

MARKET ASSESSMENT OF BIOSIMILARS AND ITS GROWTH IN INDIA

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UNDER THE GUIDANCE OF

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CONTENTS

Abstract

- The study covers the field of biosimilars with the research done on secondary data sources and covers the overview of the global market of biosimilars drugs which tells us about how the development and growth this field is happening
- The general molecules and the Indian company's biosimilar market is having, and their uses is a major part of the research.
- The market segmentation of biosimilars shows us that how much scope we have in this area
- The general trends of the Biosimilar market with future impact and trends for prediction of the growth of the biosimilars in India

INTRODUCTION

- Biosimilars (also known as subsequent bio-logicals or subsequent bio-logics) are biological medical product that are approximately identical copies of the biological product made by another company or the same company in the generic version of drug.
- Biosimilars are officially approved versions of the original "Innovator" product and can be mass produced when the exclusive rights for the patent of the original product expires.
- the biosimilar segment is becoming larger in market size & capitalization and there are recently over 250 approved biosimilars worldwide.
- Biosimilars are the only way forward to reduce cost of treatment and to decrease the overall expenditure cost for a patient and reduce the OOPe.
- The biosimilars segment is expected to generate major traction and grow in global markets over the next decade, growing from US\$12 billion in 2020 to at least US\$36 billion by 2025 at a CAGR of 24%.

INTRODUCTION CONTD....

- The Indian biosimilar market was worth around \$300 million in 2015 and is projected to grow to \$40 billion by 2030.
- Another research shows that the Indian Biopharmaceuticals industry to generate a revenue of INR 2900 Cr in cycle of 2018-23.
- The major biopharmaceutical manufacturers of India are in Sidcul, Sikkim, Hyderabad, Vishakhapatnam, Chennai, Mumbai, Pondicherry, Mysore, Ahmedabad, and Delhi NCR.
- Some common Biosimilars prevailing in Indian market are: Glaritus, Relibeta, Grafeel, Epofer, Krabeya, Herceptin, Abcixirel, Shankinase.

OBJECTIVE OF THE STUDY

- To access the present current market and trends and innovative drugs in biosimilars
- To analyze the different trends in the biosimilar drug market.

OVERVIEW OF THE GLOBAL BIOSIMILAR MARKET

- The global biosimilar market reached \$ 13 bn in 2021.
- This market is currently driven by several factors, such as the expiration of successful biopharmaceutical patents, lower prices, a higher prevalence of chronic diseases, and cost-saving initiatives by governments and third-party taxpayers.
- the market is flashed to reach \$ 60.8 bn by 2027, with a CAGR of 26.1% in 2022–2027.
- According to a report of Fortune Business Insights, the size of the US biosimilars market has been estimated at \$ 6.73 billion in 2021.
- The size of the market is forecasted to increase from \$ 9.48 bn in 2022 to \$ 100.75 bn in 2029, growing at a CAGR of 40.2% over the forecasting period.
- Due to the surge of COVID-19, the biosimilar market showed a growth of 106% in 2020 from 2019

OVERVIEW OF THE GLOBAL BIOSIMILAR MARKET CONTD....

- The biological market in India will grow at a compound annual growth rate of 22% to reach \$ 12 bn by 2025.
- The market is currently dominated by simple biologics, such as diabetes treatments, oncology, ai diseases and CV diseases
- Insulin-like and EPO-like biological products have between 80 and 85% market share in India.
- However, complicated molecular biological products such as mAbs in Asia-Pacific are estimated at \$ 5.94 billion in 2020 and are projected to reach \$ 10.9 billion by 2025 with a CAGR of 4.52%

MANUFACTURERS OF BIOSIMILARS IN INDIA:

- Intas: Filgrastim – Neukine, Pegfilgrastim – Pegasta, Rituximab – Mabtas, Ranibizumab – Razumab, Bevacizumab – Bevastas.
- Biocon: Insulin Glargine – BASALOG, Insulin Disposable Glargine pen – BASALOG ONE, Rh-Insulin – INSUGEN-30/70.
- Relaince Lifesciences: Abciximab – AbcixiRel, Adalimumab – AdaliRel, Bevacizumab – BevacRel, r-hCG – ChorioRel, Darbepoetin – DarbeRel, FSH – FostiRel
- Zydus Cadila: Adalimumab– Exemptia, Trastuzumab emtansine– Ujvira
- Lupin: Filgrastim – Lupifil, Peg-Filgrastim – Lupifil-P, Etanercept
- Dr. Reddy's Laboratories: Darbepoetin Alfa – Cresp, Filgrastim – Grafeel, Pegfilgrastim – Peg-Grafeel, Rituximab – Reditux.

MARKET SEGMENTATION OF BIOSIMILARS

The biosimilars market for human growth hormone, EPO, mABs, insulin, interferon, and colony stimulating factors is broad. The market for the use of biosimilars is segmented into blood diseases, cancer, chronic and autoimmune diseases, and growth hormone deficiency. The use of biosimilars for the treatment of blood diseases is the segment with the highest sales due to expensive biological reference substances. and frequent use.

By Product

- Human Growth hormone
- Insulin
- Interferon
- Monoclonal Antibodies
- Peptides
- Granulocyte colony stimulating factors
- Erythropoietin
- Other

By Services

- Clinical Trials
- Contract research and Manufacturing Services

By Technology

- MAb Technology
- rDNA Technology
- Chromatography
- NMR Technology
- Electrophoresis
- Mass Spectrometry
- Bioassay
- Western Blotting
- Other

By application

- Blood Disorders
 - Chemotherapy Induced Anemia
 - Hemophilia
 - Pulmonary embolism
 - Oncology Diseases
- Chronic and autoimmune Disorder
 - Diabetes
 - Neutropenia
 - Multiple Sclerosis
 - Cystic Fibrosis
 - RA
 - Leprosy
 - Growth Hormone Deficiency, others

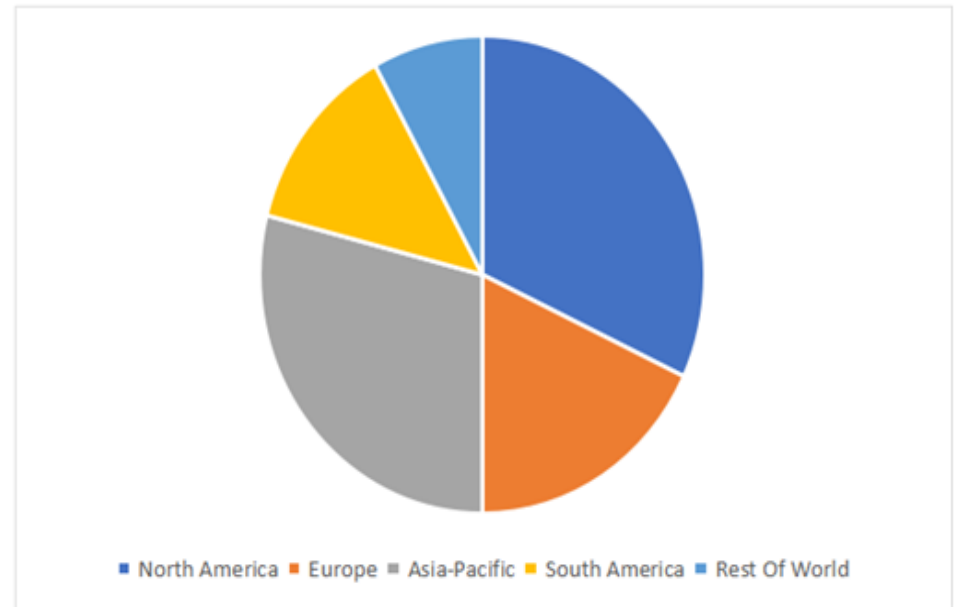
USES OF DIFFERENT BIOSIMILARS IN INDIA AND THEIR MARKET

Adalimumab:

