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Biologics Market Assessment, By Product [Monoclonal Antibodies, Recombinant Hormones/Proteins, Vaccines, Cellular Based Biologics, Gene-Based Biologics, Therapeutic Enzymes, Others] By Application [Infectious Diseases, Cancer, Autoimmune Diseases, Cardiovascular, Hematological Disorders, Others] By Drug Classification [Branded Drugs, Generic Drugs], By Mode of Purchase [Prescription Drugs, Over-the-counter Drugs] By Distribution Channel [Hospital Pharmacies, Retail Pharmacies, Online Pharmacies] By Region, Opportunities and Forecast, 2017-2031F

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Abstracts

Global biologics market size was valued at USD 401.34 billion in 2023, and is expected to reach USD 695.79 billion in 2031, with a CAGR of 7.12% for the forecast period between 2024 and 2031F. The increasing incidence and diagnosis of chronic diseases have created a significant demand for advanced diagnostics and treatment medications, consequently propelling the global biologics market. These specialized drugs have been genetically altered to target specific components of the immune system that trigger inflammation. With the emergence of coronavirus diseases, governments worldwide are taking measures to fortify the healthcare industry and ensure the availability of biologics.

Simultaneously, scientists and researchers are exploring different species and expression systems to enhance the efficiency of biological products. Moreover,

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numerous pharmaceutical companies are engaged in research and development efforts aimed at enhancing the effectiveness of oral medications for arthritis. Given the decline in productivity in small molecule medication research and development, a substantial surge in the biologics market is anticipated in the coming years. These pharmaceutical firms are actively pursuing the development of various biologic medications to sustain their market dominance. As oral medications for conditions like Crohn's disease and rheumatoid arthritis become more effective, it is predicted that a larger number of moderately affected patients will transition towards newly branded therapies. Additionally, these new compounds provide therapeutic alternatives for patients who have previously shown resistance to traditional treatments, often displaying superior safety and efficacy.

High Prevalence of Chronic Diseases

The global biologics market is witnessing a significant impact due to the high prevalence of chronic diseases. Chronic conditions like cancer, diabetes, autoimmune disorders, and cardiovascular diseases are increasingly becoming prevalent globally. Biologics, which are medicinal products derived from living organisms, have emerged as a critical treatment option for many of these conditions. These complex molecules offer targeted therapies, often with fewer side effects and greater efficacy than traditional pharmaceuticals.

For instance, as per the World Health Organization's report in September 2023, approximately 41 million individuals succumb annually to non-communicable diseases (NCD), representing 74% of the total global deaths. Each year, roughly 17 million people perish from NCDs before reaching the age of 70, with 86% of these untimely fatalities occurring on a global scale. Over 41 million individuals globally succumb to chronic diseases annually. Among these, cardiovascular disease leads, causing 17.9 million deaths per year, followed by cancer, diabetes, and respiratory disorders. Together, these four categories account for 80% of all fatalities attributed to chronic diseases. The prevalence of chronic diseases has spurred the advancement of diagnostics and treatments. Biologics, genetically engineered medications, and target specific components of the immune system are responsible for inflammation.

Increasing Emphasis on Research and Development

The expansion of the market is being driven by the increasing emphasis on research and development activities, which is expected to create advantageous prospects for biologics market growth. Moreover, scientists and researchers are exploring various

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species and expression systems to enhance the productivity of biological products. Several pharmaceutical companies are engaged in research and development activities aimed at improving the effectiveness of oral medications for conditions like rheumatoid arthritis and Crohn's disease. Furthermore, the escalating rate of drug approvals and introductions will continue to accelerate the growth trajectory of the market.

For instance, as an example, in January 2023, Lecanemab received approval from the U.S. FDA via its accelerated approval pathway, specifically intended for addressing Alzheimer's Disease. In June 2022, Alnylam Pharmaceuticals, Inc. obtained FDA approval for its RNAi therapeutic, AMVUTTRA, designed for treating the Polyneuropathy associated with hereditary transthyretin-mediated amyloidosis.

