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Familial Hypercholesterolemia – Pipeline Insight, 2020

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Abstracts

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DelveInsight's, "Familial Hypercholesterolemia – Pipeline Insight, 2020," report provides comprehensive insights about 10+ companies and 10+ pipeline drugs in Familial Hypercholesterolemia pipeline landscape. It covers the 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

Familial Hypercholesterolemia Understanding

Familial Hypercholesterolemia: Overview

Familial hypercholesterolemia is an inherited condition characterized by very high levels of cholesterol in the blood. Cholesterol is a waxy, fat-like substance that is produced in the body and obtained from foods that come from animals (particularly egg yolks, meat, poultry, fish, and dairy products). The body needs this substance to build cell membranes, make certain hormones, and produce compounds that aid in fat digestion. In people with familial hypercholesterolemia, the body is unable to get rid of extra cholesterol, and it builds up in the blood. Too much cholesterol increases a person's risk of developing heart disease.

People with familial hypercholesterolemia have a high risk of developing a form of heart

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disease called coronary artery disease at a young age. This condition occurs when excess cholesterol in the bloodstream is deposited on the inner walls of blood vessels, particularly the arteries that supply blood to the heart (coronary arteries).

Symptoms

The major symptoms and signs of familial hypercholesterolemia are:

High levels of total cholesterol and LDL cholesterol.

A strong family history of high levels of total and LDL cholesterol and/or early heart attack.

Elevated and therapy-resistant levels of LDL in either or both parents.

Xanthomas (waxy deposits of cholesterol in the skin or tendons).

Xanthelasmas (cholesterol deposits in the eyelids).

Corneal arcus (cholesterol deposit around the cornea of the eye).

If angina (chest pain) is present, it may be sign that heart disease is present.

Diagnosis

Diagnosis of familial hypercholesterolemia is based on physical examination and laboratory testing. Physical examination may find xanthomas and xanthelasmas (skin lesions caused by cholesterol rich lipoprotein deposits), and cholesterol deposits in the eye called corneal arcus.

Laboratory testing includes blood testing of cholesterol levels, studies of heart function, and genetic testing. Blood testing of cholesterol levels may show: increased total cholesterol usually above 300 mg/dl (total cholesterol of more than 250 mg/dl in children) and LDL levels usually above 200 mg/dl. Studies of heart function, such as a stress test, may be abnormal.

Genetic testing may show an alteration (mutation) in the LDL receptor gene.

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Treatment

The overall goal of treatment is to lower the risk for atherosclerotic heart disease by lowering the LDL cholesterol levels in the blood stream. Atherosclerosis is a condition in which fatty material collects along the walls of arteries. This fatty material thickens, hardens, and may eventually block the arteries.

The first step in treatment for an individual who has heterozygous familial hypercholesterolemia is changing the diet to reduce the total amount of fat eaten to 30 percent of the total daily calories.

Exercise, especially to lose weight, may also help in lowering cholesterol levels.

Drug therapy is usually necessary in combination with diet, weight loss, and exercise, as these interventions may not be able to lower cholesterol levels alone.

Familial Hypercholesterolemia Emerging Drugs Chapters

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

Familial Hypercholesterolemia Emerging Drugs

LIB 003: LIB Therapeutics

LIB Therapeutics is conducting a study to compare the safety, tolerability and LDL-C response after 24 Weeks of monthly (every 4 weeks [Q4W]) subcutaneous (SC) dosing of LIB003 300 mg with monthly (Q4W) SC dosing of 420 mg evolocumab (Repatha) in patients with HoFH on stable diet and oral LDL-C-lowering drug therapy. Patients with verified HoFH on stable and continuing doses of oral lipid lowering therapy will be randomized to either evolocumab 420 mg Q4W or LIB003 300 mg Q4W for 24 weeks (Period A). At Week 24, subjects will be crossed over to LIB003 if they were on evolocumab and vice versa for the next 24 weeks (Period B).

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Tafolecimab: Innovent Biologics

Tafolecimab (IBI306) is a recombinant fully human monoclonal antibody against proprotein convertase subtilisin/kexin type 9 (PCSK9) developed by Innovent for the treatment of hypercholesterolemia. PCSK9 binds the LDL-R/LDL-C complex and prevents LDL-R dissociation, make it to degrade with LDL-C and thus cannot circulate back to the hepatic cell surface. As the amount of LDL-R expression on the cell surface decreases, the level of LDL-C in the blood will accumulate and increase. Tafolecimab targets PCSK9 and inhibits its binding to LDL-R on the liver cell surface, maintaining the expression of LDL-R on the hepatocyte surface, thereby reducing LDL-C levels. Early phase clinical trials have preliminarily demonstrated that Tafolecimab has good safety, tolerability and efficacy.

Further product details are provided in the report

Familial Hypercholesterolemia: Therapeutic Assessment

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

Major Players in Familial Hypercholesterolemia

There are approx. 10+ key companies which are developing the therapies for Familial Hypercholesterolemia. The companies which have their Familial Hypercholesterolemia drug candidates in the mid to advanced stage, i.e. phase III and Phase II include, Jiangsu HengRui Medicine, Amgen, Innovent Biologics (Suzhou) Co. Ltd., Regeneron Pharmaceuticals, The Medicines Company etc.

Phases

DelveInsight’s report covers around 10+ products under different phases of clinical development like

Mid-stage products (Phase II and Phase I/II)

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

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Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

Familial Hypercholesterolemia 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

Oral

Intramuscular

Molecule Type

Products have been categorized under various Molecule types such as

Small molecules

Recombinant fusion proteins

Monoclonal antibodies

Immunoglobulins

Immunoproteins

Serum globulins

Product Type

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

Familial Hypercholesterolemia: Pipeline Development Activities

The report provides insights into different therapeutic candidates in phase II, I, preclinical and discovery stage. It also analyses Familial Hypercholesterolemia therapeutic 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 Familial Hypercholesterolemia drugs.

Report Highlights

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

August 2020: Innovent announces the results of the phase 1/2 clinical study of PCSK9 antibody tafolecimab at the European Society of Cardiology Annual Conference

The accepted results were from CIBI306A101 and CIBI306B101, which demonstrated satisfactory safety and efficacy profiles of Tafolecimab.

Specially, compared with the marketed PCSK9 inhibitors, Tafolecimab preliminarily demonstrated longer dosing interval, which is 6 or even up to 8 weeks.

Familial Hypercholesterolemia Report Insights

Familial Hypercholesterolemia Pipeline Analysis

Therapeutic Assessment

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Key Questions

Current Treatment Scenario and Emerging Therapies:

How many companies are developing Familial Hypercholesterolemia drugs?

How many Familial Hypercholesterolemia drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Familial Hypercholesterolemia?

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

What are the recent trends, drug types and novel technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for Familial Hypercholesterolemia and

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their status?

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

Key Players

Jiangsu HengRui Medicine Co., Ltd.

Amgen

Innovent Biologics (Suzhou) Co. Ltd.

Regeneron Pharmaceuticals

Akeso

The Medicines Company

Regenxbio Inc.

LIB Therapeutics LLC

Key Products

SHR-1209

Evolocumab

IBI306

Evinacumab

AK102

AAV directed hLDLR gene therapy

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