

Global Oncology Biosimilars-Pipeline Insights - 2025 -2033

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Abstracts

Oncology Biosimilars

In recent years, cancer cases are increasing at a very rapid phase globally. The high cost of treatment of existing cancer therapeutics raises the interest in biosimilars.

Nearly every blockbuster that is close to losing its major patent protection faces the threat of several biosimilar competitors.

Biosimilars are biological products that contain a highly similar version of the active substance of an already approved biologic reference product for therapeutic use.

A biosimilar has the same mechanism of action as the reference biologic, and its condition of use is the same as the approved area, although inference is permitted across indications under regulatory guidance.

The relatively easy manufacturing of biosimilars and the license to manufacture biosimilars are acting in favor of the global oncology biosimilars market.

The high cost of treatment of existing cancer therapeutics raises the interest in biosimilars which is synergized by the patent expiry of many therapeutics.

Various methods of manufacturing biosimilars include the use of biologic components such as proteins, monoclonal antibodies, nucleic acids, hormones, colony stimulating factors, enzymes, and interleukins.

Growing incidence of cancer offers huge growth opportunities for vendors in the market. Currently, there is a giant clinical pipeline for cancer biosimilars, hallmarking candidates in different stages of development.

Nearly 30% of all the biosimilars that are anticipated for US FDA's approval are monoclonal antibodies, including biosimilars of Avastin, MabThera, and Herceptin. Various companies and their R&D departments such as Pfizer Inc., Zydus Cadila are involved in the development of biosimilars, which is under clinical trial. Pfizer's biosimilar clinical stage pipeline includes five monoclonal antibodies fare under clinical trial phase I to phase III which will be used for the treatment of autoimmune disease and oncology.

There are few drugs, which are under the last phase of clinical trial like BI695502 of Boehringer Ingelheim, PF- 06439535 of Pfizer and FKB238 of Census Biotherapeutics for NSCLC.

There is a need for complex infrastructure and stringent regulations applied for approval when compared to generics are the significant challenges faced by the biosimilar pipeline market.

Development and validation of biosimilars are an essential part of the overall production process. Regulation for biosimilar drugs plays a vital role in maintaining the efficiency and balance between original and biosimilar drugs. Biosimilars developed by different manufacturers differ from the original product as well as from each other.

A rise in the number of patent expiries, increase in the prevalence of cancer, growing the aging population, promising drug pipeline, need for cost-effective treatment, favorable government regulations are some of the crucial drivers promoting the growth of oncology biosimilars market.

Contents

Oncology Biosimilars Pipeline Analysis

- The “Oncology Biosimilars – Pipeline Insights 2018?” report covers an in-depth analysis of oncology biosimilar drug molecules currently undergoing clinical studies.
- It provides a deep understanding of potential oncology biosimilar drug molecules across all drug development phases.
- The report assesses the pipeline oncology biosimilar molecules by clinical application, stage of development (discovery, pre-clinical, IND, Phase I, Phase II, Phase III and pre-registration), by recruitment status (recruiting, active not recruiting, completed, NA, and unknown), therapy type (monotherapy, combination products) molecule type (small molecules, mAbs) and route of administration (oral, IV, and others).
- The report provides a snapshot of discontinued and dormant drugs too. In addition, the report includes key insights on other development activities, including (but not limited to) – licensing, collaborations, acquisitions, funding, patent, and regulatory designations.
- The report covers company profiles key players in developing oncology biosimilar drug molecules. The company profile includes key info on overview, financial highlights, product portfolio, business strategies, and key recent developments.

The scope of the report?

- Provides comprehensive understanding of active oncology biosimilar pipeline drug candidates
- Includes extensive pipeline product coverage with segregation by various stages of the pipeline from discovery to late-stage.
- Offers pipeline assessment by monotherapy, combination therapy products, and route of administration
- Provides a comparative analysis of key marketed products and pipeline drug candidates
- Includes detailed pipeline drug profiles covering – product description, chemical information, molecule type, mechanism of action, route of administration, product safety and efficacy, developers and collaborators
- Provides key info on players involved in clinical R&D of oncology biosimilar drug candidates.
- Provides in-depth coverage of key news related to oncology biosimilar drug molecules, including major mergers and acquisitions and product development updates such as clinical trial progression updates and regulatory updates.

Reasons for purchasing this report?

- To obtain an understanding of the current oncology biosimilar pipeline landscape.
- To determine drug development dynamics and leverage it for innovation of novel or

repositioned drugs.

- To valuably optimize R&D activities in-line with robust therapeutic drug markets.
- To devise strategic initiatives by identifying prospective partners with progressing projects.

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