

Insulin Glargine- - Biosimilar Insight, 2022

<https://marketpublishers.com/r/I5B68462BCC2EN.html>

Date: January 2022

Pages: 90

Price: US\$ 2,000.00 (Single User License)

ID: I5B68462BCC2EN

Abstracts

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DelveInsight's, "Insulin Glargine– Biosimilar 2022," report provides comprehensive insights about 10+ companies and 10+ marketed and pipeline drugs in Insulin Glargine 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

Insulin Glargine Understanding

Insulin Glargine: Overview

Insulin glargine, marketed under the names Lantus among others, is a long-acting insulin, used in the management of type I and type II diabetes. It is typically the recommended long acting insulin in the United Kingdom. It is used once a day as an injection just under the skin. Insulin glargine is produced by recombinant DNA technology using a non-pathogenic laboratory strain of *Escherichia coli* (K12) as the production organism. Insulin glargine differs from endogenous human insulin by the replacement of an asparagine residue at position A21 of the A-chain with glycine and addition of two arginines to the C-terminus (positions B31 and 32) of the B-chain. The resulting protein is soluble at pH 4 and forms microprecipitates at physiological pH 7.4 allowing for the slow release of small amounts of insulin glargine, giving the drug a long

duration of action and no pronounced peak concentration.

Insulin Glargine Biosimilars: Drugs Chapters

This segment of the Insulin Glargine 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.

Insulin Glargine Biosimilars: Marketed Drugs

Semglee: Mylan/Biocon

Semglee contains insulin glargine. This is a modified insulin, very similar to human insulin. Semglee is used to treat diabetes mellitus in adults, adolescents and children aged 2 years and above. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar.

Abasaglar: Eli Lilly

Insulin glargine biosimilar (Abasaglar) is licensed for the treatment of diabetes mellitus in adults, young people and children over 2 years. Abasaglar is a basal insulin for once daily use and is bioequivalent to insulin glargine (Lantus). Basaglar is not approved for use by anyone younger than 6 years old, and should not be used to treat type 2 diabetes in a child of any age.

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

Insulin Glargine Biosimilars: Emerging Drugs

Insulin RinGlar: Geropharm

Insulin RinGlar is being developed by Geropharm for the treatment of Type 1 diabetes mellitus. This is the fifth insulin in the company portfolio, which will complete the Geropharm line of human recombinant insulins and analogues. RinGlar will become the first insulin glargine, which will be produced in Russia on a full cycle basis – from

substance to the finished dosage form.

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

Insulin Glargine: Therapeutic Assessment

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

Major Players in Insulin Glargine

There are approx. 10+ key companies which are developing the therapies for Insulin Glargine.

Phases

DelveInsight's report covers around 10+ 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

Insulin Glargine 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

Small molecule

Product Type

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

Insulin Glargine: Pipeline Development Activities

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

Report Highlights

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

development are focused on novel approaches to treat/improve Insulin Glargine.

In June 2020, Mylan and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Semglee (insulin glargine injection), in vial and pre-filled pen presentations, to control high blood sugar in adults with type 2 diabetes and adult and pediatric patients with type 1 diabetes. Semglee has an identical amino acid sequence to Sanofi's Lantus and is approved for the same indications.

In July 2019, there was an official signing ceremony for the partnership agreement between GEROPHARM and NatiVita (Belarus) that stipulates a transfer of the Russian insulin production technology to the Belarussian party. This partnership between the companies is a strategy and facilitates strengthening bilateral relationship between the Russian Federation and the Republic of Belarus. Implementation of the project will make it possible to adjust highly technological production of insulins in Belarus within a short-term period of time and provide the citizens with modern, effective and affordable drugs.

In July 2019, GEROPHARM received marketing authorization for long-action insulin analog – glargine under RinGlar invented name. The drug in two dosage forms - 3 ml cartridges and pre-filled disposable insulin pens RinAstra II - will take part in the state procurement procedure in the autumn of 2019.

Insulin Glargine Biosimilars Report Insights

Insulin Glargine Biosimilar Pipeline Analysis

Therapeutic Assessment

Sales Assessment

Unmet Needs

Impact of Drugs

Insulin Glargine 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 Insulin Glargine Biosimilars?

How many Insulin Glargine 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 Insulin Glargine biosimilars therapeutics?

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

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

Key Players

Mylan

Polus BioPharm

Biocon

Wockhardt

Boehringer Ingelheim

Eli Lilly and Company

LG Chem

Harvest Moon Pharmaceuticals

GEROPHARM

Merck

Paras Biopharmaceuticals

GC Pharma

Key Products

Semglee

PDP808

Glaricon

Glaritus

Abasaglar

Basalog

Basugine

Insulin glargine biosimilar

Insulin RinGlar

Lusduna

PB (MDT)-3030

Glarzia

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