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Idiopathic Pulmonary Fibrosis - Pipeline Insight, 2022

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Abstracts

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DelveInsight's, "Idiopathic Pulmonary Fibrosis - Pipeline Insight, 2022," report provides comprehensive insights about 80+ companies and 80+ pipeline drugs in Idiopathic Pulmonary Fibrosis 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

Idiopathic Pulmonary Fibrosis Understanding

Idiopathic Pulmonary Fibrosis: Overview

Idiopathic Pulmonary Fibrosis (IPF) is a rare, chronic, progressive fibrosing interstitial pneumonia that is found to affect the middle-aged and older adults; and affects lung tissue (alveoli in particular) by either thickening, stiffening, or persistent and progressive scarring (fibrosis) which increases irreversibly over time. If an individual has IPF, scarring affects the air sacs, limiting the amount of oxygen that gets into the blood. With less oxygen in the blood, one can get breathlessness from everyday activities, like walking. This group of lung disorders is also known as 'Diffuse Parenchymal Lung Diseases,' which is characterized by a broader umbrella of 'Interstitial Lung Diseases (IDLs). Cause of IPF is still unknown; researchers postulate that the disease probably results from a combination of genetic and environmental factors. There exists a strong

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possibility that genetic changes increase a person’s risk of developing IPF and subsequent exposure to certain environmental factors that trigger the disease further. However, much is still unknown about this emerging field of study.

'Idiopathic Pulmonary Fibrosis - Pipeline Insight, 2022' report by DelveInsight outlays comprehensive insights of present scenario and growth prospects across the indication. A detailed picture of the Idiopathic Pulmonary Fibrosis pipeline landscape is provided which includes the disease overview and Idiopathic Pulmonary Fibrosis treatment guidelines. The assessment part of the report embraces, in depth Idiopathic Pulmonary Fibrosis commercial assessment and clinical assessment of the pipeline products under development. In the report, detailed description of the drug is given which includes mechanism of action of the drug, clinical studies, NDA approvals (if any), and product development activities comprising the technology, Idiopathic Pulmonary Fibrosis collaborations, licensing, mergers and acquisition, funding, designations and other product related details.

Report Highlights

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

In February 2022, Endeavor BioMedicines, announced the completion of a $101 million Series B financing, led by Ally Bridge Group and Avidity Partners. New investors participating in the round include Perceptive Advisors, Piper Heartland Healthcare Capital, Revelation Partners, funds managed by Tekla Capital Management LLC, and funds and accounts advised by T. Rowe Price Associates, Inc. Existing investors Omega Funds and Longitude Capital also participated. Proceeds will support the advancement of Endeavor’s pipeline programs, including ENV-101 (taladegib), a small molecule inhibitor of the PTCH1 receptor in the Hedgehog signaling pathway for the treatment of cancer and idiopathic pulmonary fibrosis (IPF), as well as ENV-201, a potentially best-in-class small molecule inhibitor of ULK1/2 for the treatment of KRAS-driven cancers.

In October 2021, Agomab Therapeutics NV entered into a definitive agreement under which it will acquire Origo Biopharma S.L., a Spanish clinical-stage biotechnology company developing organ-restricted small molecule drug

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candidates targeting the transforming growth factor beta (TGF-?) pathway for the treatment of fibrosis-related disorders.

In September 2021, Syndax Pharmaceuticals, Inc. and Incyte entered into an exclusive worldwide collaboration and license agreement to develop and commercialize axatilimab, Syndax's anti-CSF-1R monoclonal antibody. Syndax and Incyte are seeking to develop axatilimab as a backbone therapy for patients with cGVHD as well as in additional immune-mediated diseases where CSF-1R-dependent monocytes and macrophages are believed to contribute to organ fibrosis.

In April 2021, Syndax Pharmaceuticals, Inc. announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to axatilimab, its anti-CSF-1R monoclonal antibody, for the treatment of patients with idiopathic pulmonary fibrosis (IPF).

