

Monoclonal Antibody Therapeutics Market- Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Product Type (Naked, Fusion Protein, Antibody Fragment, Conjugate, Multi-specific), By Application (Cancer, Autoimmune Diseases, Infectious Diseases, Others), By Production Source (Human, Humanized, Chimeric, Others),By End User (Hospital, Specialty Centers, Research Institutes), By Region, and Competition

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Abstracts

Global Monoclonal Antibody Therapeutics Market is anticipated to project impressive growth in the forecast period. The global healthcare landscape has witnessed a significant transformation in recent years, with groundbreaking advancements in medical research and technology. One such advancement that has gained widespread attention is the development and utilization of monoclonal antibodies in therapeutics. Monoclonal antibodies, or mAbs, have revolutionized the treatment of various diseases, and the Lower Monoclonal Antibody Therapeutics Market is a key segment within this evolving field. Monoclonal antibodies are a class of drugs designed to target specific proteins or antigens in the body. They are created by cloning a single type of immune cell, called a B cell, to produce identical antibodies. These antibodies can be engineered to recognize and bind to particular molecules, such as those found on the surface of cancer cells, pathogens, or autoimmune triggers. This highly targeted approach allows for precision in treating a wide range of diseases.

The global Lower Monoclonal Antibody Therapeutics Market comprises a diverse range of therapeutic applications and has been experiencing remarkable growth in recent

years. Chronic conditions such as cancer, autoimmune disorders, and infectious diseases continue to be a major global health concern. Monoclonal antibodies have emerged as a promising avenue for treating these diseases effectively, contributing to the market's expansion. Ongoing advancements in biotechnology, particularly in the field of antibody engineering, have led to the development of more effective and specialized monoclonal antibodies. This has broadened the scope of therapeutic applications, leading to increased market demand. Monoclonal antibodies are at the forefront of personalized medicine, allowing for treatments tailored to an individual's specific genetic makeup and disease profile. This customization has improved treatment outcomes and patient satisfaction, driving market growth. Various governments worldwide are actively promoting research and development in the biotechnology sector, including monoclonal antibody therapeutics. Funding and support for innovative projects have accelerated market expansion.

Key Market Drivers

Rising Prevalence of Chronic Diseases is Driving the Global Monoclonal Antibody Therapeutics Market

In recent years, the world has witnessed a significant increase in the prevalence of chronic diseases, including cancer, autoimmune disorders, and various infectious diseases. This rise has led to a surge in the demand for advanced and effective treatment options, propelling the growth of the global monoclonal antibody therapeutics market. Monoclonal antibodies have emerged as a promising class of biopharmaceuticals, offering targeted therapies that address the underlying causes of these chronic illnesses.

Chronic diseases, often characterized by their long duration and slow progression, have become a global health crisis. These conditions, which include cardiovascular diseases, diabetes, cancer, autoimmune disorders, and neurodegenerative diseases, account for a significant portion of the global disease burden. According to the World Health Organization (WHO), chronic diseases are responsible for approximately 71% of all global deaths, with 15 million people dying prematurely each year due to these conditions. Several factors contribute to the rising prevalence of chronic diseases, including an aging population, sedentary lifestyles, poor dietary habits, and increased exposure to risk factors such as tobacco and alcohol. Additionally, environmental factors, genetic predisposition, and infectious agents play crucial roles in the development of these illnesses. As the incidence of chronic diseases continues to grow, the need for innovative and effective treatments has never been more pressing.

The global monoclonal antibody therapeutics market has experienced significant growth in recent years, driven by the rising prevalence of chronic diseases and the increasing acceptance of these biopharmaceuticals in clinical practice. The market is characterized by a wide range of monoclonal antibody products, with new drugs continually entering the pipeline. Pharmaceutical companies and research institutions are investing heavily in developing novel monoclonal antibody therapies for various chronic diseases, creating a robust pipeline of potential treatments. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA), have approved an increasing number of monoclonal antibody drugs, expanding their use in clinical settings. Collaborations between pharmaceutical companies, academic institutions, and research organizations have accelerated the development and commercialization of monoclonal antibody therapies.