- Adalimumab is used to relieve pain and swelling caused by certain types of arthritis. The drug is used to treat certain skin conditions (psoriasis vulgaris, hidradenitis suppurativa, etc.), as well as other conditions. The drug works by blocking proteins that are found in the body's immune system and can cause swelling and damage to the joints in arthritis and psoriasis. Adalimumab is a type of medicine known as a TNF blocker. This medicine helps to reduce joint swelling and may help to maintain joint function.
- It is also used to treat certain enteropathy (colitis) and eye diseases like uveitis.
- The market size of adalimumab is projected to be US \$ 5.1 bn by 2027. In addition, it is flashed to grow at a CAGR of 5.1% over the forecast period of 2022-27.

As seen in the above pictorial description the Asia-Pacific market holds at least one-third of the market of Adalimumab, India being one of the major countries of this region have a huge potential of growth. The global arthritis market is being growing at a CAG Rate of 8.8% which will increase the use of Adalimumab for the treatment.

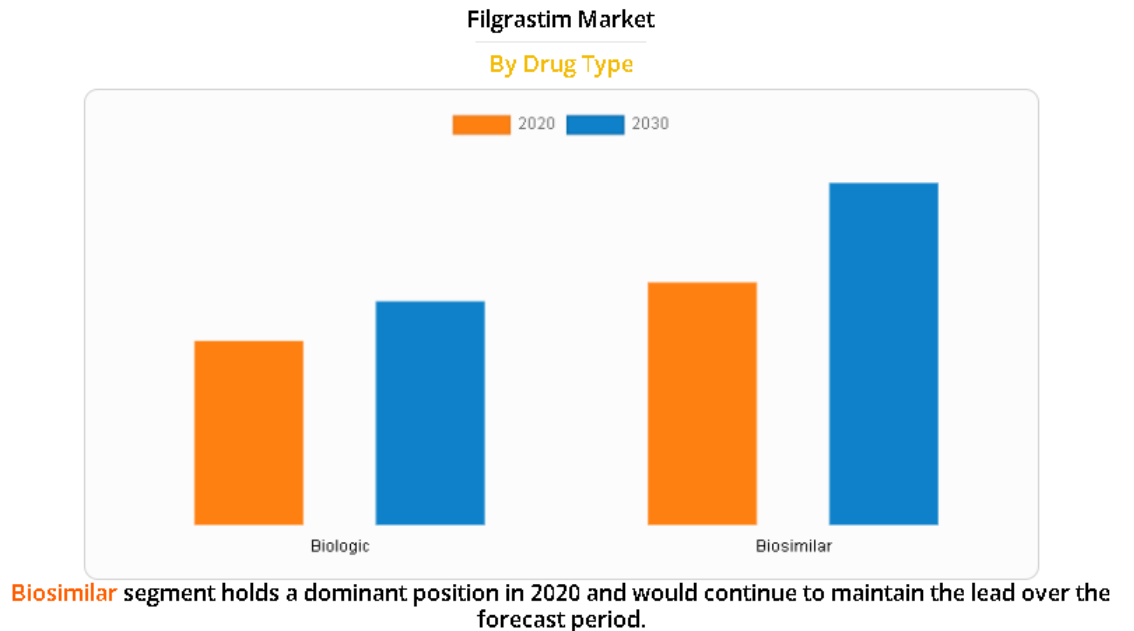
Adalimumab Market: Market Share (%) by region, 2021



Filgrastim:

- Filgrastim is a recombinant version of the naturally occurring G-CSF that stimulates the production of neutrophils. It is also commonly used when Leukemia is associated with an increase in white blood cells. Filgrastim has many side effects, including joint discomfort, chest pain, hair loss, and vomiting.
- The global Filgrastim market is valued at US \$ 562.5 mn in 2020 and is estimated to reach US \$ 745.9 million by 2030 to treat low blood levels of neutrophils 2021 – Grow from 2030 with a CAGR of 2.80%.

As seen from above pictorial representation the 2020 market share of filgrastim is almost the same as the biosimilar one but due to inflation rate and different economic factor of OOPe, the biosimilar version of Filgrastim will take the lead over the time in the forecast period from 2020-2030



Insulin Glargine:

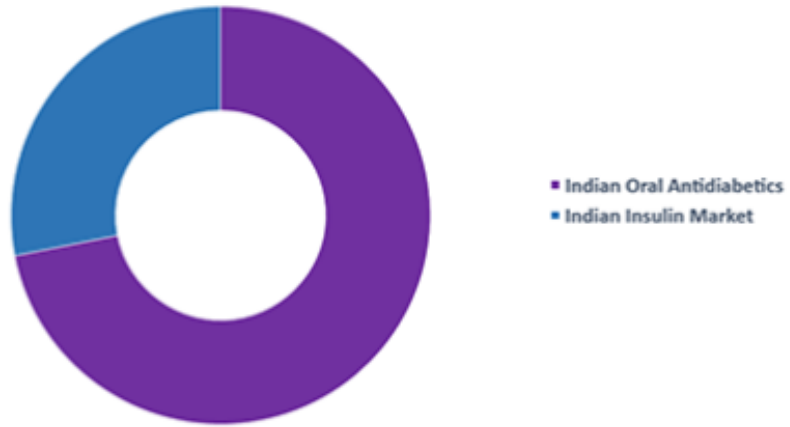
Insulin is used in combination with a diet and exercise program to control blood sugar levels in people with diabetes.

Controlling hyperglycemia helps prevent kidney damage, blindness, nerve problems, loss of limbs, and problems with sexual function. Proper diabetes management can also reduce the risk of heart attack and stroke.

India's diabetes market reached US \$ 1.957 bn in 2020. The market is estimated to grow at a CAGR of approximately 16.5% between the forecast period 2022 and 2027. The market size is projected to be worth about \$ 4,892.7 mn by 2026.

