figure 8.5: U.S. Sales Data for Humira
- Figure 8.6: U.S. Sales Data for Neulasta
- Figure 8.7: U.S. Sales Data for Neupogen
- Figure 8.8: U.S. Sales Data for Remicade
- Figure 8.9: U.S. Sales Data for Rituxan
- Figure 9.1: Global Market for Monoclonal Antibodies
- Figure 9.2: Global Market for TNF-alpha Blockers, Through 2021
- Figure 9.3: Global Market for Originator Erythropoietin, Through 2021
- Figure 9.4: Global Market for Human Insulins, Through 2021
- Figure 10.1: The Growing Share (%) of Biologics, 2014-2023
- Figure 10.2: Top Biologic Therapy Areas
- Figure 10.3: Distribution of Biopharmaceutical Companies
- Figure 10.4: The Daily Cost of Cerezyme, Kadyla, Humira, Branded Small Molecule Drugs and Generics in the U.S
- Figure 10.5: The Average Cost of Treatment with Biologic Drugs in the U.S. and Europe
- Figure 10.6: Top 15 Biopharma Companies by Revenue
- Figure 10.7: Global Market for Top-Selling Biologics, 2013-2020
- Figure 10.8: Projected Sales of Top-Selling Biologics in the U.S. Market
- Figure 11.1: Steadily-Growing Percent Share (%) of Biologics in Total Pharmaceutical Market
- Figure 11.2: Global Market for Biologics: Sales and Growth Rate, 2008-2014
- Figure 11.3: Percent Share of Geographical Markets for Biologics

Figure 11.4: Projected Global Markets for Biologics by Geography, Through 2021

Figure 11.5: Anticipated Decline for Originator Biologics' Share in the E.U., Through 2021

Figure 11.6: Top Ten Biopharmaceutical Companies, 2014

Figure 11.7: Top-Selling Biologics by Class

Figure 11.8: Global Market for Humira, Through 2021

Figure 11.9: Global Market for Lantus, Through 2021

Figure 11.10: Global Market for Xarelto, Through 2021

Figure 11.11: Global Market for Prenvar13, Through 2021

Figure 11.12: Global Market for Eylea, Through 2021

Figure 11.13: Global Market for Enbrel, Through 2021

Figure 11.14: Global Market for Avastin, Through 2021

Figure 11.15: Global Market for Rituxan, Through 2021

Figure 11.16: Global Market for Herceptin, Through 2021

Figure 12.1: Biosimilar Market Performance, 2007-2014

Figure 12.2: Biosimilars' Market Compared with Biologics', Through 2021

Figure 12.3: Market for Biosimilars by Geography, Through 2021

Figure 12.4: Global Market for Biosimilars by Drug Class, Through 2021

Figure 12.5: The Four Biosimilar Market Leaders and their Market Shares, 2008-2014

Figure 12.6: Distribution of Biosimilar Companies by Geography

Figure 12.7: Leading Biosimilar Markets in Europe, 2007-2013

Figure 12.8: Saving Potential of Biosimilars in Germany, Through 2020

Figure 12.9: Projected U.S. Biosimilar Market, Through 2020

Figure 12.10: Projected Savings with Biosimilars of 11 Specific Biologics in the U.S., 2012-2024

List Of Tables

LIST OF TABLES

- Table 2.1: Differences between SMDs and Biologics
- Table 2.2: Comparison between Biosimilars, Biologics and Generics
- Table 2.3: Methods for QSE Assessment of Biosimilars
- Table 2.4: Differences between Generics and Biosimilars
- Table 2.5: Variations in Development Efforts for Biosimilars, Biologics and Generics
- Table 2.6: E.U. and U.S. Approved Biosimilars and Their Therapeutic Areas
- Table 2.7: Different Names for Biosimilars
- Table 3.1: Biosimilar Drug Registration in Europe
- Table 3.2: Rules against Automatic Substitution of Biosimilars in E.U. Member States
- Table 3.3: Shareholders' Attitudes towards Biosimilars in E.U.
- Table 3.4: Biosimilar Guidelines in China
- Table 3.5: Regulatory Pathway for the Approval of Biosimilars in India
- Table 3.6: Regulatory Pathway for the Approval of Biosimilars in the U.S
- Table 3.7: U.S. Regulation on Interchangeability of Biosimilars
- Table 4.1: Strengths and Weaknesses of the Four Types of Biosimilar Firms
- Table 4.2: Key Markets with Biosimilar Approval Pathways
- Table 4.3: Success Rates in the Development of Biosimilar Drugs
- Table 4.4: The Most Popular Biosimilar Targets
- Table 4.5: Total Number Biosimilars in Development for the Corresponding Biologics
- Table 4.6: Selected Biosimilars in Development for Avastin
- Table 4.7: Biosimilars in Development for Originator Enbrel (Etanercept)
- Table 4.8: Biosimilars in Phase III Development for Herceptin (Trastuzumab)
- Table 4.9: Biosimilars in Development for Humira (Adalimumab)
- Table 4.10: Biosimilars in Development for Neulasta (Pegfilgrastim)
- Table 4.11: Biosimilars in Development for Rituxan (Rituximab)
- Table 4.12: Selected Biosimilar Mabs Developers
- Table 4.13: Number of Biosimilar MAbs in the Pipeline
- Table 4.14: Development of Biosimilar MAb in South Korea
- Table 4.15: Indian Players in Biosimilar Industry
- Table 4.16: Biosimilar Pipelines of Indian Players
- Table 4.17: Biosimilar Developers from China
- Table 4.18: Biosimilar Developers from Korea
- Table 4.19: Biosimilar Developers from Europe
- Table 4.20: Biosimilar Developers from the U.S
- Table 4.21: Biosimilar Developers from India

