+44 20 8123 2220
info@marketpublishers.com

US Biosimilars Market, Dosage, Price & Clinical Pipeline Outlook 2025

https://marketpublishers.com/r/UBA254E189DEN.html
Date: April 2019
Pages: 300
Price: US$ 2,400.00 (Single User License)
ID: UBA254E189DEN

Abstracts

Please note: extra shipping charges are applied when purchasing Hard Copy License depending on the location.

REPORT HIGHLIGHTS:

US Biosimilar Market Current Scenario

US Biosimilars Clinical Pipeline by Company, Indication & Phase: 28 Biosimilars

Marketed Biosimilars Clinical Insight by Company & Indication: 9 Biosimilars

Biosimilars Market Opportunity: US$ 5 Billion

FDA Rules & Regulations For Biosimilars Development & Market

Approved & Marketed Biosimilars: Clinical Insight, Price & Dosage

'US Biosimilars Market, Dosage, Price & Clinical Pipeline Outlook 2025' report gives comprehensive insight on clinical and non-clinical issues involved in the development of biosimilars market in US. Report highlights the ongoing market trends and initiatives undertaken by various stake holders to advance the approval and commercialization of biosimilars in the US pharmaceutical market.

Biosimilars have started gaining attention worldwide as they are cheaper but equally effective than their original product. Biosimilars cost lesser than biologics as they take less time to develop and go through only four stages of testing - analytical, non-clinical,

+44 20 8123 2220
info@marketpublishers.com

clinical pharmacology and clinical studies. Biosimilars are not similar or same as generic drugs due to difference in their physiochemical properties.

Globally they are at different stages of progression with respect to adoption of biosimilars in main stream pharmaceutical market. Although European market is the most mature market in comparison to US market but it is catching up to speed. Total of 19 biosimilars have been approved by FDA since 2014, but only 9 biosimilars have been able to make it to the market as of 2019. The most recent approved biosimilar is Trazimera of Pfizer (March 11, 2019).

Most successful biosimilar in the US market has been Sandoz's Zarxio. It captured more market than Inflectra. Biosimilars market has a bright future. The market has the potential to grow faster if some of the issues like interchangeability status, extrapolation, shortening exclusivity period etc. are solved. In addition, market competition needs to be promoted.

Currently, US biosimilars market is at the interim state. With most of the biologic products going off patent by 2025 and increasing rate of patients suffering from chronic diseases. The biosimilars market has a huge opportunity to spread it swings in the US drug market. With few reforms and education to the stakeholders this goal is achievable. The US biosimilar market will continue to evolve and grow exponentially but with small degree of uncertainty. The regulatory authorities need to form a more concrete framework to keep these grey areas of the biosimilar market in check. This, accompanied with education of physicians/patients to speed market uptake, new development and commercial paradigms can provide the proper platform for developing new commercially successful biosimilars.

+44 20 8123 2220
info@marketpublishers.com

Contents

1. OVERVIEW OF BIOSIMILARS MARKET

1.1 History & Evolution Of Biosimilars
1.2 Global Biosimilars Market: Flourishing

2. ENGINEERING BEHIND BIOSIMILARS

2.1 Designing From Scratch
2.2 Developing Biosimilars
  2.2.1 Quality
  2.2.2 Nonclinical Evaluation
  2.2.3 Clinical Evaluation

3. WORKING OF BIOSIMILARS

4. TECHNICAL INNOVATIONS IN BIOSIMILARS

4.1 Improved Expression Systems
4.2 Higher Titers To Reduce Capacity Requirements
4.3 Analytical Technology
4.4 Quality By Design

5. BIOSIMILARS & GENERICS : DIFFERENT OR SAME?

6. BUDDING US BIOSIMILAR MARKET

6.1 Market Overview
6.2 US Biosimilar Pipeline Overview

7. FDA RULES & REGULATIONS FOR BIOSIMILARS DEVELOPMENT & MARKET

7.1 Data Required For Approval
7.2 Need For Abbreviated Approval Pathway
7.3 Biosimilar User Fees
7.4 Biosimilars Action Plan

