

# Etanercept– Biosimilar Insight, 2022

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## Abstracts

This report can be delivered to the clients within 24 Hours

DelveInsight's, "Etanercept– Biosimilar 2022," report provides comprehensive insights about 20+ companies and 20+ marketed and pipeline drugs in Etanercept 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

### Etanercept Understanding

#### Etanercept: Overview

Etanercept is indicated for the treatment of moderately to severely active rheumatoid arthritis in adults and in chronic moderate to severe plaque psoriasis in patients 4 years of age and older. It is also used to manage signs and symptoms of polyarticular idiopathic arthritis in those aged 2 years and older. Etanercept is also used to manage the symptoms of psoriatic arthritis and ankylosing spondylitis. Dimeric fusion protein consisting of the extracellular ligand-binding portion of the human 75 kilodalton (p75) tumor necrosis factor receptor (TNFR) linked to the Fc portion of human IgG1. The Fc component of etanercept contains the CH2 domain, the CH3 domain and hinge region, but not the CH1 domain of IgG1. Etanercept is produced by recombinant DNA technology in a Chinese hamster ovary (CHO) mammalian cell expression system. It

consists of 934 amino acids. It is used to treat or manage a variety of inflammatory conditions including rheumatoid arthritis (RA), ankylosing spondylitis (AS), and juvenile idiopathic poly-articular arthritis (JIA).

### Etanercept Biosimilars: Drugs Chapters

This segment of the Etanercept 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.

### Etanercept Biosimilars: Marketed Drugs

#### GP 2015: Sandoz

GP2015 is the second biosimilar of the reference p75 TNF receptor-Fc fusion protein etanercept. It is approved for use in all indications for which reference etanercept is approved, including rheumatoid arthritis, juvenile idiopathic arthritis, and psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis. GP2015 has similar physiochemical and pharmacodynamic properties to those of reference etanercept, and the pharmacokinetic biosimilarity of the agents has been shown in healthy volunteers. GP2015 demonstrated clinical efficacy equivalent to that of reference etanercept in patients with moderate-to-severe plaque psoriasis; the tolerability, safety and immunogenicity profiles of the two agents were also generally similar.

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

### Etanercept Biosimilars: Emerging Drugs

#### CHS-0214: Coherus BioSciences

CHS-0214 is being developed in phase III stage of development. Coherus BioSciences (CHRS) and Baxalta (BXLT) announced that CHS-0214, a proposed biosimilar of Enbrel, met its primary endpoint in a confirmatory, double-blind, randomized, and controlled, two-part clinical study. This ongoing study is evaluating the efficacy and safety of CHS-0214 compared to Enbrel in patients with moderate-to-severe rheumatoid

arthritis that is inadequately controlled with methotrexate alone.

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

### Etanercept: Therapeutic Assessment

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

#### Major Players in Etanercept

There are approx. 20+ key companies which are developing the therapies for Etanercept.

#### Phases

DelveInsight's report covers around 20+ 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

Etanercept 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

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.

Etanercept: Pipeline Development Activities

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

Report Highlights

The companies and academics are working to assess challenges and seek opportunities that could influence Etanercept R&D. The therapies under

development are focused on novel approaches to treat/improve Etanercept.

In June 2020, Mylan and Lupin Limited announced that the European Commission (EC) has granted marketing authorization for Nepexto, a biosimilar to Enbrel (etanercept), for all indications of the reference product including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis), plaque psoriasis and paediatric plaque psoriasis.

In April 2019, Samsung Bioepis announced that the US Food and Drug Administration (FDA) has approved eticovo (etanercept-ykro), a biosimilar referencing ENBREL (etanercept), across all eligible indications for the treatment of rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis and polyarticular juvenile idiopathic arthritis. ETICOVO is Samsung Bioepis' second anti-TNF biosimilar approved for marketing in the United States (US).

## Etanercept Biosimilars Report Insights

Etanercept Biosimilar Pipeline Analysis

Therapeutic Assessment

Sales Assessment

Unmet Needs

Impact of Drugs

## Etanercept 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 Etanercept Biosimilars?

How many Etanercept 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 Etanercept biosimilars therapeutics?

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

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

## Key Players

YL Biologics (Lupin/Yoshida)

Shanghai CP Guojian Pharmaceutical

Sandoz

Samsung Bioepis

Reliance Life Sciences

Protalix Biotherapeutics

Probiomed

Pfizer

Nanogen

Mycenax Biotech

TSH Biopharm Corp, Taiwan

Mochida Pharmaceutical

Merck

mAbxience

Lupin

LG Life Sciences (LG Chem)

Intas Pharmaceuticals

Hisun Pharmaceuticals

Harvest Moon Pharmaceuticals

Hanwha Chemical

Coherus BioSciences

Clover Biopharmaceuticals

Cipla

Celltrion

BioXpress Therapeutics

Biosidus

Biocon

Mylan

Avesthagen

AryoGen Pharmed

Amega Biotech

## Key Products

YLB113

Etanar

Qiangke

Erelzi (GP2015)

Eticovo (SB4)

EtanerRel

PRX-106

Infinitam

Lifmior

Nanercept

TuNEX (ENIA11)



Eucept (LBEC0101)

Brenzys

mAbx01

RTXM93

YLB-113

Eucept (LBEC0101)

TNFcept

Intacept

AnBaiNuo

Davictrel (HD203)

CHS-0214

SCB-808

Etacept

CT-P05

BX2922

Avent

Altebrel

Enerceptan

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