Indian Diabetes Market

Market Share by Segment (%)

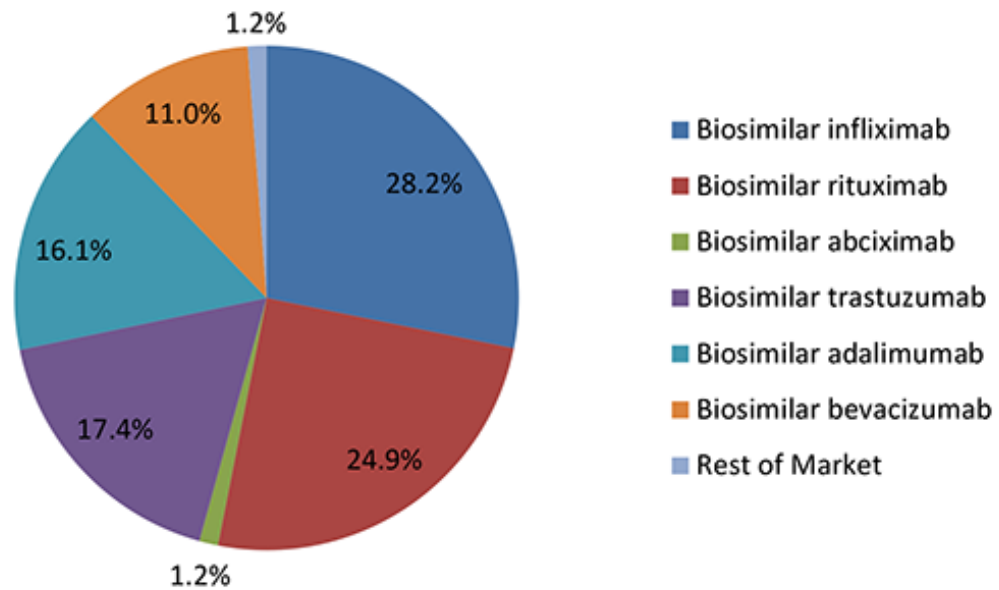


Source: www.expertmarketresearch.com

India is country with more and more cases of Diabetes Mellitus and the market reaching to a market size of \$4893 million by 2026, the use of Insulin will increase and will result in the growth of biosimilar market of the Insulin Glargine.

Monoclonal antibodies:

- Biosimilar monoclonal antibodies (mAbs) are a type of biosimilar. They are large, complex proteins used by the immune system to identify and neutralize foreign substances such as bacteria and viruses and are usually given to treat diseases such as cancer and RA.
- The global biosimilar monoclonal antibody market is expected to reach US \$ 5.9 bn in 2023 and will grow at a CAGR of 19% from period of 2016–2028.



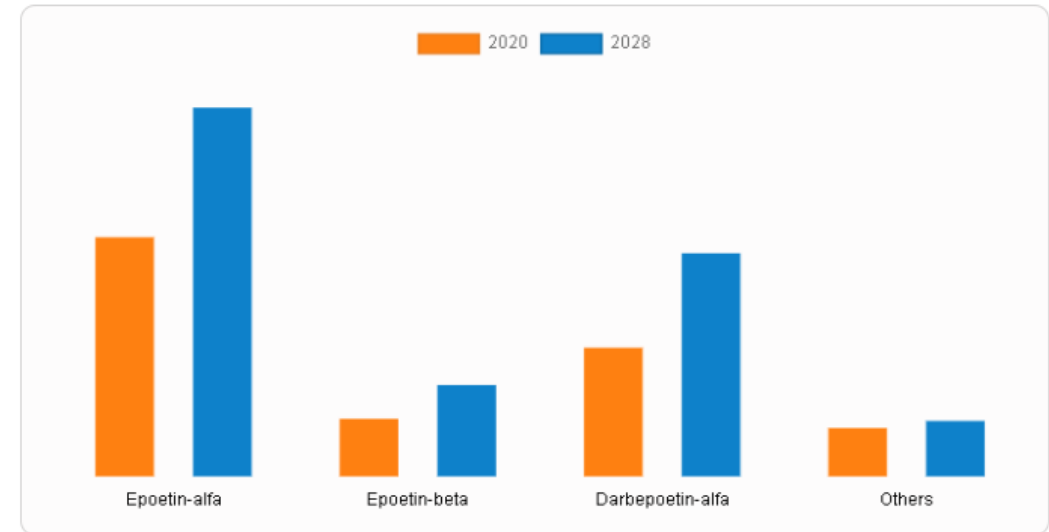
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- The different mABs market share is depicting how these major players in the biosimilar market are playing as compared to rest of the biosimilars.

Erythropoietin

EPO is a glycoprotein hormone that helps to produce red blood cells in the bone marrow. Erythropoiesis is the process of creating new red blood cells. The drug erythropoietin was developed to help treat end-stage renal disease (ESRD) and anemia caused by dialysis procedures.

Erythropoietin Drugs Market

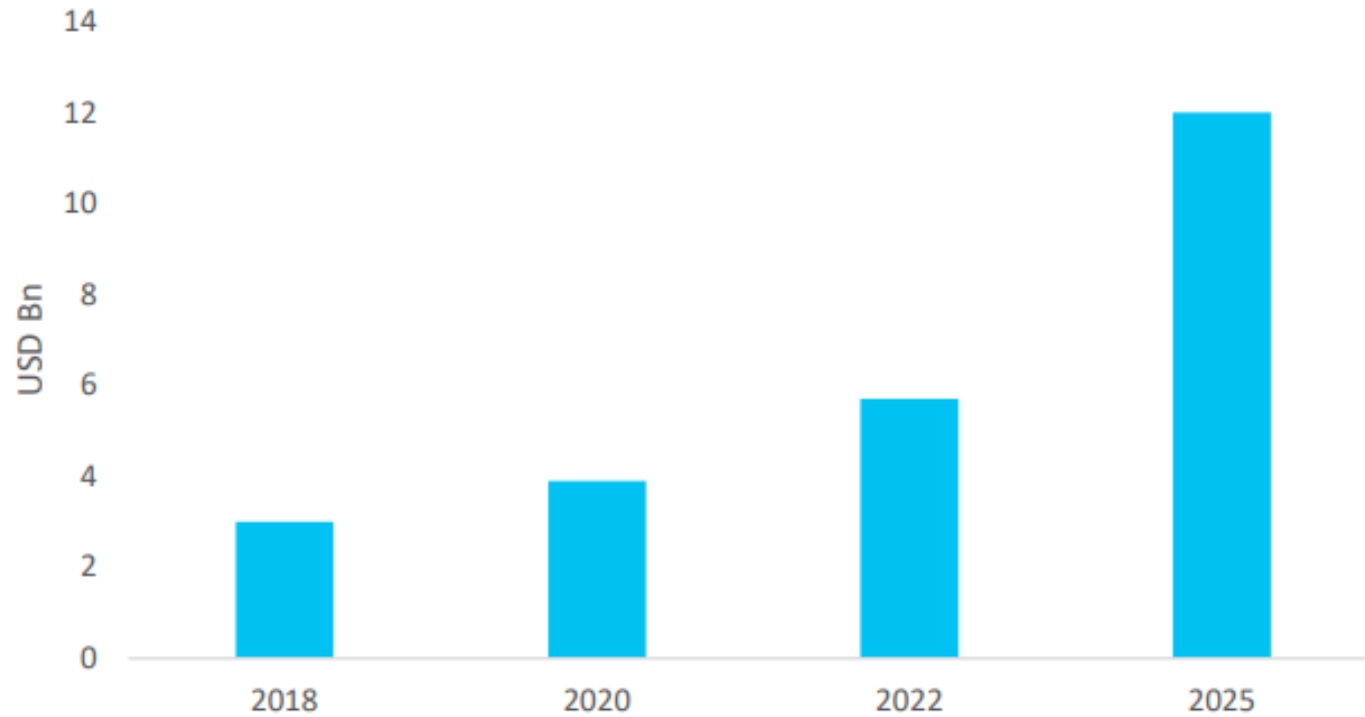
By Therapeutic Class



Etanercept:

- Etanercept is a recombinant molecule composed of two soluble TNF receptors (p75) subunits fused to the Fc portion of human IgG1. This fusion protein is a novel paradigm for TNF receptor therapy. TNF α is produced when the body is exposed to inflammation, such as from an illness or injury. The following drugs interfere with TNF α by inhibiting its activity. This results in increased inflammation and apoptosis. TNF receptors are a major factor involved in both of these processes. This drug is most often recommended for treating severe or moderate rheumatoid arthritis, ankylosing spondylitis, and other immune disorders.
- The market size for Etanercept is estimated to be \$21.2 billion by 2027 at a CAGR of 3.9%

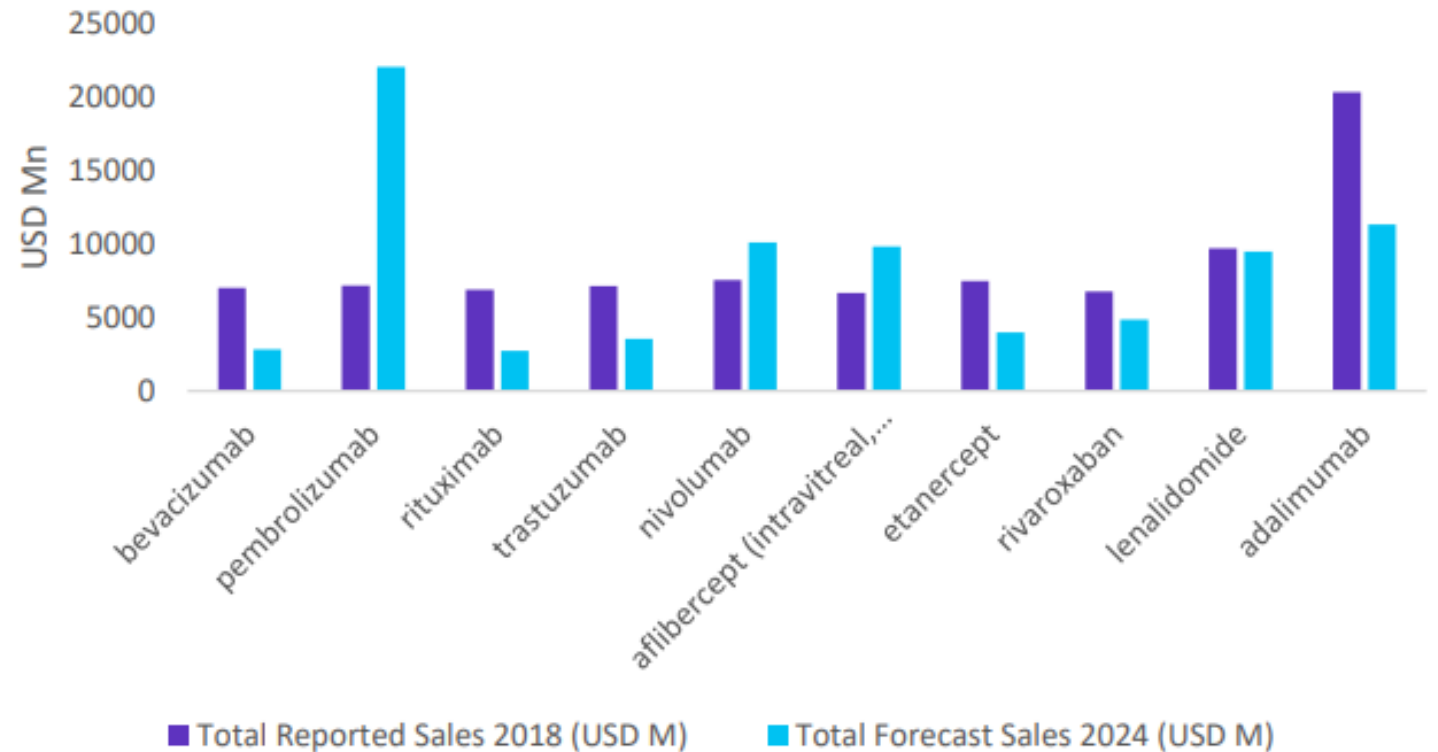
TRENDS IN BIOSIMILAR MARKET IN INDIA COMPARISON TO DIFFERENT PHARMA PRODUCTS



EXPECTED GROWTH
OF THE
BIOSIMILAR
MARKET.