8. BIOLOGICS COMING OFF PATENT BY 2025

+44 20 8123 2220
info@marketpublishers.com

9. FDA APPROVED BIOSIMILARS

10. US - APPROVED & MARKETED BIOSIMILARS: CLINICAL, PRICE & DOSAGE

10.1 Retacrit (epoetin alfa-epbx)
10.2 Zarxio (filgrastim-sndz)
10.3 Nivestym (filgrastim-aafi)
10.4 Granix (tbo-filgrastim)
10.5 Inflectra (infliximab-dyyb)
10.6 Renflexis (infliximab-abda)
10.7 Fulphila (pegfilgrastim-jmdb)
10.8 Udenyca (pegfilgrastim-cbqv)

11. US - APPROVED NOT MARKETED BIOSIMILARS

11.1 Trazimera (trastuzumab-qyyp)
11.2 Amjevita (adalimumab-atto)
11.3 Cyltezo (adalimumab-adbm)
11.4 Hyrimoz (adalimumab-adaz)
11.5 Mvasi (bevacizumab-awwb)
11.6 Erelzi (etanercept-szzs)
11.7 Ixifi (infliximab-qbtx)
11.8 Truxima (rituximab-abbs)
11.9 Ogivri (trastuzumab-dkst)
11.10 Herzuma (trastuzumab-pkrb)
11.12 Ontruzant (trastuzumab-dttb)

12. TACKLING THE HIGH PRICE

12.1 Promote Competition
12.2 Shortening Exclusivity Period
12.3 Interchangeability
12.4 Extrapolation
12.5 Reforms for Cost Effective Drug

13. PAYERS: CONCIERGE TO US BIOSIMILAR MARKET

14. US BIOSIMILAR MARKET DYNAMICS

+44 20 8123 2220
info@marketpublishers.com

14.1 Market Drivers
14.2 Hurdles To Cross

15. US BIOSIMILAR MARKET PEST ANALYSIS

16. US BIOSIMILAR MARKET FUTURE PROSPECTS

17. US - BIOSIMILARS CLINICAL PIPELINE BY COMPANY, INDICATION & PHASE

17.1 Research
17.2 Preclinical
17.3 Clinical
17.4 Phase-I
17.5 Preregistration
17.6 Registered

18. US - MARKETED BIOSIMILARS CLINICAL INSIGHT BY COMPANY & INDICATION

18.1 Adalimumab (Humira & Raheara)
18.2 Insulin Glargine Biosimilar (Abasaglar, Abasria & Basaglar)
18.3 Somatropin Biosimilar (Omnitrope & PrOmnitrope)
18.4 Insulin Lispro Biosimilar (Admelog & Insulin lispro Sanofi)
18.5 Trenonacog Alfa (IXINITY)
18.6 Pegfilgrastim Biosimilar - Biocon/Mylan
18.7 Infliximab Biosimilar (Flixabi & RENFLEXIS)
18.8 Bevacizumab Biosimilar (Mvasi)
18.9 Desvenlafaxine - Extended Release – Alembic

19. SUSPENDED BIOSIMILARS IN CLINICAL PIPELINE BY COMPANY, INDICATION & PHASE

19.1 No Development Reported
19.2 Discontinued
19.3 Suspended

20. COMPETITVE LANDSCAPE

+44 20 8123 2220
info@marketpublishers.com

20.1 Alembic
20.2 Allergan
20.3 Aptevo Therapeutics
20.4 Biocon
20.5 Celltrion
20.6 Eli Lilly
20.7 MedImmune
20.8 Pfizer
20.9 Polpharma
20.10 Samsung Bioepis
20.11 Sandoz
20.12 Sanofi
20.13 Teva

