Global & USA BioSimilar Market Analysis to 2021

Description: BioBetters, 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

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.

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 MAbs 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 MAbs 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?
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

4.0 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

5.0 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

6.0 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 Binocif
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

7.0 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

8.0 Top Ten Biologics on the Focus of Biosimilar Developers
8.1 Aranesp (Darbepoietin alfa)
8.2 Enbrel
8.3 Epogen/Procrit/Eprex/Erypo
8.4 Genotropin
8.5 Herceptin
8.6 Humira
8.7 Neulasta
8.8 Neupogen
8.9 Remicade
8.10 Rituxan

9.0 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

10.0 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
10.2 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

11.0 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 Prevnar13: 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

12.0 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

13.0 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 150
13.13.2 Regen-D 60
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 Etacept
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 Biogastim
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 Gennova Biopharmaceuticals Ltd.
13.45.1 Gennova's Biosimilar
13.46 Genor BioPharma Co., Ltd.
13.46.1 Genor's Pipeline
13.47 Glenmark Pharmaceuticals Ltd.
13.47.1 GBR 830
13.47.2 GBR 900
13.47.3 GBR 500
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 & 303
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 MIRel
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)
14.0 Biosimilar Market Participants and their Focused Products

INDEX 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/Biobetters
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. 5
Figure 6.16: Price Differential between Branded Eprex and Biosimilars in E.U. 5
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/Eprex/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 8.10: Global Market for Monoclonal Antibodies
Figure 8.11: Global Market for TNF-alpha Blockers, Through 2021
Figure 8.12: Global Market for Originator Erythropoietin, Through 2021
Figure 8.13: Global Market for Human Insulins, Through 2021
Figure 8.14: The Growing Share (%) of Biologics, 2014-2023
Figure 8.15: Top Biologic Therapy Areas
Figure 8.16: 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

INDEX 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. 5
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 MAbs 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 5.7: Biosimilars Approved in E.U. as of February 2015
Table 5.8: Approved Biosimilars in Europe by Class
Table 5.9: Biosimilar Penetration in Europe for HGH, EPO and G-CSF
Table 5.10: Approved Biosimilar G-CSF in Europe
Table 5.11: Price Differential between Branded Neupogen, Eprex, Genotropin and their Biosimilars
Table 5.12: Biosimilars Approved and Marketed in Germany
Table 5.13: Biosimilars Approved and Marketed in Netherlands
Table 5.14: Biosimilars Available in U.K. for Myeloma
Table 5.15: Biosimilars Approved and Marketed in South Korea
Table 5.16: Biosimilars Approved and Marketed in Japan
Table 5.17: Biosimilar MAbs Marketed in Latin America and others in Development
Table 5.18: Biosimilars Approved and Marketed in India as of January 2015
Table 6.1: Available Biosimilars for Epogen
Table 6.2: Biosimilars of AbbVie's Humira
Table 6.3: Biosimilars of Remicade
Table 6.4: Biosimilars of Neupogen
Table 6.5: Biosimilars of Neulasta
Table 6.6: Biosimilars to Enbrel
Table 6.7: Biosimilars of Rituxan
Table 6.8: Biosimilars of Herceptin
Table 6.9: Biosimilars of Avastin
Table 6.10: Biosimilars of Lantus
Table 6.11: Latest Available U.S. Sales Data for Aranesp
Table 6.12: U.S. Sales Data for Enbrel
Table 6.13: U.S. Sales Data for Eprex/Erypo
Table 6.14: U.S. Sales Data for Herceptin
Table 6.15: U.S. Sales Data for Humira
Table 6.16: U.S. Sales Data for Neupogen
Table 6.17: U.S. Sales Data for Neulasta
Table 6.18: U.S. Sales Data for Remicade
Table 6.19: U.S. Sales Data for Rituxan
Table 7.1: MAbs Approved and being Reviewed in the U.S. and Europe
Table 7.2: Biosimilar MAbs in the Pipeline
Table 7.3: Biosimilar TNF-Alpha Blockers Available in Less-Regulated Markets
Table 7.4: Biosimilar TNF-alpha Blockers in Development
Table 7.5: Biosimilars in Development or Approved
Table 7.6: FDA-Approved Human Insulins
Table 7.7: The Original G-CSF Products
Table 7.8: Biosimilars of Neupogen
Table 7.9: Biosimilars of Lantus
Table 8.1: Biologics, Among the Top Ten Drugs, 2009-2014
Table 8.2: Domination of Biologics among the Top Ten Drugs in the U.S., 2010-2014
Table 8.3: Medicare Part B Spending on Biologics
Table 8.4: U.S. Patent Expiry Dates for Best-Selling Biologics
Table 8.5: Top Eight Biologics among the Top Ten Pharmaceuticals in Europe
Table 8.6: Domination of Biologics in Germany, 2009-2014
Table 8.7: Top Biologic Therapy Areas
Table 8.8: Distribution of Biopharmaceutical Companies
Table 8.9: The Average Cost of Treatment with Biologic Drugs in the U.S. and Europe
Table 8.10: 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, Prevnar 13 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

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 Dosier in Argentina
App. 2.3.5: Amgen Announces Positive Results of Phase III Study of Biosimilar Candidate ABP 501
App. 2.3.6: Innovent Biologics Inc. Completes Financing Funds to Advance Novel Biologic Pipeline

Ordering:

Order Online - http://www.researchandmarkets.com/reports/3382595/

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 and select the format(s) you require.

Product Name: Global & USA BioSimilar Market Analysis to 2021
Web Address: http://www.researchandmarkets.com/reports/3382595/
Office Code: SCH3X2VQ

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

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF) - Single User:</td>
<td>USD 3400</td>
</tr>
<tr>
<td>Electronic (PDF) - 1 - 10 Users:</td>
<td>USD 6800</td>
</tr>
<tr>
<td>Electronic (PDF) - Enterprisewide:</td>
<td>USD 10000</td>
</tr>
</tbody>
</table>

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