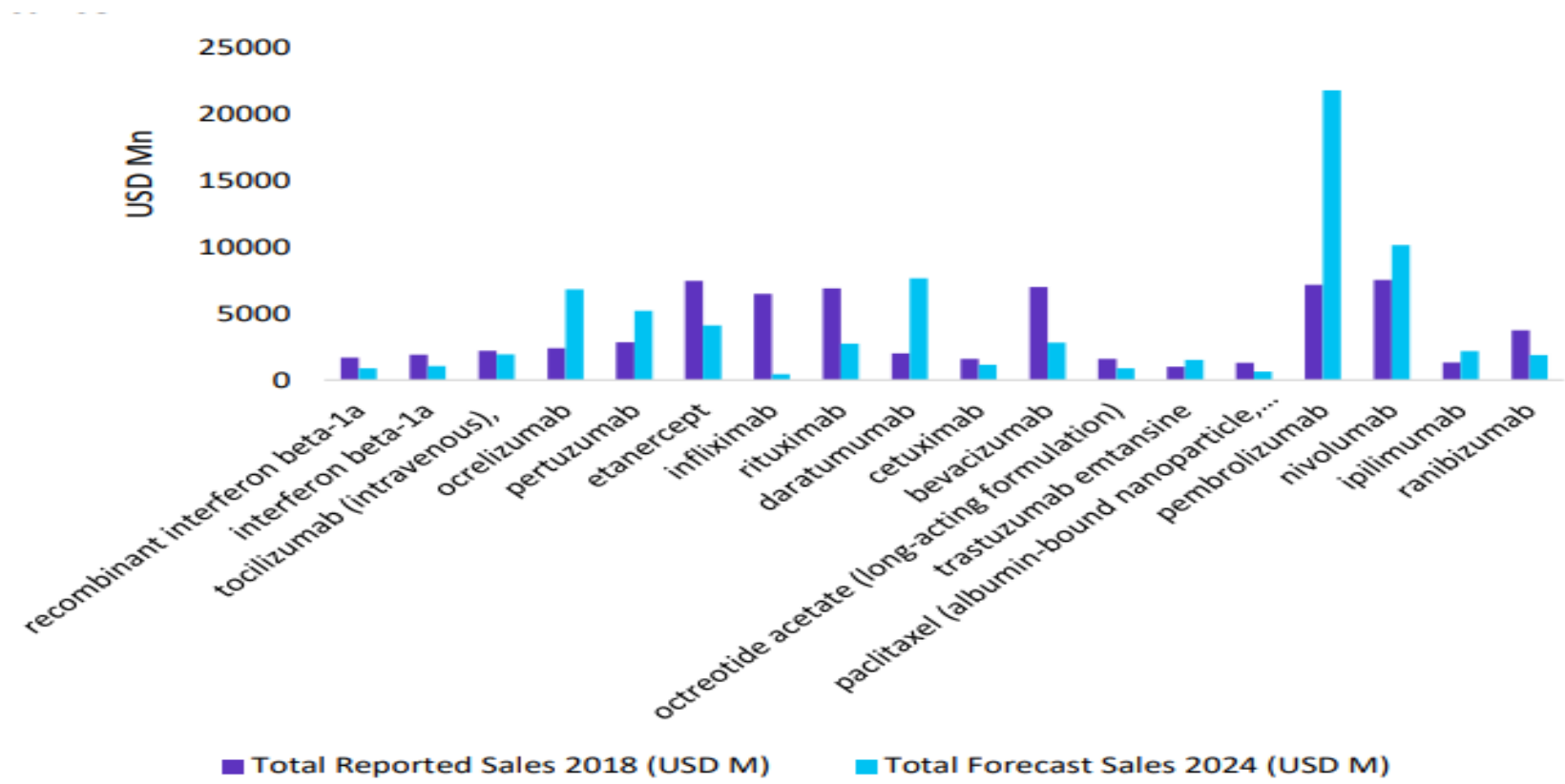


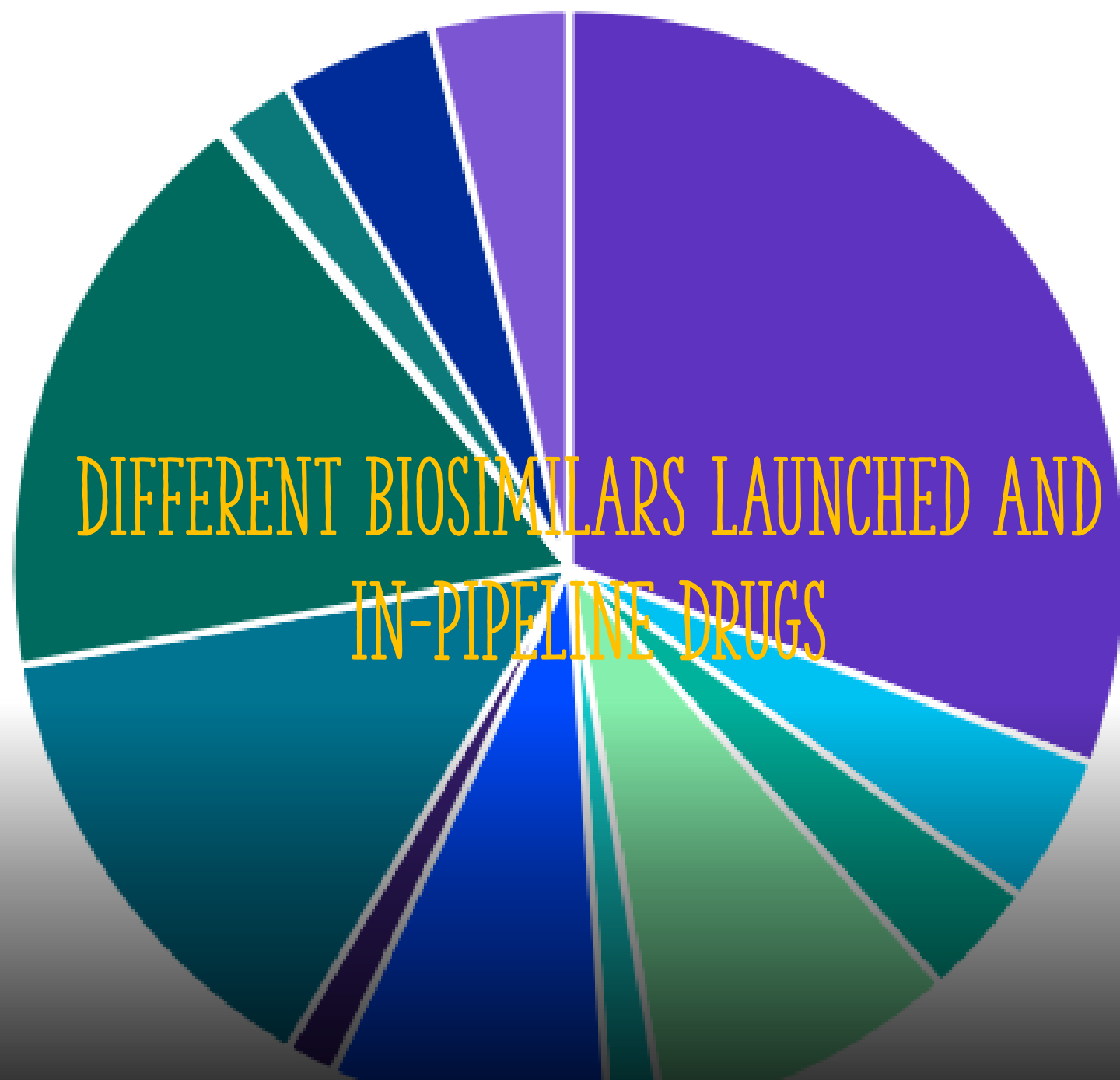
TOP 10 BLOCKBUSTER BIOSIMILAR DRUGS SALES