Expanding Indications and Approvals is Driving the Global Monoclonal Antibody Therapeutics Market

One of the primary drivers behind the growth of the global monoclonal antibody therapeutics market is the continuous expansion of indications for these therapies. Initially, mAbs were predominantly used in the treatment of cancer, targeting specific cancer cell markers. However, over the years, researchers have discovered their potential in treating a wide range of diseases, including autoimmune disorders, infectious diseases, and neurological conditions.

Monoclonal antibodies have been groundbreaking in cancer treatment. Antibodies such as Herceptin (trastuzumab) and Rituxan (rituximab) have been instrumental in targeting cancer cells and improving survival rates in breast cancer and lymphoma patients. Conditions like rheumatoid arthritis, multiple sclerosis, and Crohn's disease have seen significant advancements in treatment with the approval of mAb therapies. Drugs like Humira (adalimumab) and Remicade (infliximab) have transformed the lives of patients suffering from these debilitating autoimmune disorders. Monoclonal antibodies have played a critical role in the fight against infectious diseases. The emergency use authorization of mAb therapies to combat the COVID-19 pandemic, such as Regeneron's REGEN-COV and Eli Lilly's bamlanivimab and etesevimab, highlights their potential in infectious disease management. Monoclonal antibodies are also being explored for the treatment of neurological conditions like Alzheimer's disease and multiple sclerosis, offering hope for patients with limited treatment options.

While the expansion of indications and approvals is driving the global monoclonal

antibody therapeutics market, it is not without challenges. These challenges include the high cost of development, pricing concerns, and potential side effects. However, ongoing research and technological advancements are addressing these issues, paving the way for a brighter future for mAb therapies.

Key Market Challenges

High Development Costs

One of the foremost challenges in the monoclonal antibody therapeutics market is the exorbitant cost associated with research, development, and clinical trials. The process of discovering, designing, and testing monoclonal antibodies is lengthy and resource-intensive. Additionally, regulatory compliance and the need for extensive safety and efficacy testing further escalate costs. These high development costs can be a significant barrier for smaller biotech companies and may limit the diversity of therapeutic options available.

Regulatory Hurdles

The monoclonal antibody therapeutics market is subject to stringent regulatory oversight. Receiving approval from regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) can be a lengthy and complex process. Meeting the rigorous standards for safety, efficacy, and quality control is essential but can lead to delays in bringing innovative therapies to market. Navigating these regulatory hurdles requires significant time and financial resources.

Biosimilar Competition

As patents for some of the first-generation monoclonal antibodies expire, biosimilar competition is intensifying. Biosimilars are highly similar to existing monoclonal antibody drugs but can be marketed at a lower price, potentially eroding market share for originator companies. Managing this competition while maintaining product quality and innovation is a delicate balancing act for established players in the market.

Pricing Pressures

The high cost of monoclonal antibody therapies has raised concerns about their affordability and accessibility, particularly in healthcare systems with limited resources. Payers, governments, and healthcare organizations are increasingly scrutinizing the

pricing of these drugs, putting pressure on manufacturers to justify their pricing strategies. Striking a balance between recouping development costs and ensuring patient access remains a significant challenge.

Manufacturing Complexities

Monoclonal antibody production involves intricate biotechnological processes, including cell culture, purification, and formulation. Maintaining consistent product quality and supply can be challenging due to the sensitivity of these biological products to variations in manufacturing conditions. Companies need to invest in advanced manufacturing technologies and quality control measures to overcome these complexities and ensure product reliability.

Market Competition

The monoclonal antibody therapeutics market is highly competitive, with numerous players vying for market share. The entry of new companies and emerging biotechnology advancements constantly reshapes the competitive landscape. To succeed in this environment, companies must differentiate themselves through innovation, robust clinical trial data, and effective marketing strategies.

