

# 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,

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 its wings 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.

## 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**

## **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-szsz)
- 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**

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. COMPETITIVE LANDSCAPE**

- 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

## 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\$)

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



## 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

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

## 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](mailto: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**

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