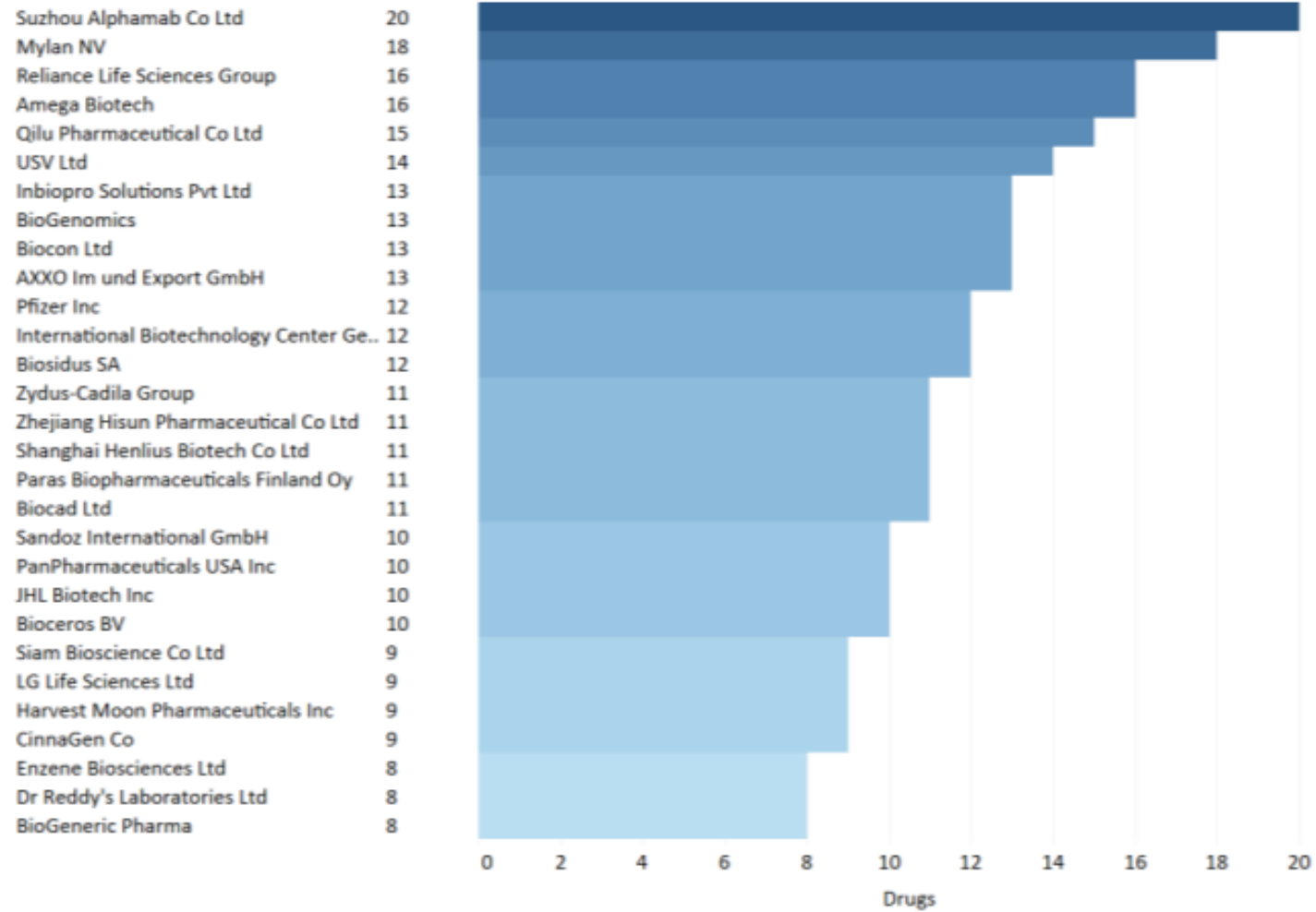
Source: Cortellis Competitive Intelligence

SALES OF BLOCKBUSTER BIOLOGICS USED IN THE TREATMENT OF CANCER





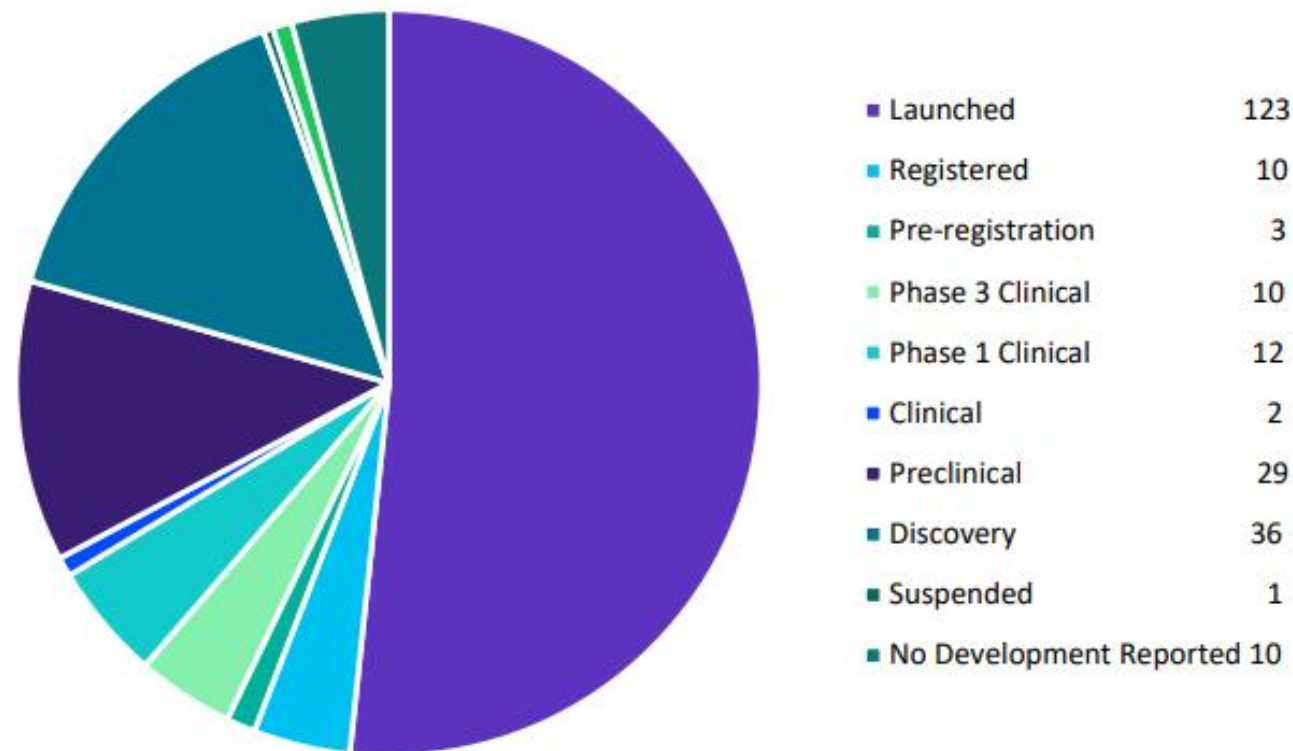
■ Launched	447
■ Registered	63
■ Pre-registration	49
■ Phase 3 Clinical	129
■ Phase 2 Clinical	23
■ Phase 1 Clinical	118
■ Clinical	21
■ Preclinical	200
■ Discovery	248
■ Suspended	3
■ No Development Reported	65
■ Outlicensed	58



