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Adalimumab-Biosimilars Insight, 2022

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Abstracts

This report can be delivered to the clients within 72-96 hours

DelveInsight's, "Adalimumab– Biosimilar 2022," report provides comprehensive insights about 35+ companies and 45+ marketed and pipeline drugs in Adalimumab 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

Adalimumab Understanding

Adalimumab: Overview

Adalimumab, sold under the brand name Humira among others, is a medication used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, psoriasis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis. It works by blocking a protein (tumor necrosis factor or TNF) found in the body's immune system that causes joint swelling and damage in arthritis as well as red scaly patches in psoriasis. Adalimumab belongs to a class of drugs known as TNF blockers. By reducing joint swelling, this medication helps to reduce further joint damage and preserve joint function. After treatment with adalimumab, a decrease in levels of acute phase reactant proteins of inflammation (C reactive protein [CRP] and erythrocyte sedimentation rate [ESR]) and serum cytokines (IL-6) was measured

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compared to baseline in patients diagnosed with rheumatoid arthritis.

Adalimumab Biosimilars: Drugs Chapters

This segment of the Adalimumab 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.

Adalimumab Biosimilars: Marketed Drugs

Abrilada: Pfizer

Abrilada is an FDA-approved biosimilar version of adalimumab. Abrilada (adalimumab-afzb) injection is supplied as a sterile, preservative-free solution for subcutaneous administration. The drug product is supplied as either a single-dose prefilled pen (Abrilada pen), as a single-dose 1 mL prefilled glass syringe, or as a single-dose institutional use vial. Enclosed within the pen is a single-dose 1 mL prefilled glass syringe. Though approved, it is not yet marketed in the US like several other manufacturers of approved biosimilar versions of adalimumab, Pfizer has signed a licensing agreement with AbbVie; under the agreement, Samsung would be able to launch the drug in November 2023.

Halimatoz: Sandoz

Halimatoz is mostly used in adults when their conditions are severe, moderately severe or getting worse, or when patients cannot use other treatments. Halimatoz contains the active substance adalimumab and is a ‘biosimilar medicine’. The active substance in Halimatoz, adalimumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a substance in the body called tumour necrosis factor (TNF). TNF is involved in causing inflammation and is found at high levels in patients with the diseases that Halimatoz is used to treat. By attaching to TNF, adalimumab blocks its activity, thereby reducing inflammation and other symptoms of the diseases.

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

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Adalimumab Biosimilars: Emerging Drugs

IBI303: Innovent Biologics

IBI303 is a recombinant human monoclonal antibody of TNF-?, which has the same amino acid sequence as branded adalimumab (Humira) and shows high degrees of similarity in respect to: chemical properties, in vitro biological activity (binding affinity and neutralizing activity against TNF-?), potency, and PK/PD. Pharmacologic and toxicologic studies of IBI303 also showed high similarity to Humira. Clinical studies have demonstrated that IBI303 can significantly alleviate the symptoms and physical signs of AS and decrease the disease activity and enthesitis, while improving both somatic motor ability and mobility of spine in patients with AS. It also improved the quality of life in patients with AS and reduced the disease's impact on their activities of daily life. IBI303 also generated an acceptable safety profile with most of the adverse events graded as mild or moderate. IBI303 may meet Chinese patients' urgent needs with an affordable price at global quality standards.

CT-P17: Celltrion

CT-P17 is the first high-concentration type of medicine for a biosimilar made of adalimumab. The company has differentiated CT-P17 from existing Humira biosimilars by halving the dosage. By taking the latest trend into account, Celltrion has also removed citrate, which can cause pain in self-injection, from its latest product. If Celltrion launches CT-P17, it will be able to complete a robust portfolio of CT-P17 in the global autoimmune disorder treatment market.

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

Adalimumab: Therapeutic Assessment

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

Major Players in Adalimumab

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

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Adalimumab.

Phases

DelveInsight's report covers around 45+ 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

Adalimumab 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

Molecule Type

Products have been categorized under various Molecule types such as

Monoclonal antibodies

Peptide

Protein

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Small molecule

Product Type

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

Adalimumab: Pipeline Development Activities

The report provides insights into different therapeutic candidates in marketed, phase III, II, I and preclinical stage. It also analyses Adalimumab 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 Adalimumab biosimilar drugs.

Report Highlights

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

In July 2020, the FDA has approved an adalimumab biosimilar (Hulio) from Fujifilm Kyowa Kirin Biologics, making it the sixth adalimumab biosimilar to AbbVie’s reference product Humira that has been approved and the 28th biosimilar approved by the FDA. Mylan will handle the commercialization in the United States.

In March 2020, Alvotech announced that it entered into an exclusive license partnership with DKSH, a market expansion services provider, for the commercialization of AVT02, a biosimilar to AbbVie’s HUMIRA (adalimumab), in selected Asia-Pacific (APAC) markets.

In October 2018, Orion Corporation and Amgen have signed an agreement for

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the marketing and sales of AMGEVITA, Finland's first adalimumab biosimilar. Based on its sales value, the original adalimumab product is the most-sold medicine globally and in Finland, and its impact on medicine reimbursement costs is substantial.

Adalimumab Biosimilars Report Insights

- Adalimumab Biosimilar Pipeline Analysis
- Therapeutic Assessment
- Sales Assessment
- Unmet Needs
- Impact of Drugs

Adalimumab 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:

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How many companies are developing Adalimumab Biosimilars?

How many Adalimumab 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 Adalimumab biosimilars therapeutics?

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

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

Key Players

Zydus Cadila

Tanvex Biopharma

Synermore Biologics

Shanghai Henlius Biotech

Sandoz

Samsung Bioepis

Prestige BioPharma

PlantPraxis

Pfizer

Outlook Therapeutics

Mylan

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Mylan and Fujifilm Kyowa Kirin Biologics

Mycenax Biotech

Momenta Pharmaceuticals

Meiji Seika Pharma

LG Chem

ISU Abxis

Innovent Biologics

HisunPharmaceuticals

Hetero Group

Harvest Moon Pharmaceuticals

Gene Techno Science

Fresenius Kabi, Germany [Bought from Merck KGaA (Merck Group)

Epirus Biopharmaceuticals

Daiichi Sankyo

Coherus BioSciences

CinnaGen

Celltrion

Boehringer Ingelheim

BioXpress Therapeutics

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Bio-Thera Solutions

Bionovis/The Instituto Vital Brazil

Biogen

Biocon/Mylan

BIOCND/Genor Biopharma

Biocad

Amgen

Alvotech

mAbxience

Key Products

Adaly

TX17

SYN-060

HLX 03

Halimatoz

Hyrimoz

Hadlima

PBP 1502

Abrilada/Amsparity

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Abrilada

ONS-3010

MYL-1401A

Hulio

M 923

DMB-3113

LBAL

ISU202

IBI-303

HS 016

Pamera

Idacio/Kromeya

BOW 050

CHS-1420

Cinnora

CT-P17

Cyltezo

BX 2922

BAT-1406/Qleti

QLETLI

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Imraldi

MYL 1401A

GB 232

BCD-057

BCD-058

Amgevita

Amjevita

Solymbic

AVT-02

HLX03

SB5/HADLIMA

AMAB

BCD 057

GBS 005

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*More Companies and products would be added in the final report

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11. ADALIMUMAB BIOSIMILARS: COMPETITIVE LANDSCAPE

*More information would be added in the final report

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