Drug Resistance and Limited Indications

Monoclonal antibody therapies are not immune to the development of drug resistance, especially in conditions like cancer. Additionally, some monoclonal antibodies have limited indications, limiting their market potential. Addressing these challenges requires ongoing research into resistance mechanisms and efforts to expand the range of treatable conditions.

Key Market Trends

Technological Advancements

The field of medicine and healthcare has witnessed remarkable progress over the years, owing much of its success to advancements in technology. One notable advancement is the development and utilization of monoclonal antibodies (mAbs) in therapeutics. Monoclonal antibodies are engineered molecules designed to target specific proteins or antigens in the body, and they have become a key player in the pharmaceutical industry. As technology continues to evolve, it is propelling the growth of

the global monoclonal antibody therapeutics market to unprecedented heights.

Recent technological advancements in genomics, proteomics, and bioinformatics have revolutionized the process of identifying disease-related targets. This enables researchers to pinpoint specific proteins or receptors associated with diseases with greater accuracy, paving the way for the development of highly targeted monoclonal antibody therapies. Phage display technology allows the rapid screening of large libraries of antibodies to select the most suitable candidates. It enables the creation of custom antibodies designed to bind with high affinity to a particular antigen. This technology accelerates the discovery and development of novel mAbs for various therapeutic purposes. One limitation of monoclonal antibodies is their potential to induce an immune response in patients. Technological advancements in antibody engineering have led to the development of humanized and fully human antibodies, reducing the likelihood of immunogenicity. This has expanded the potential patient population for mAb therapies. Technological innovations in bioprocessing and cell culture techniques have increased the scalability and efficiency of monoclonal antibody production. These advancements have resulted in reduced manufacturing costs and greater accessibility to mAb therapies for patients worldwide. The development of innovative bioconjugation techniques allows for the attachment of various payloads, such as chemotherapy drugs or radioisotopes, to monoclonal antibodies. This has led to the creation of antibody-drug conjugates (ADCs), which have shown significant promise in the treatment of cancer and other diseases.

The global monoclonal antibody therapeutics market has experienced substantial growth in recent years, and this trend is expected to continue. Monoclonal antibodies are now being used to treat a wide range of diseases, including cancer, autoimmune disorders, infectious diseases, and more. As technology allows for the development of mAbs targeting new antigens, the number of indications continues to expand. Advances in genetic profiling and biomarker identification are enabling the development of personalized monoclonal antibody therapies tailored to individual patients. This approach enhances treatment efficacy and minimizes adverse effects. Improved manufacturing processes have made monoclonal antibody therapies more accessible and affordable, even in resource-limited regions. This has the potential to address unmet medical needs and reduce healthcare disparities worldwide. Technological innovations have facilitated the development of combination therapies, where monoclonal antibodies are used alongside other treatments like immunotherapies or small molecule drugs. This approach often results in synergistic effects and improved patient outcomes.

Segmental Insights

Production Source Insights

Based on the category of Production Source, Humanized emerged as the dominant player in the global market for Monoclonal Antibody Therapeutics in 2022. Humanized antibodies retain the antigen-binding portion from a murine source but incorporate significant portions of human sequences. This reduces immunogenicity to a minimum while preserving the binding specificity. Humanized antibodies strike a delicate balance between retaining the antigen-binding specificity of murine antibodies and minimizing the risk of immune reactions in humans. This reduction in immunogenicity ensures a safer and more effective treatment. Humanized antibodies can bind to their target antigens with greater affinity than murine or chimeric antibodies. This higher binding affinity often translates into improved therapeutic outcomes. Humanized antibodies are well-suited for a wide range of therapeutic applications, including cancer, autoimmune disorders, and infectious diseases. Their adaptability contributes to their dominance in the market. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have shown a preference for humanized antibodies due to their favorable safety and efficacy profiles. This has accelerated their approval and adoption.