Source: Cortellis Competitive Intelligence

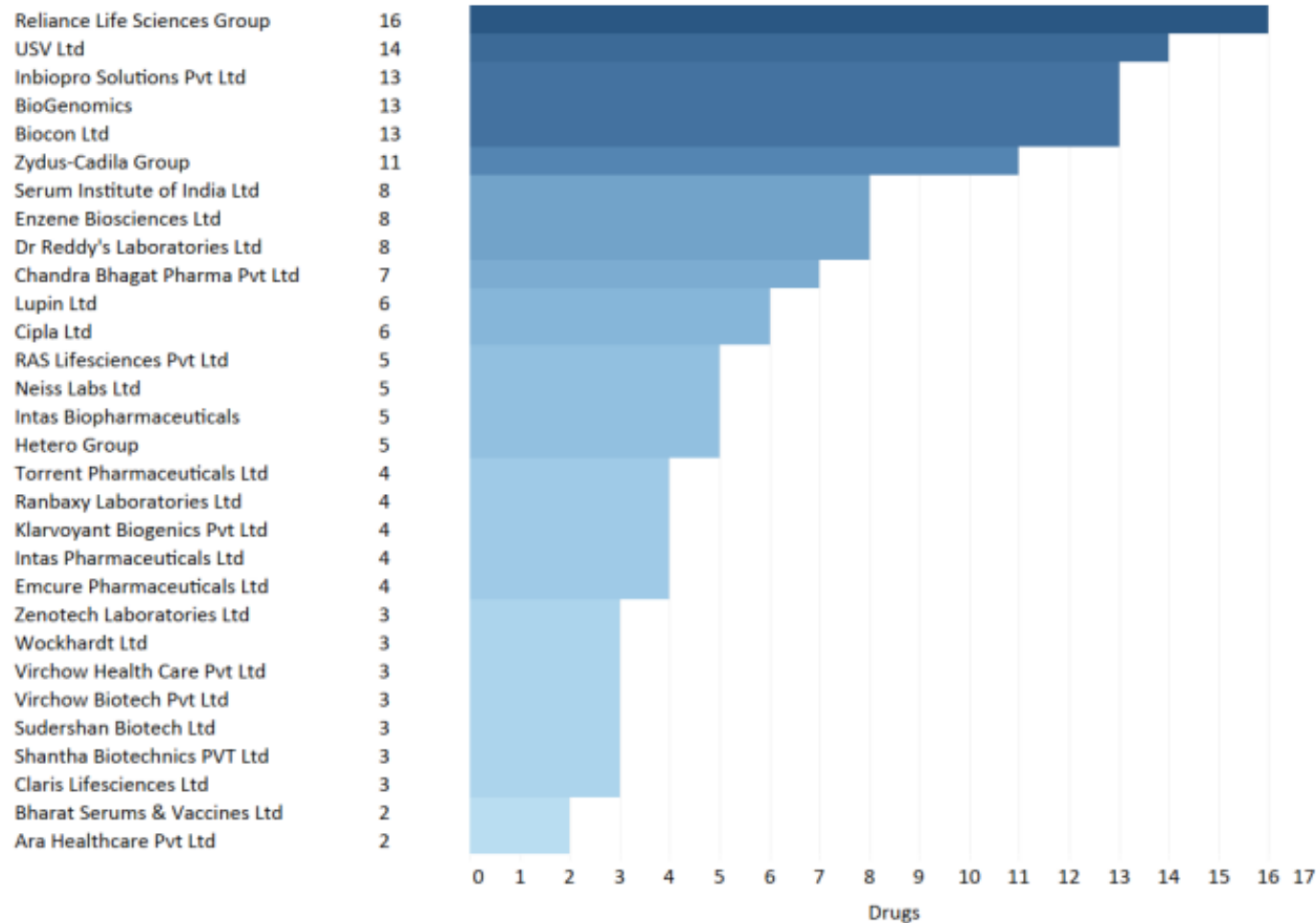
GLOBAL COMPANIES BY BIOSIMILARS AND FOLLOW-ON-BIOLOGICS DRUGS LAUNCHED AND IN PIPELINE