Growing Investments by Key Players

The global biologics market continues to witness a surge in investments by key players, indicative of the sector's growth and potential. Major pharmaceutical companies, biotech firms, and research institutions are channeling substantial investments into research, development, and manufacturing of biologics. The financial commitment aims to bolster innovation, expand product portfolios, and enhance manufacturing technologies, ultimately meeting the rising demand for advanced and personalized healthcare solutions.

The competitive landscape is evolving rapidly as companies are planning to introduce novel biologics, focusing on diverse therapeutic areas like oncology, autoimmune diseases, and infectious diseases. The growing investment trend signifies the industry's confidence in the market's promising future, fostering groundbreaking advancements and improved treatment options for global healthcare challenges. For Instance, in March 2023, Novartis announced the intention of its division, Sandoz to allocate roughly USD 400 million towards establishing a biologics manufacturing plant situated in Slovenia. During March 2023, Eli Lilly disclosed its proposal to invest USD 500 million into expanding its current 500,000 sq. ft. biologics manufacturing site in Limerick.

Technological Advancements

The global biologics market has witnessed remarkable technological advancements, revolutionizing the landscape of medicine and healthcare. Innovations in biotechnology, particularly in areas like genetic engineering, monoclonal antibodies, and recombinant DNA technology, have significantly enhanced the development and production of biologics industry.

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Advanced techniques in cell culture systems, gene editing (like CRISPR), and bioprocessing have streamlined the manufacturing of complex biological molecules. Furthermore, the emergence of personalized medicine has driven a shift towards more tailored and effective treatments, utilizing biologics designed to target specific patient populations. The progress has led to the development of novel biologics, including therapeutic proteins, vaccines, and monoclonal antibodies, fostering breakthroughs in treating various diseases like cancer, autoimmune disorders, and infectious diseases.

For Instance, in February 2022 CARVYKTI, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson obtained approval from the US Food and Drug Administration (FDA) for sale. The biologic medication is designated for individuals with relapsed or refractory multiple myeloma (RRMM) who have undergone four prior lines of therapy, which may include proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody treatments.

Impact of COVID-19

The COVID-19 pandemic had a significant impact on the global biologics market. Biologics are complex, large-molecule drugs used to treat a variety of diseases, including autoimmune disorders, cancer, and infectious diseases. The pandemic disrupted supply chains and manufacturing processes, leading to production delays and shortages of some biologics. Additionally, the increased focus on vaccine development and monoclonal antibody therapies to combat the virus diverted resources and attention from other biologic drug development efforts.

On the contrary, the pandemic has highlighted the importance of biotechnology and accelerated innovation in the field. The rapid development of mRNA vaccines, such as the Pfizer-BioNTech and Moderna vaccines, showcased the potential of biologics in responding to infectious diseases. Furthermore, the pandemic has driven investment in research and development of biologics, leading to advancements in bioprocessing and manufacturing technologies. During April 2022, GSK, a British multinational pharmaceutical and biotechnology company, together with SK bioscience, presented a biologics license application for SKYCovione, a COVID-19 vaccine candidate based on recombinant proteins, to the Korean Ministry of Food and Drug Safety (KMFDS).

Key Players Landscape and Outlook

Prominent industry stakeholders are allocating significant funds to research and

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development endeavors, aiming to diversify their product portfolios, thereby stimulating the expansion of the global biologics market. The market participants are implementing various strategic measures to enhance their global presence, including pivotal actions such as launching new products, engaging in mergers and acquisitions, forming contractual agreements, amplifying investments, and fostering collaborations with other organizations. In the competitive landscape of the biologics sector, companies must provide cost-effective offerings to broaden their scope and endure in an intensifying, competitive, and burgeoning market environment.

For Instance, the FDA granted approval to Leqembi (lecanemab-irmb) through the Accelerated Approval pathway in January 2023 for addressing Alzheimer's disease. The medication diminishes amyloid-? plaques and moderately retards mild cognitive decline in individuals with early-stage Alzheimer's disease.

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