+44 20 8123 2220
info@marketpublishers.com

List Of Figures

LIST OF FIGURES

Figure 1-1: Geographic Division Of Biosimilar Market
Figure 1-2: Global - Biosimilars Market Share (%), 2018
Figure 2-1: Sources Of Variation Between Biosimilar Productions
Figure 2-2: Phases Of Biosimilar Development
Figure 2-3: Stages Of Comparability Exercise
Figure 2-4: New Drug Development: Cost & Time Comparison
Figure 3-1: Working Of Biosimilar On Active Rheumatoid Arthritis
Figure 4-1: Technology Needed For Cost Effectiveness Of Biosimilars
Figure 6-1: US - Filgrastim Market Share (%), 2018
Figure 6-2: US - Infliximab Market Share (%), 2018
Figure 6-3: US – Biosimilar Clinical Pipeline By Phase (%), 2019 till 2025
Figure 6-4: US – Biosimilar Clinical Pipeline By Phase (Number), 2019 till 2025
Figure 6-5: US – Biosimilar Discontinued in Clinical Pipeline By Phase (%),2019 till 2025
Figure 6-6: US – Biosimilar Discontinued in Clinical Pipeline By Phase (Number), 2019 till 2025
Figure 10-1: FDA Approved Biosimilars: Marketed
Figure 10-2: US - Cost Of 10 ml Retacrit In Different Concentration (US$), March'2019
Figure 10-3: US - Price Comparison In Different Concentration Of Zarxio & Neupogen (US$)
Figure 10-4: US - Cost Of Zarxio In Concentration – 300mgc/0.5 ml & 480mgc/0.8 ml (US$)
Figure 10-5: Wholesale Acquisition Cost Of Zarxio, Neupogen & Nivestym - 480mcg/ 0.8 ml (US$)
Figure 10-6: US - Cost Of Nivestym In Different Concentration (300mcg/0.5ml, 480mgc/0.8ml) (US$)
Figure 10-7: US - Cost Of 300 mcg Syringe & Vial Of Granix (US$)
Figure 10-8: US - Cost Of 480 mcg Syringe & Vial Of Granix (US$)
Figure 10-9: US - Cost Of Inflectra & Remicade For Injection dyyb 100 mg Powder (US$)
Figure 10-10: Global - Sale Of Inflectra & Remicade In 2017 (US$ Billions)
Figure 10-11: US - Sale Of Inflectra & Remicade In 2018 (US$ Billions)
Figure 10-12: US - Cost Difference Between Renflexis & Remicade (US$)
Figure 10-13: US - Cost Difference Between Renflexis & Inflectra (US$)
Figure 10-14: US - US - WAC Of Udenyca & Neulasta (US$)
Figure 10-15: US - WAC Of Udenyca & Neulasta (US$)

+44 20 8123 2220
info@marketpublishers.com

Figure 10-16: US - Cost Difference Between Udenyca, Fulphila, Neulasta For 6mg/0.6mL (US$)
Figure 11-1: US – Market Share Of Amjevita & Humira By 2032 (%)
Figure 11-2: US - WAC of Mvasi & Avastin (US$)
Figure 13-1: US - Prescription Drug Expenditure By Out of Pocket & Health Insurance (US$ Million), 2018 - 2025
Figure 13-2: US - Prescription Drug Expenditure By Out of Pocket & Health Insurance (US$ Million), 2018
Figure 13-3: US - Prescription Drug Expenditure By Out of Pocket & Health Insurance (%), 2018
Figure 13-4: US - Prescription Drug Expenditure By Out of Pocket & Health Insurance (US$ Million), 2025
Figure 13-5: US - Prescription Drug Expenditure By Out of Pocket & Health Insurance (%), 2025
Figure 13-6: Payers Strategies On Handling Biosimilars.
Figure 13-7: US - Health Care Expenditure By Out of Pocket & Health Insurance (US$ Million), 2018
Figure 13-8: US - Health Care Expenditure By Out of Pocket & Health Insurance (%), 2018
Figure 13-9: US - Health Care Expenditure By Out of Pocket & Health Insurance (US$ Million), 2025
Figure 13-10: US - Health Care Expenditure By Out of Pocket & Health Insurance (US$ Million), 2025
Figure 14-1: Main Therapeutics Areas Of Biosimilar Development (%), 2016
Figure 14-2: US - Share of generic and innovator products in small molecule and large molecule market (%)
Figure 15-1:PEST Analysis Of The Biosimilar Market
Figure 16-1: US - Biosimilar Market Opportunity(US$ Billion), 2019 - 2025
Figure 16-2: Global - GDP Expenditure On Healthcare (%), 2017
Figure 16-3: US - Savings by Biosimilar Molecule Class