Idiopathic Pulmonary Fibrosis Emerging Drugs Chapters

This segment of the Idiopathic Pulmonary Fibrosis 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.

Idiopathic Pulmonary Fibrosis Emerging Drugs

PRM-151: Hoffmann-La Roche

PRM-151 is an anti-fibrotic immunomodulator being developed for treatment of fibrotic diseases. It is a recombinant form of human pentraxin-2 (PTX-2) protein, presents new opportunities for treating a wide range of systemic fibrotic diseases. Currently, it is in Phase III stage of development to treat Idiopathic pulmonary fibrosis. Pentraxin-2 is an endogenous human protein that plays an important role in regulating the response to fibrosis. It directs the immune system to naturally turn off and reverse the process of fibrosis, which occurs as a result of excess collagen secretion and cellular growth and differentiation. Unlike other formulations that work by stopping a single target on the downstream side of fibrosis, this protein works by reversing and possibly healing the

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fibrotic tissue. Research suggests that it may localize specifically to sites of injury and function to aid in the removal of damaged tissue. Combined with the ability to regulate monocyte differentiation (another inflammatory regulator), it has been proven to have ‘first-class’ effects in reversal of fibrosis and promotion of healing.

Pamrevlumab: FibroGen

Pamrevlumab is a first-in-class antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), and for the treatment of Duchenne muscular dystrophy (DMD). The U.S. Food and Drug Administration has granted Orphan Drug Designation (ODD) to pamrevlumab for the treatment of patients with IPF, LAPC, and DMD. Pamrevlumab has also received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with IPF and LAPC. Across all clinical studies, pamrevlumab has consistently demonstrated a good safety and tolerability profile to date.

Tipelukast: MediciNova

MN-001 (tipelukast) is a novel, orally bioavailable small molecule compound which exerts its effects through several mechanisms to produce its anti-fibrotic and anti-inflammatory activity in preclinical models, including leukotriene (LT) receptor antagonism, inhibition of phosphodiesterases (PDE) (mainly 3 and 4), and inhibition of 5-lipoxygenase (5-LO). The 5-LO/LT pathway has been postulated as a pathogenic factor in fibrosis development and MN-001’s inhibitory effect on 5-LO and the 5-LO/LT pathway is considered to be a novel approach to treat fibrosis. MN-001 has been shown to down-regulate expression of genes that promote fibrosis including LOXL2, Collagen Type 1 and TIMP-1. MN-001 has also been shown to down-regulate expression of genes that promote inflammation including CCR2 and MCP-1. In addition, histopathological data shows that MN-001 reduces fibrosis in multiple animal models. Previously, MediciNova evaluated MN-001 for its potential clinical efficacy in asthma and had positive Phase 2 results. MN-001 has been exposed to more than 600 subjects and considered generally safe and well-tolerated.

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PLN-74809: Pliant Therapeutics

PLN-74809 is an oral, small molecule, dual-selective inhibitor of ?v?6 and ?v?1 being developed for the treatment of idiopathic pulmonary fibrosis (IPF) and primary sclerosing cholangitis (PSC). While expressed at very low levels in normal tissues, ?v?6 and ?v?1 integrins are upregulated in the pulmonary tissues of IPF patients, and in the liver tissues of PSC patients. Both of these integrins serve as activators of TGF-?, leading to increased collagen production and, ultimately, fibrosis in these tissues. By blocking the activation of TGF-? by both ?v?6 and ?v?1, we believe PLN-74809 may slow and potentially halt the progression of fibrosis in these patient populations. In November 2018, the US FDA granted orphan drug designation for PLN 74809 for the treatment of primary sclerosing cholangitis. Earlier, in August 2018, the drug received orphan drug designation for the treatment of idiopathic pulmonary fibrosis.