End User Insights

The Hospitals segment is projected to experience rapid growth during the forecast period. Hospitals serve as primary points of care for patients with various medical conditions. Their wide reach ensures that patients have access to monoclonal antibody treatments, regardless of their location. Hospitals typically have highly trained medical professionals, including specialists who can diagnose and administer monoclonal antibody treatments. This expertise is crucial in ensuring the safe and effective use of these therapies. Hospitals are equipped with the necessary infrastructure and facilities for storing, preparing, and administering monoclonal antibodies. This ensures that the drugs are handled and administered under optimal conditions. Many hospitals are involved in cutting-edge research and clinical trials related to monoclonal antibody therapeutics. This involvement not only advances medical knowledge but also allows hospitals to stay at the forefront of treatment options. Hospitals are the primary institutions responsible for responding to public health emergencies, including disease outbreaks. Monoclonal antibody therapies have been crucial in managing these emergencies, and hospitals are well-prepared to deploy them effectively.

Regional Insights

North America emerged as the dominant player in the global Monoclonal Antibody Therapeutics market in 2022, holding the largest market share in terms of value. North America boasts a thriving biotechnology industry, with numerous biotech companies, research institutions, and academic centers dedicated to advancing antibody-based therapies. This ecosystem provides a fertile ground for research, development, and innovation. North America is home to some of the world's largest pharmaceutical companies, many of which have made substantial investments in monoclonal antibody research and development. These companies have the resources, infrastructure, and expertise required to bring antibody-based drugs from the lab to the market.

Key Market Players

F. Hoffmann-La Roche Ltd.

Novartis AG

Merck & Co. Inc.

Pfizer Inc.

Eli Lilly and Co. (Lilly)

Sanofi S.A

AstraZeneca inc.

Bayer AG

Regeneron Pharmaceuticals Inc.

GSK Plc.

Report Scope:

In this report, the Global Monoclonal Antibody Therapeutics Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Monoclonal Antibody Therapeutics Market, By Product Type:

Others

Naked

Fusion Protein

Antibody Fragment

Conjugate

Multi-specific

Monoclonal Antibody Therapeutics Market, By Application:

Cancer

Autoimmune Diseases

Infectious Diseases

Others

Monoclonal Antibody Therapeutics Market, By Production Source:

Human

Humanized

Chimeric

Others

Monoclonal Antibody Therapeutics Market, By End user:

Hospital

Specialty Centers

Research Institutes

Monoclonal Antibody Therapeutics Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Monoclonal Antibody Therapeutics Market.

Available Customizations:

Global Monoclonal Antibody Therapeutics market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

Contents

1. PRODUCT OVERVIEW

- 1.1. Market Definition
- 1.2. Scope of the Market
 - 1.2.1. Markets Covered
 - 1.2.2. Years Considered for Study
 - 1.2.3. Key Market Segmentations

2. RESEARCH METHODOLOGY

- 2.1. Objective of the Study
- 2.2. Baseline Methodology
- 2.3. Key Industry Partners
- 2.4. Major Association and Secondary Applications
- 2.5. Forecasting Methodology
- 2.6. Data Triangulation & Validations
- 2.7. Assumptions and Limitations

3. EXECUTIVE SUMMARY

- 3.1. Overview of the Market
- 3.2. Overview of Key Market Segmentations
- 3.3. Overview of Key Market Players
- 3.4. Overview of Key Regions/Countries
- 3.5. Overview of Market Drivers, Challenges, Trends

4. VOICE OF CUSTOMER

5. GLOBAL MONOCLONAL ANTIBODY THERAPEUTICS MARKET OUTLOOK

- 5.1. Market Size & Forecast
 - 5.1.1. By Value
- 5.2. Market Share & Forecast
 - 5.2.1. By Product Type (Naked, Fusion Protein, Antibody Fragment, Conjugate, Multi-specific)
 - 5.2.2. By Application (Cancer, Autoimmune Diseases, Infectious Diseases, Others)
 - 5.2.3. By Production Source (Human, Humanized, Chimeric, Others)