BIOSIMILARS IN PIPELINE OF INDIAN PHARMACEUTICAL COMPANIES

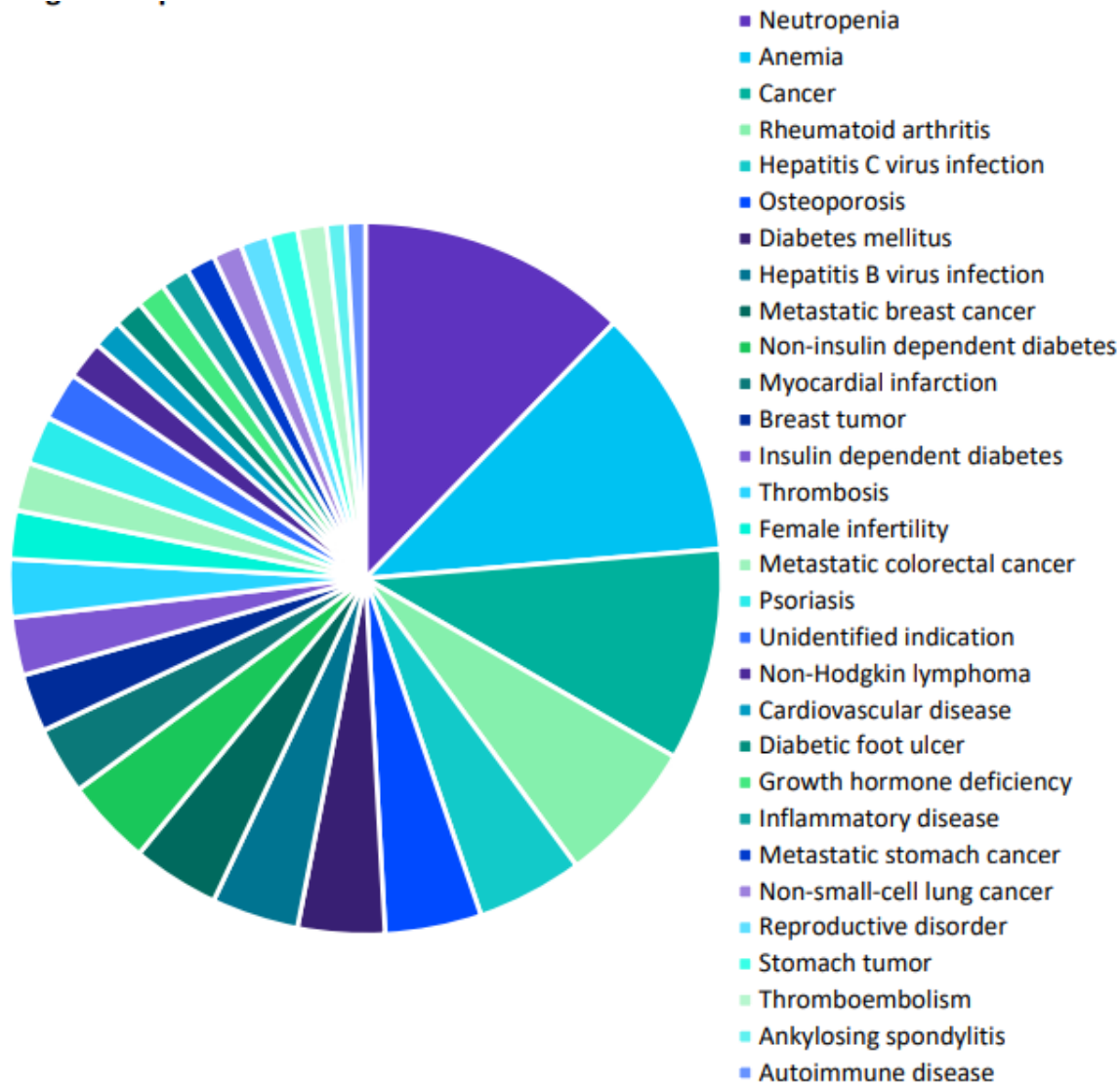


Source: Cortellis Competitive Intelligence

TOP INDIAN COMPANIES BY BIOSIMILARS AND FOLLOW-ON-BIOLOGICS LAUNCHED AND UNDER ACTIVE DEVELOPMENT

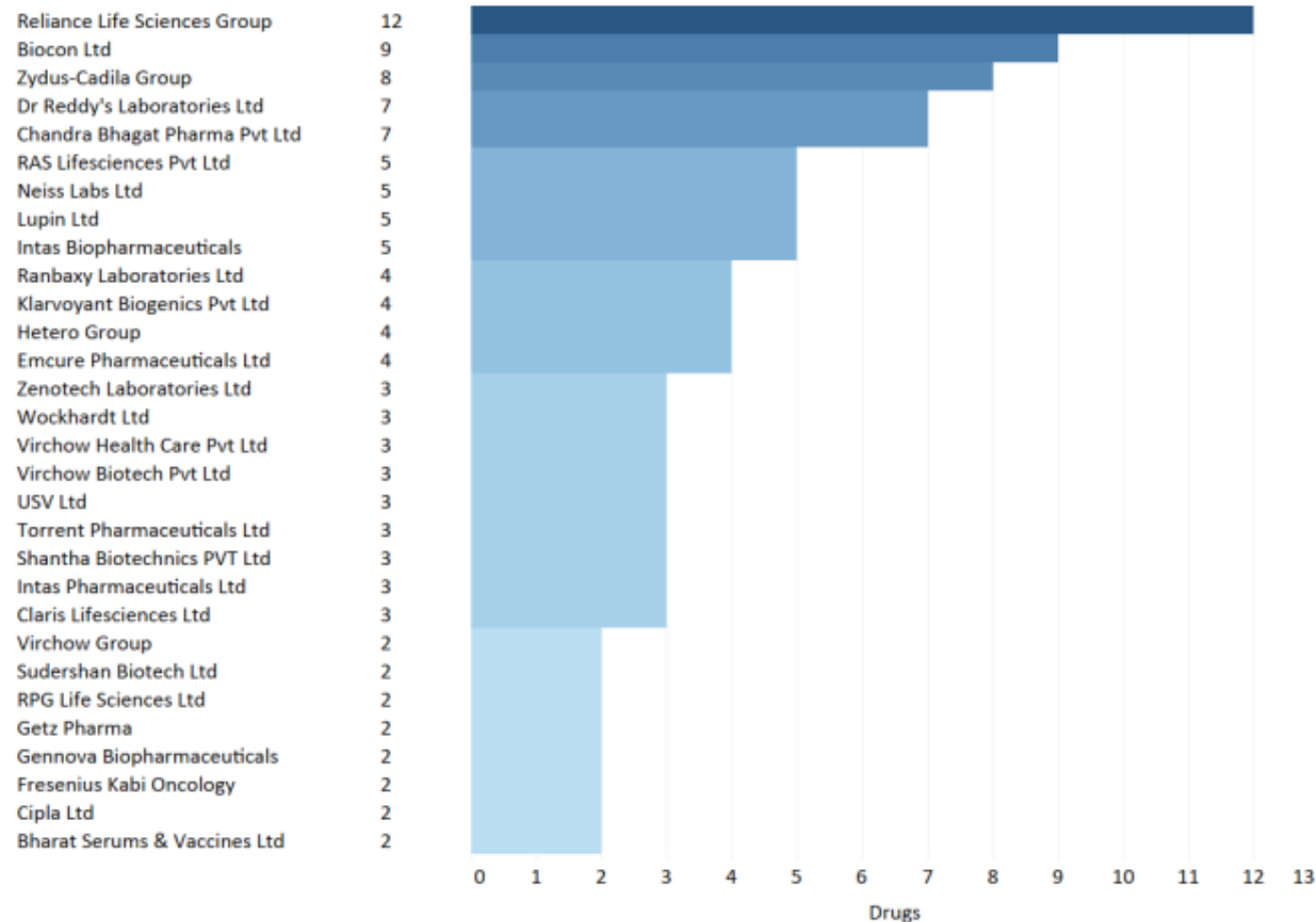


Source: Cortellis Competitive Intelligence



TARGETED INDICATIONS FOR BIOSIMILARS AND FOLLOW-ON BIOLOGICS BEING DEVELOPED

TOP INDIAN COMPANIES BY BIOSIMILARS AND FOLLOW-ON BIOLOGICS LAUNCHED



Source: Cortellis Competitive Intelligence

CONCLUSION FOR MARKET GROWTH IN INDIAN BIOSIMILAR MARKET.

- The pharmaceutical industry is facing many changes both in India and internationally.
- Biotherapeutics/biologics are more promising than small molecule therapeutics in many areas, such as oncology. Small molecule therapeutics have certain advantages, but biologics are more targeted and have fewer side effects.
- Therefore, biosimilar has become the treatment of choice for physicians and patients, generating significant revenue and enjoying greater market share. Rituximab and trastuzumab are on the WHO list of recommended medications.
- The blockbuster drugs that have generated the most revenue in recent years are novel biologics. The research and development community and the pharmaceutical industry are increasingly interested in follow-on biologics/biosimilars.

CONCLUSION FOR MARKET GROWTH IN INDIAN BIOSIMILAR MARKET CONTD...

- As a cheaper alternative to novel biologics, they have the potential for large cost savings depending on the size of the patient population.
- The Indian drug/biotech industry is very much positioned to take advantage of the tremendous open door presented by biologics and biosimilars and right now has a broad pipeline of biosimilars being worked on.
- Given advancement in innovation and economies of scale, India is probably going to accomplish USD 12 bn market size for Biologics and Biosimilars by 2025.

REFERENCES

1. <https://www.frontiersin.org/articles/10.3389/fbioe.2022.832059/full>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6394151/>
3. Comparison Of Global Regulatory Approvals for Biosimilar Products.
4. <https://www.ibef.org/download/Biotechnology-January-2021.pdf>
5. Biosimilars in India; Current Status and Future Perspectives (Bikash R. Meher, Sakthi Balan¹, Rashmi R. Mohanty², Monalisa Jena, Smita Das³)
6. Biosimilars Pharmaceutical Market in India: Current Status, Challenges and Future Perspective, Ujalayan Gyan Prakash and John Shibu, Department of Healthcare and Pharmaceutical Management, Jamia Hamdard.
7. [https://www.webmd.com/drugs/2/drug-64712/adalimumab-subcutaneous/details#:~:text=Adalimumab%20is%20used%20to%20reduce,type%20psoriasis%2C%20hidradenitis%20suppurativa\).](https://www.webmd.com/drugs/2/drug-64712/adalimumab-subcutaneous/details#:~:text=Adalimumab%20is%20used%20to%20reduce,type%20psoriasis%2C%20hidradenitis%20suppurativa).)
8. <https://www.industryarc.com/Report/15276/adalimumab-market.html>
9. <https://www.alliedmarketresearch.com/filgrastim-market>
10. <https://www.alliedmarketresearch.com/global-biosimilars-market>
11. <https://www.expertmarketresearch.com/reports/indian-diabetes-market>
12. <https://www.expertmarketresearch.com/reports/indian-diabetes-market>
13. <https://www.marketwatch.com/press-release/biosimilars-market-in-india-size-by-product-monoclonal-antibodies-infliximab-rituximab-trastuzumab-insulin-interferon-etanercept-glucagon-calcitonin-indication-oncology-chronic-disease-blood-disorder-autoimmune-disease-region---global-forecast-2022-to-2031-2022-04-13>
14. <https://www.biospectrumindia.com/views/17/20488/capitalising-on-global-biosimilar-opportunity.html>
15. <https://pubmed.ncbi.nlm.nih.gov/34126171/>
16. https://birac.nic.in/webcontent/Knowledge_Paper_Clarivate_ABLE_BIO_2019.pdf

THANK YOU