Table 4.22: Biosimilar Developers from South America

Table 4.23: Biosimilar Developers from Japan

Table 5.1: Differences between the Development of Biosimilars and Biobetters

Table 5.2: Selected Biobetters in Development

Table 5.3: Number of Biobetters in Development by Stage

Table 5.4: Number of Biobetters in Development by Region/Country

Table 5.5: Companies with the Largest Pipeline of Biosimilars/Biobetters

Table 5.6: Selected Biobetter Development in South Korea

Table 6.1: Biosimilars Approved in E.U. as of February 2015

Table 6.2: Approved Biosimilars in Europe by Class

Table 6.3: Biosimilar Penetration in Europe for HGH, EPO and G-CSF

Table 6.4: Approved Biosimilar G-CSF in Europe

Table 6.5: Price Differential between Branded Neupogen, Eprex, Genotropin and their Biosimilars

Table 6.6: Biosimilars Approved and Marketed in Germany

Table 6.7: Biosimilars Approved and Marketed in Netherlands

Table 6.8: Biosimilars Available in U.K. for Myeloma

Table 6.9: Biosimilars Approved and Marketed in South Korea

Table 6.10: Biosimilars Approved and Marketed in Japan

Table 6.11: Biosimilar MAb's Marketed in Latin America and others in Development

Table 6.12: Biosimilars Approved and Marketed in India as of January 2015

Table 7.1: Available Biosimilars for Epogen

Table 7.2: Biosimilars of AbbVie's Humira

Table 7.3: Biosimilars of Remicade

Table 7.4: Biosimilars of Neupogen

Table 7.5: Biosimilars of Neulasta

Table 7.6: Biosimilars to Enbrel

Table 7.7: Biosimilars of Rituxan

Table 7.8: Biosimilars of Herceptin

Table 7.9: Biosimilars of Avastin

Table 7.10: Biosimilars of Lantus

Table 8.1: Latest Available U.S. Sales Data for Aranesp

Table 8.2: U.S. Sales Data for Enbrel

Table 8.3: U.S. Sales Data for Epogen/Procrit/Eprex/Erypo

Table 8.4: U.S. Sales Data for Herceptin

Table 8.5: U.S. Sales Data for Humira

Table 8.6: U.S. Sales Data for Neulasta

Table 8.7: U.S. Sales Data for Neupogen

Table 8.8: U.S. Sales Data for Remicade

Table 8.9: U.S. Sales Data for Rituxan

Table 9.1: MABs Approved and being Reviewed in the U.S. and Europe

Table 9.2: Biosimilar MABs in the Pipeline

Table 9.3: Biosimilar TNF-Alpha Blockers Available in Less-Regulated Markets

Table 9.4: Biosimilar TNF-alpha Blockers in Development

Table 9.5: Biosimilars in Development or Approved

Table 9.6: FDA-Approved Human Insulins

Table 9.7: The Original G-CSF Products

Table 9.8: Biosimilars of Neupogen

Table 10.1: Biologics, Among the Top Ten Drugs, 2009-2014

Table 10.2: Domination of Biologics among the Top Ten Drugs in the U.S., 2010-2014

Table 10.3: Medicare Part B Spending on Biologics

Table 10.4: U.S. Patent Expiry Dates for Best-Selling Biologics

Table 10.5: Top Eight Biologics among the Top Ten Pharmaceuticals in Europe

Table 10.6: Domination of Biologics in Germany, 2009-2014

Table 10.7: Top Biologic Therapy Areas

Table 10.8: Distribution of Biopharmaceutical Companies

Table 10.9: The Average Cost of Treatment with Biologic Drugs in the U.S. and Europe

Table 10.10: Top 15 Biopharma Companies by Revenue

Table 10.11: Projected Global Market for Top-Selling Biologics, Through 2020

Table 10.12: Projected Sales of Top-Selling Biologics in the U.S. Market

Table 10.13: Comparison of Treatment Costs of Biologics and Non-Biologics

Table 11.1: Global Market for Biologics: Sales and Growth Rate, 2008-2014

Table 11.2 Projected Global Markets for Biologics by Geography, Through 2021

Table 11.3: Revenue Forecast for Humira, Lantus, Xarelto, Prenvar13 and Eylea, Through 2021

Table 11.4: Marginal Decline in Sales for Enbrel, Remicade, Avastin, Rituxan and Herceptin, Through 2021