5.2.4. By End User (Hospital, Specialty Centers, Research Institutes)

5.2.5. By Region

5.2.6. By Company (Shares of Top 5 Market Players)

5.3. Market Map

5.3.1. By Product Type

5.3.2. By Application

5.3.3. By Production Source

5.3.4. By End User

5.3.5. By Region

6. NORTH AMERICA MONOCLONAL ANTIBODY THERAPEUTICS MARKET OUTLOOK

6.1. Market Size & Forecast

6.1.1. By Value

6.2. Market Share & Forecast

6.2.1. By Product Type

6.2.2. By Application

6.2.3. By Production Source

6.2.4. By End User

6.2.5. By Country

6.2.5.1. United States Monoclonal Antibody Therapeutics Market Outlook

6.2.5.1.1. Market Size & Forecast

6.2.5.1.1.1. By Value

6.2.5.1.2. Market Share & Forecast

6.2.5.1.2.1. By Product Type

6.2.5.1.2.2. By Application

6.2.5.1.2.3. By Production Source

6.2.5.1.2.4. By End User

6.2.5.2. Canada Monoclonal Antibody Therapeutics Market Outlook

6.2.5.2.1. Market Size & Forecast

6.2.5.2.1.1. By Value

6.2.5.2.2. Market Share & Forecast

6.2.5.2.2.1. By Product Type

6.2.5.2.2.2. By Application

6.2.5.2.2.3. By Production Source

6.2.5.2.2.4. By End User

6.2.5.3. Mexico Monoclonal Antibody Therapeutics Market Outlook

6.2.5.3.1. Market Size & Forecast

- 6.2.5.3.1.1. By Value
- 6.2.5.3.2. Market Share & Forecast
 - 6.2.5.3.2.1. By Product Type
 - 6.2.5.3.2.2. By Application
 - 6.2.5.3.2.3. By Production Source
 - 6.2.5.3.2.4. By End User

7. EUROPE MONOCLONAL ANTIBODY THERAPEUTICS MARKET OUTLOOK

- 7.1. Market Size & Forecast
 - 7.1.1. By Value
- 7.2. Market Share & Forecast
 - 7.2.1. By Product Type
 - 7.2.2. By Application
 - 7.2.3. By Production Source
 - 7.2.4. By End User
 - 7.2.5. By Country
 - 7.2.5.1. France Monoclonal Antibody Therapeutics Market Outlook
 - 7.2.5.1.1. Market Size & Forecast
 - 7.2.5.1.1.1. By Value
 - 7.2.5.1.2. Market Share & Forecast
 - 7.2.5.1.2.1. By Product Type
 - 7.2.5.1.2.2. By Application
 - 7.2.5.1.2.3. By Production Source
 - 7.2.5.1.2.4. By End User
 - 7.2.5.2. Germany Monoclonal Antibody Therapeutics Market Outlook
 - 7.2.5.2.1. Market Size & Forecast
 - 7.2.5.2.1.1. By Value
 - 7.2.5.2.2. Market Share & Forecast
 - 7.2.5.2.2.1. By Product Type
 - 7.2.5.2.2.2. By Application
 - 7.2.5.2.2.3. By Production Source
 - 7.2.5.2.2.4. By End User
 - 7.2.5.3. United Kingdom Monoclonal Antibody Therapeutics Market Outlook
 - 7.2.5.3.1. Market Size & Forecast
 - 7.2.5.3.1.1. By Value
 - 7.2.5.3.2. Market Share & Forecast
 - 7.2.5.3.2.1. By Product Type
 - 7.2.5.3.2.2. By Application

