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Filgrastim - Biosimilar Insight, 2022

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Abstracts

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

Filgrastim Understanding

Filgrastim: Overview

Filgrastim, sold under the brand name Neupogen among others, is a medication used to treat low neutrophil count. Low neutrophil counts may occur with HIV/AIDS, following chemotherapy or radiation poisoning, or be of an unknown cause. It is marketed as the brand name Neupogen by Amgen (initially approved in 1998). Filgrastim is a growth factor that stimulates the production, maturation, and activation of neutrophils (a type of white blood cell). Filgrastim also stimulates the release of neutrophils from the bone marrow. In patients receiving chemotherapy, filgrastim can accelerate the recovery of neutrophils, reducing the neutropenic phase (the time in which people are susceptible to infections).

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Filgrastim Biosimilars: Drugs Chapters

This segment of the Filgrastim 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.

Filgrastim Biosimilars: Marketed Drugs

Nivestym: Pfizer

Nivestym is a leukocyte growth factor that primarily stimulates neutrophils. The G-CSF receptor through which Nivestym acts has also been found on tumor cell lines. The possibility that Nivestym acts as a growth factor for any tumor type cannot be excluded. The safety of filgrastim products in chronic myeloid leukemia (CML) and myelodysplasia has not been established. Nivestym is used to treat neutropenia, a lack of certain white blood cells caused by cancer, bone marrow transplant, receiving chemotherapy, or by other conditions. Nivestym may also be used for purposes not listed in this medication guide. In July 2018, Pfizer announced that the United States (U.S.) Food and Drug Administration (FDA) has approved NIVESTYM (filgrastim-aafi), a biosimilar to Neupogen1 (filgrastim), for all eligible indications of the reference product.

Grastofil: Apotex/Intas

Grastofil is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of Grastofil are similar in adults and children receiving cytotoxic chemotherapy. Grastofil is indicated for the mobilisation of peripheral blood progenitor cells (PBPCs). The active substance in Grastofil, filgrastim, is very similar to a human protein called granulocyte colony stimulating factor (G-CSF). Filgrastim acts in the same way as naturally produced G-CSF by encouraging the bone marrow to produce more white blood cells.

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

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Filgrastim Biosimilars: Emerging Drugs

TX-01: Tanvex Biopharma

Tanvex Biopharma is developing Filgrastim biosimilar labeled as TX-01 for the treatment of Neutropenia. The mechanism of action of the drug is that it acts as Haematopoietic cell growth factor stimulants. In 2019, Tanvex BioPharma receives complete response letter from the US FDA for filgrastim biosimilar (TX 01) in Neutropenia.

GranNEX: Mycenax Biotech

GranNEX is Mycenax's filgrastim, the biosimilar version of Neupogen, and the recombinant human granulocyte colony-stimulating factor, G-CSF. It can stimulate the growth of the white cell. The development of GranNEX followed the regulatory pathway of the biosimilar, with high biosimilarity to its reference product, and complied with the requirements of the European Medicine Agency. This project is granted by the Ministry of Economic Affairs (MOEA) and selected as the critical path project by the Center for Drug Evaluation (CDE) in Taiwan. Mycenax has completed GranNEX's pre-clinical development and will focus on the application of the new delivery system or new formulation for patient's ease of using GranNEX.

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

Filgrastim: Therapeutic Assessment

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

Major Players in Filgrastim

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

Phases

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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

Filgrastim 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
- Parenteral
- Molecule Type

Products have been categorized under various Molecule types such as

- Monoclonal antibodies
- Peptide
- Protein
- Small molecule

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Product Type

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

Filgrastim: Pipeline Development Activities

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

Report Highlights

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

In November 2019, Sandoz announced that the US Food and Drug Administration (FDA) approved its biosimilar ZiextenzoTM (pegfilgrastim-bmez).

In April 2019, Sandoz announced resubmission of its Biologics License Application (BLA) for a proposed biosimilar pegfilgrastim to the US Food and Drug Administration (FDA) to address an FDA complete response letter received in June 2016.

Filgrastim Biosimilars Report Insights

Filgrastim Biosimilar Pipeline Analysis

Therapeutic Assessment

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- Sales Assessment
- Unmet Needs
- Impact of Drugs

Filgrastim 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 Filgrastim Biosimilars?
- How many Filgrastim 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 Filgrastim biosimilars therapeutics?
- What are the clinical studies going on for Filgrastim biosimilars and their status?

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

Key Players

Zydus Cadila

Teva Generics

Sandoz

Reliance Life Sciences

Ratiopharm

Pfizer

Novartis

Mycenax Biotech

Laboratorio Elea

Hexal

Harvest Moon Pharmaceuticals

Harvest Moon Pharmaceuticals

Hangzhou Jiuyuan Gene Engineering

Fuji Pharmaceutical

Mochida Pharmaceutical

Gene Techno Science

Emcure Pharmaceuticals

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Dr Reddy's Laboratories

Dong-A ST Co.

Claris Lifesciences

Bionovis

Bionaturis

Curaxys

Bio-Ker

Biocon

Mylan

Biocad

Apotex

Aequus

CTI BioPharma

Accord Healthcare

Key Products

G-CSF

Tevagrastim

Zarzio

ReliGrast

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Ratiograstim

Nivestim

Zarxio

GranNEX

Recombinant human granulocyte colony-stimulating factor

Filgrastim Hexal

JILIFEN

Filgrastim BS; FSK-0808; GBS 001

Grafeel

Leucostim

Fegrast

Biofigran

BNT002

BK 0023

Nufil

Leucostim

Grastofil

AQB-101;

Accofil

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