Table 12.1: Biologics Losing Patent Protection, Through 2019

Table 12.2: Biosimilars' Market Compared with Biologics', Through 2021

Table 12.3: Market for Biosimilars by Geography, Through 2021

Table 12.4: Global Market for Biosimilars by Drug Class, Through 2021

Table 12.5: The Four Biosimilar Market Leaders and their Market Shares, 2008-2014

Table 12.6: Timeline for U.S. Patent Expiration of Branded Biologics

Table 12.7: Cost of Developing and Bringing a Biosimilar into the U.S. Market

Table 12.8: Break-Even Analysis for Biosimilars in the U.S., Under Three Different Scenarios

Table 12.9: Top Five Players Focused on Developing Biosimilars for the U.S. Market

Table 13.1: Amgen's Biosimilar Programs in Pivotal Trial (Phase III)

Table 13.2: Amgen's Other Biosimilar Products in Development
Table 13.3: Biocon's Biosimilar Pipeline
Table 13.4: Bionovis' Product Development Partnerships
Table 13.5: Binovis' Internal Product Development
Table 13.6: BioXpress' Biosimilar Pipeline
Table 13.7: Bolder's Product Pipeline
Table 13.8: Dong-A's Biomedicine Pipeline
Table 13.9: GeneScience's R&D Plan
Table 13.10: Genexine's hyFc Pipeline
Table 13.11: Genor's Pipeline
Table 13.12: Glenmark's Novel Drugs Pipeline
Table 13.13: Glycotope's Pipeline
Table 13.14: Green Cross' Biopharmaceutical Pipeline
Table 13.15: HanAll's Pipeline
Table 13.16: Biologics/Biosimilars from Intas Pharmaceuticals
Table 13.17: Kyowa's Pipeline
Table 13.18: MJ Biopharm's Products and Products in Development
Table 13.19: Oncobiologic's Biosimilars Pipeline
Table 13.20: Pfizer's Biosimilar Pipeline
Table 13.21: Samsung's Biosimilar Pipeline
Table 13.22: Sandoz's Biosimilar Pipeline
Table 13.23: Xencor's Pipeline
Table 14.1: Representative Biosimilar Companies and Product Focus
Table 14.1: (Continued)
Table 14.1: (Continued)

APPENDIX

Appendix 1: Competitive Strategies in Life Sciences: Biobetters vs. Biosimilars

Appendix 2: Biosimilar News Updates as of April 2015

App. 2.1: Regulatory Framework Updates

App. 2.1.1: EMA Issues Finalized Insulin Biosimilars Guideline

App. 2.1.2: FDA Announces List of Guidance Documents for 2015

App. 2.1.3: Australia Reviewing Plans for Naming Biosimilars

App. 2.1.4: Mexico Issues Rules on Biolimbos

App. 2.2: Biosimilar Applications Approved and Under Review

App. 2.2.1: EMA Accepts Bioepis' Enbrel Biosimilar Candidate SB4 for Regulatory Review

App. 2.2.2: Samsung Bioepis Submits Marketing Authorization Application for SB2, a

Remicade (Infliximab) Biosimilar Candidate to the EMA

App. 2.2.3: FDA Approves First Biosimilar Product Zarxio

App. 2.2.4: Hospira Submits Applications to FDA for the Proposed Eopetin alfa Biosimilar

App. 2.2.5: FDA Postpones Celltrion's Remicade Biosimilar Review Meeting

App. 2.2.5: Apotex Announces FDA has Accepted for Filing its Biosimilar Application for Filgrastim (Grastofil)

Appendix 2.3: Company News

App. 2.3.1: Pfizer to Acquire Hospira

App. 2.3.2: Hospira Launches First Biosimilar MAb Inflectra (Infliximab) in Major European Markets

App. 2.3.3: Oncobiologics' ONS-3010 Meets Primary Endpoints

App. 2.3.4: Mabion Submits Registration Dossier in Argentina

App. 2.3.5: Amgen Announces Positive Results of Phase III Study of Biosimilar Candidate ABP

App. 2.3.6: Innovent Biologics Inc. Completes Financing Funds to Advance Novel Biologic Pipeline

I would like to order

Product name: Global & USA BioSimilar Market Analysis to 2021; BioBettters, Erythropoietin (EPO), Human Growth Hormone (HGH), Granulocyte Colony-Stimulating Factor (G-CSF), Anti-Tumor Necrosis Factor (Anti-TNF), Monoclonal Antibodies (MAbs), Insulins, Interferons, Product Pipelines, Trends, Key Players, Regulations and Strategic Outlook.

Product link: <https://marketpublishers.com/r/G5C928F5490EN.html>

Price: US\$ 3,400.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/G5C928F5490EN.html>

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:
Last name:
Email:
Company:
Address:
City:
Zip code:
Country:
Tel:
Fax:
Your message:

****All fields are required**

Customer signature _____

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms & Conditions at <https://marketpublishers.com/docs/terms.html>

To place an order via fax simply print this form, fill in the information below
and fax the completed form to +44 20 7900 3970