- 7.2.5.3.2.3. By Production Source
- 7.2.5.3.2.4. By End User
- 7.2.5.4. Italy Monoclonal Antibody Therapeutics Market Outlook
 - 7.2.5.4.1. Market Size & Forecast
 - 7.2.5.4.1.1. By Value
 - 7.2.5.4.2. Market Share & Forecast
 - 7.2.5.4.2.1. By Product Type
 - 7.2.5.4.2.2. By Application
 - 7.2.5.4.2.3. By Production Source
 - 7.2.5.4.2.4. By End User
- 7.2.5.5. Spain Monoclonal Antibody Therapeutics Market Outlook
 - 7.2.5.5.1. Market Size & Forecast
 - 7.2.5.5.1.1. By Value
 - 7.2.5.5.2. Market Share & Forecast
 - 7.2.5.5.2.1. By Product Type
 - 7.2.5.5.2.2. By Application
 - 7.2.5.5.2.3. By Production Source
 - 7.2.5.5.2.4. By End User

8. ASIA PACIFIC MONOCLONAL ANTIBODY THERAPEUTICS MARKET OUTLOOK

- 8.1. Market Size & Forecast
 - 8.1.1. By Value
- 8.2. Market Share & Forecast
 - 8.2.1. By Product Type
 - 8.2.2. By Application
 - 8.2.3. By Production Source
 - 8.2.4. By End User
 - 8.2.5. By Country
 - 8.2.5.1. China Monoclonal Antibody Therapeutics Market Outlook
 - 8.2.5.1.1. Market Size & Forecast
 - 8.2.5.1.1.1. By Value
 - 8.2.5.1.2. Market Share & Forecast
 - 8.2.5.1.2.1. By Product Type
 - 8.2.5.1.2.2. By Application
 - 8.2.5.1.2.3. By Production Source
 - 8.2.5.1.2.4. By End User
 - 8.2.5.2. India Monoclonal Antibody Therapeutics Market Outlook
 - 8.2.5.2.1. Market Size & Forecast

- 8.2.5.2.1.1. By Value
- 8.2.5.2.2. Market Share & Forecast
 - 8.2.5.2.2.1. By Product Type
 - 8.2.5.2.2.2. By Application
 - 8.2.5.2.2.3. By Production Source
 - 8.2.5.2.2.4. By End User
- 8.2.5.3. South Korea Monoclonal Antibody Therapeutics Market Outlook
 - 8.2.5.3.1. Market Size & Forecast
 - 8.2.5.3.1.1. By Value
 - 8.2.5.3.2. Market Share & Forecast
 - 8.2.5.3.2.1. By Product Type
 - 8.2.5.3.2.2. By Application
 - 8.2.5.3.2.3. By Production Source
 - 8.2.5.3.2.4. By End User
- 8.2.5.4. Japan Monoclonal Antibody Therapeutics Market Outlook
 - 8.2.5.4.1. Market Size & Forecast
 - 8.2.5.4.1.1. By Value
 - 8.2.5.4.2. Market Share & Forecast
 - 8.2.5.4.2.1. By Product Type
 - 8.2.5.4.2.2. By Application
 - 8.2.5.4.2.3. By Production Source
 - 8.2.5.4.2.4. By End User
- 8.2.5.5. Australia Monoclonal Antibody Therapeutics Market Outlook
 - 8.2.5.5.1. Market Size & Forecast
 - 8.2.5.5.1.1. By Value
 - 8.2.5.5.2. Market Share & Forecast
 - 8.2.5.5.2.1. By Product Type
 - 8.2.5.5.2.2. By Application
 - 8.2.5.5.2.3. By Production Source
 - 8.2.5.5.2.4. By End User

9. SOUTH AMERICA MONOCLONAL ANTIBODY THERAPEUTICS MARKET OUTLOOK

- 9.1. Market Size & Forecast
 - 9.1.1. By Value
- 9.2. Market Share & Forecast
 - 9.2.1. By Product Type
 - 9.2.2. By Application