GLPG4716: Galapagos NV

GLPG4716 (formerly OATD-01, in-licensed from OncoArendi) is a novel, small molecule CHIT1/AMCase inhibitor targeting a key pathway in tissue remodeling. It has shown compelling translational data, a favorable profile in animal studies at expected therapeutic doses and it has successfully completed Phase I studies in healthy volunteers. Galapagos aims to bring GLPG4716 to a Phase II clinical trial for the treatment of IPF and possibly other diseases with a fibrotic component. Chitinases (predominantly CHIT1) are involved in macrophage activation. Inhibition of chitinase activity translates into a potential therapeutic benefit, as shown in a range of preclinical models. GLPG4716 has shown robust anti-fibrotic activity in multiple animal models, when compared with the standard of care.

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

Idiopathic Pulmonary Fibrosis: Therapeutic Assessment

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

Major Players in Idiopathic Pulmonary Fibrosis

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There are approx. 80+ key companies which are developing the therapies for Idiopathic Pulmonary Fibrosis. The companies which have their Idiopathic Pulmonary Fibrosis drug candidates in the most advanced stage, i.e. phase III include, Hoffmann-La Roche.

Phases

DelveInsight's report covers around 80+ products under different phases of clinical development like

Late stage products (Phase III)

Mid-stage products (Phase II)

Early-stage product (Phase I) along with the details of

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

Idiopathic Pulmonary Fibrosis pipeline report provides the therapeutic assessment of the pipeline drugs by the Route of Administration. Products have been categorized under various ROAs such as

Inhalation

Intravenous

Oral

Parenteral

Subcutaneous

Molecule Type

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Products have been categorized under various Molecule types such as

- Gene therapy
- Antibody
- Peptides
- Recombinant proteins
- RNA
- Small molecule
- Stem cell therapy
- Product Type

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

Idiopathic Pulmonary Fibrosis: Pipeline Development Activities

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

Idiopathic Pulmonary Fibrosis Report Insights

- Idiopathic Pulmonary Fibrosis Pipeline Analysis
- Therapeutic Assessment

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Unmet Needs

Impact of Drugs

Idiopathic Pulmonary Fibrosis Report Assessment

Pipeline Product Profiles

Therapeutic Assessment

Pipeline Assessment

Inactive drugs assessment

Unmet Needs

Key Questions

Current Treatment Scenario and Emerging Therapies:

How many companies are developing Idiopathic Pulmonary Fibrosis drugs?

How many Idiopathic Pulmonary Fibrosis drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Idiopathic Pulmonary Fibrosis?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Idiopathic Pulmonary Fibrosis 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 Idiopathic Pulmonary Fibrosis and their

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status?

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

Key Players

Roche

FibroGen

United Therapeutics

Bellerophon Therapeutics

MediciNova

Novartis

Endeavor BioMedicines

Pliant Therapeutics

Nitto Denko

Kadmon Pharmaceuticals

Calliditas Therapeutics

Avalyn Pharmaceuticals

PureTech Health

Taiho Pharmaceutical

Syndax Pharmaceuticals

Bristol-Myers Squibb

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Galecto Biotech AB

CSL Behring

Celgene Pharmaceutical

Vicore Pharma

Boehringer Ingelheim

Guangdong Raynovent

Sunshine Lake Pharma co

Suzhou Zelgen Biopharmaceuticals

Algernon Pharmaceuticals

Horizon Therapeutics

Daewoong Pharmaceutical

Metagone Biotech

Astra Zeneca

Regend Therapeutics

Lung Therapeutics

Bridge Biotherapeutics

AstraZeneca

Kinarus AG

Insmed

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Key Products

PRM-151

Pamrevlumab

Treprostinil

Nitric oxide inhalation - INOpulse

MN-001 (tipelukast)

VAY736

ENV-101

PLN-74809

ND-L02-s0201

KD025

GKT137831

AP 01

LYT-100

TAS-115

Axatilimab

BMS-986278

GB0139

CSL312

CC-90001

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C21

BI1015550

ZSP1603

HEC585

Jaktinib Dihydrochloride Monohydrate

Ifenprodil

HZN-825

DWN12088

MG-S-2525

Saracatinib

Lung stem cells

LTI-03

BBT-877

AZD5055

KIN001-IPF

Treprostinil palmitil inhalation powder (TPIP)

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