+44 20 8123 2220
info@marketpublishers.com

List Of Tables

LIST OF TABLES

Table 5-1: Difference Between Generics & Biosimilars
Table 8-1: US - Coming Off Patent Biologicals: Humanized Antibody
Table 8-2: US - Coming Off Patent Biologicals: Not Humanized Antibody
Table 8-3: US - Coming Off Patent Biologicals: Not Antibodies
Table 9-1: List Of All The FDA Approved Biosimilars
Table 10-1: US - Recommended Dosing of Retacrit For Patients With Chronic Kidney Disease (CKD)
Table 10-2: US - Recommended Dosing Of Retacrit For Zidovudine-Treated Patients With HIV Infection
Table 10-3: US - Recommended Dosing Of Retacrit For Patients Undergoing Cancer Chemotherapy
Table 10-4: US - Recommended Dosing Of Retacrit For Patients Undergoing Elective, Non-Cardiac, Non-Vascular Surgery
Table 10-5: US - Recommended Dosage Of Zarxio For Cancer Patients Receiving Myelosuppressive Chemotherapy Or Induction &/or Consolidation Chemotherapy For AML
Table 10-6: US - Recommended Dosage Of Zarxio For Cancer Patients Undergoing Bone Marrow Transplantation
Table 10-7: US - Recommended Dosage Of Zarxio For Cancer Patients Undergoing Autologous PBPC Collection & Therapy
Table 10-8: US - Recommended Dosage Of Zarxio For Patients With Severe Chronic Neutropenia
Table 10-9: US - Recommended Dosage Of Nivestym For Cancer Patients Receiving Myelosuppressive Chemotherapy Or Induction &/Or Consolidation Chemotherapy For AML
Table 10-10: US - Recommended Dosage Of Nivestym For Cancer Patients Undergoing Bone Marrow Transplantation
Table 10-11: US - Recommended Dosage Of Nivestym For Cancer Patients Undergoing Autologous PBPC Collection & Therapy
Table 10-12: US – Recommended Dosage Of Nivestym For Patients & Severe Chronic Neutropenia
Table 10-13: Indications For Inflectra
Table 10-14: US - Recommended dosage Of Inflectra For Different Indications
Table 10-15: Indications of Renflexis
Table 10-16: US - Recommended Dosage Of Renflexis In Different Diseases

+44 20 8123 2220
info@marketpublishers.com

Table 10-17: US - Recommended Dosage of Fulphila For Different Indications
Table 10-18: US - Recommended Dosage of Udenyca For Different Indications
Table 11-1: US - Recommended Dosage Of Trazimera For Different Indications
Table 11-2: Indications of Amjevita
Table 11-3: US - Recommended Dosage Of Amjevita For Different Indications
Table 11-4: Indications of Cyltezo
Table 11-5: --US - Recommended Dosage Of Cyltezo For Different Indications
Table 11-6: Indications of Hyrimoz
Table 11-7: US - Recommended Dosage Of Hyrimoz For Different Indications
Table 11-8: Indications of Mvasi
Table 11-9: US - Recommended Dosage Of Mvasi For Different Indications
Table 11-10: US - Recommended Dosage Of Erelzi For Different Indications
Table 11-11: Indications of Ixifi
Table 11-12: US - Recommended Dosage Of Ixifi For Different Indications
Table 11-13: US - Recommended Dosage Of Ogivri For Different Indications
Table 11-14: US - Recommended Dosage Of Herzuma For Different Indications
Table 11-15: US - Recommended Dosage Of Ontruzant For Different Indications

+44 20 8123 2220
info@marketpublishers.com

I would like to order

Product name: US Biosimilars Market, Dosage, Price & Clinical Pipeline Outlook 2025
Product link: https://marketpublishers.com/r/UBA254E189DEN.html
Price: US$ 2,400.00 (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/UBA254E189DEN.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

Custumer 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