9.2.3. By Production Source

9.2.4. By End User

9.2.5. By Country

9.2.5.1. Brazil Monoclonal Antibody Therapeutics Market Outlook

9.2.5.1.1. Market Size & Forecast

9.2.5.1.1.1. By Value

9.2.5.1.2. Market Share & Forecast

9.2.5.1.2.1. By Product Type

9.2.5.1.2.2. By Application

9.2.5.1.2.3. By Production Source

9.2.5.1.2.4. By End User

9.2.5.2. Argentina Monoclonal Antibody Therapeutics Market Outlook

9.2.5.2.1. Market Size & Forecast

9.2.5.2.1.1. By Value

9.2.5.2.2. Market Share & Forecast

9.2.5.2.2.1. By Product Type

9.2.5.2.2.2. By Application

9.2.5.2.2.3. By Production Source

9.2.5.2.2.4. By End User

9.2.5.3. Colombia Monoclonal Antibody Therapeutics Market Outlook

9.2.5.3.1. Market Size & Forecast

9.2.5.3.1.1. By Value

9.2.5.3.2. Market Share & Forecast

9.2.5.3.2.1. By Product Type

9.2.5.3.2.2. By Application

9.2.5.3.2.3. By Production Source

9.2.5.3.2.4. By End User

10. MIDDLE EAST & AFRICA MONOCLONAL ANTIBODY THERAPEUTICS MARKET OUTLOOK

10.1. Market Size & Forecast

10.1.1. By Value

10.2. Market Share & Forecast

10.2.1. By Product Type

10.2.2. By Application

10.2.3. By Production Source

10.2.4. By End User

10.2.5. By Country

10.2.5.1. South Africa Monoclonal Antibody Therapeutics Market Outlook

10.2.5.1.1. Market Size & Forecast

10.2.5.1.1.1. By Value

10.2.5.1.2. Market Share & Forecast

10.2.5.1.2.1. By Product Type

10.2.5.1.2.2. By Application

10.2.5.1.2.3. By Production Source

10.2.5.1.2.4. By End User

10.2.5.2. Saudi Arabia Monoclonal Antibody Therapeutics Market Outlook

10.2.5.2.1. Market Size & Forecast

10.2.5.2.1.1. By Value

10.2.5.2.2. Market Share & Forecast

10.2.5.2.2.1. By Product Type

10.2.5.2.2.2. By Application

10.2.5.2.2.3. By Production Source

10.2.5.2.2.4. By End User

10.2.5.3. UAE Monoclonal Antibody Therapeutics Market Outlook

10.2.5.3.1. Market Size & Forecast

10.2.5.3.1.1. By Value

10.2.5.3.2. Market Share & Forecast

10.2.5.3.2.1. By Product Type

10.2.5.3.2.2. By Application

10.2.5.3.2.3. By Production Source

10.2.5.3.2.4. By End User

11. MARKET DYNAMICS

11.1. Drivers

11.2. Challenges

12. MARKET TRENDS & DEVELOPMENTS

12.1. Recent Development

12.2. Mergers & Acquisitions

12.3. Technology Launches

13. COMPETITIVE LANDSCAPE

13.1. F. Hoffmann-La Roche Ltd

- 13.1.1. Business Overview
- 13.1.2. Patient Offerings
- 13.1.3. Recent Developments
- 13.1.4. Key Personnel
- 13.1.5. SWOT Analysis
- 13.2. Novartis AG
- 13.3. Merck & Co. Inc.
- 13.4. Pfizer Inc.
- 13.5. Eli Lilly and Co. (Lilly)
- 13.6. Sanofi S.A
- 13.7. AstraZeneca inc.
- 13.8. Bayer AG
- 13.9. Regeneron Pharmaceuticals Inc.
- 13.10. GSK Plc

14. STRATEGIC RECOMMENDATIONS

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