

Trastuzumab-Biosimilars Insight, 2022

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Abstracts

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DelveInsight's, "Trastuzumab– Biosimilar 2022," report provides comprehensive insights about 35+ companies and 35+ marketed and pipeline drugs in Trastuzumab Biosimilars landscape. It covers the marketed and pipeline drug profiles, including clinical and nonclinical stage products. It also covers the therapeutics assessment by product type, stage, route of administration, and molecule type. It further highlights the inactive pipeline products in this space.

Geography Covered

Global coverage

Trastuzumab Understanding

Trastuzumab: Overview

Trastuzumab, sold under the brand name Herceptin among others, is a monoclonal antibody used to treat breast cancer and stomach cancer. It is specifically used for cancer that is HER2 receptor positive. It may be used by itself or together with other chemotherapy medication. Trastuzumab is a humanized IgG1 kappa monoclonal antibody that selectively binds with high affinity to the extracellular domain of the human epidermal growth factor receptor 2 protein, HER2. Trastuzumab is produced by recombinant DNA technology in a mammalian cell (Chinese Hamster Ovary) culture which may contain the antibiotic gentamicin. Gentamicin is not detectable in the final product. Herceptin (trastuzumab) for injection is a sterile, white to pale yellow, preservative-free lyophilized powder with a cake-like appearance, for intravenous

administration.

Trastuzumab Biosimilars: Drugs Chapters

This segment of the Trastuzumab report encloses its detailed analysis of various drugs in different stages of clinical development, including marketed, phase III, II, I and preclinical. It also helps to understand clinical trial details, expressive pharmacological action, agreements and collaborations, and the latest news and press releases.

Trastuzumab Biosimilars: Marketed Drugs

Kanjinti: Amgen

Kanjinti is a biosimilar to trastuzumab, a recombinant DNA-derived humanized monoclonal immunoglobulin G1 kappa antibody. The active ingredient of KANJINTI is a humanized monoclonal antibody that has the same amino acid sequence, structure and function as trastuzumab. Kanjinti has the same pharmaceutical dosage form and same strength after reconstitution as trastuzumab.

Herzuma: Celltrion

Herzuma is a HER2/neu receptor antagonist indicated for the treatment of HER2-overexpressing breast cancer. Herzuma is the second FDA-approved trastuzumab biosimilar, following Mylan and Biocon's approval for Ogivri in December 2017 (Ogivri has not yet launched in the United States). Herzuma has also earned approval in the European Union (where it is marketed by Mundipharma), in Japan (where it is marketed by Daiichi Sankyo), and in Australia.

Further product details are provided in the report.....

Trastuzumab Biosimilars: Emerging Drugs

EG12014: EirGenix

EG12014 is a biosimilar of trastuzumab, which is Roche's monoclonal antibody with brand name called Herceptin. A biosimilar drug is a near-identical copy of an original

biologics and a different company can manufacture it after the expiration of the original biologics' patent. Eirgenix has begun preparations for a phase III clinical trial which would be conducted in the US and European nations. The outcome paves the way for new opportunities for lower-priced biosimilar drugs as patents on mainstream oncology drugs approach their expiration dates in the next few years.

HD201: Prestige BioPharma

HD201 is a mAb biosimilar to Roche's Herceptin which is used to treat patients with HER2-overexpressing breast cancer, HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Prestige's HD201 is in phase-III clinical development for filing with European Medicines Agency (EMA) and United States Food and Drug Administration (USFDA) in 2019.

Further product details are provided in the report.....

Trastuzumab: Therapeutic Assessment

This segment of the report provides insights about the different Trastuzumab biosimilars segregated based on following parameters that define the scope of the report, such as:

Major Players in Trastuzumab

There are approx. 35+ key companies which are developing the therapies for Trastuzumab.

Phases

DelveInsight's report covers around 35+ products under different phases of clinical development like

Marketed stage products

Late stage products (BLA Filed and Phase III)

Mid-stage products (Phase II and

Early-stage products (Phase I) along with the details of

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

Trastuzumab pipeline report provides the therapeutic assessment of the pipeline drugs by the Route of Administration. Products have been categorized under various ROAs such as

Subcutaneous

Intravenous

Parenteral

Molecule Type

Products have been categorized under various Molecule types such as

Monoclonal antibodies

Peptide

Protein

Small molecule

Product Type

Drugs have been categorized under various product types like Mono, Combination and Mono/Combination.

Trastuzumab: Pipeline Development Activities

The report provides insights into different therapeutic candidates in marketed, phase III, II, I and preclinical stage. It also analyses Trastuzumab biosimilars drugs key players involved in developing key drugs.

Pipeline Development Activities

The report covers the detailed information of collaborations, acquisition and merger, licensing along with a thorough therapeutic assessment of emerging Trastuzumab biosimilar drugs.

Report Highlights

The companies and academics are working to assess challenges and seek opportunities that could influence Trastuzumab R&D. The therapies under development are focused on novel approaches to treat/improve Trastuzumab.

In June 2019, Amgen and Allergan announced that the U.S. Food and Drug Administration (FDA) has approved Kanjinti (trastuzumab-anns) for all approved indications of the reference product, Herceptin (trastuzumab): for the treatment of HER2-overexpressing adjuvant and metastatic breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Trastuzumab Biosimilars Report Insights

Trastuzumab Biosimilar Pipeline Analysis

Therapeutic Assessment

Sales Assessment

Unmet Needs

Impact of Drugs

Trastuzumab Biosimilar Report Assessment

Marketed Product profiles

Pipeline Product Profiles

Therapeutic Assessment

Pipeline Assessment

Sales Assessment

Inactive drugs assessment

Unmet Needs

Key Questions

Current Treatment Scenario and Emerging Therapies:

How many companies are developing Trastuzumab Biosimilars?

How many Trastuzumab biosimilars are developed by each company?

How many emerging biosimilars are in mid-stage, and late-stage?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Trastuzumab biosimilars therapeutics?

What are the clinical studies going on for Trastuzumab biosimilars and their status?

What are the key designations that have been granted to the emerging drugs?

Key Players

Sunshine Guojian Pharmaceutical

STC Biologics

Shanghai Institute of Biological Products

Samsung Bioepis

Protheragen

Prestige Biopharma

Outlook Therapeutics

Nichi-Iko Pharmaceutical

Aprogen

NeuClone

Serum Institute of India

Mycenax Biotech

Meiji Seika Pharma

Mabpharm

Mabion

Jiangsu Hengrui Medicine Co.

ISU Abxis

International Biotech Center Generium

HisunPharmaceuticals

Hetero Group

Glenmark Pharmaceuticals

Genentech

Gedeon Richter

EirGenix

Dr Reddy's Laboratories

DM Bio

BioXpress Therapeutics

BioSavita

Bionovis

BioIntegrator

BIOCND

Biocad

AryoGen Pharmed

Apobiologix

Alteogen

Shanghai Henlius Biotech

Key Products

Cipterbin

STC 101

SIBP 01

SB3

Pro-S06

HD 201

ONS-1050

NeuCeptin

DMB-3111

CMAB 809

MabionHER2

SHR-1309

ISU103

GNR-027

HS-022

HBP7

HBP8

HBP9

HBP10

GBR-200

Anti-erbB-2- monoclonal antibody

EG12014

Hervycta

DA-3111

BX-2318

Anti-HER2 mAb biosimilar

BI-MAB-03

GB 221

BCD-022

AryoTrust

ALT02

HLX02

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