

Primary Hyperoxaluria - Pipeline Insight, 2021

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Abstracts

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DelveInsight's, "Primary Hyperoxaluria – Pipeline Insight, 2021," report provides comprehensive insights about 8+ companies and 8+ pipeline drugs in Primary Hyperoxaluria 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

Primary Hyperoxaluria Understanding

Primary Hyperoxaluria: Overview

Primary hyperoxaluria (PH) is a group of rare genetic metabolic disorders that are characterized by the accumulation of a substance known as oxalate in the kidneys and other organ systems of the body. Affected individuals lack functional levels of a specific enzyme that normally prevents the accumulation of oxalate. There are three main types of PH – PH types I, II, and III – differentiated by the specific enzyme that is deficient. In the kidneys, excess oxalate binds with calcium to form a hard compound (calcium oxalate) that is the main component of kidney and urinary stones. Common symptoms include the formation of stones throughout the urinary tract (urolithiasis) and kidneys (nephrolithiasis) and progressively increased levels of calcium in the kidneys (nephrocalcinosis). PH type I is caused by changes (mutations) in the AGXT gene. PH

type II is caused by mutations in the GRHPR gene. PH type III is caused by mutations in the HOGA1 gene. A diagnosis of PH is based upon identification of characteristic symptoms (e.g. chronic stone formation), a detailed patient history, a thorough clinical evaluation and a variety of specialized tests. X-ray examinations can reveal the presence of kidney stones or calcium oxalate deposits in tissue. Computed tomography (CT) scanning, a specialized imaging technique, uses a computer and x-rays to create a film showing cross-sectional images of certain tissue structures such as kidney tissue. CT or MRI can detect the severity of systemic oxalosis by imaging the retina, heart, and bone in greater detail. Certain medications may be used to treat individuals with PH including potassium citrate, thiazides, magnesium, or orthophosphates. These medications in combination with water intake can further reduce the risk of calcium and oxalate crystallization but often do not entirely prevent stone formation or kidney failure.

'Primary Hyperoxaluria - Pipeline Insight, 2021' report by DelveInsight outlays comprehensive insights of present scenario and growth prospects across the indication. A detailed picture of the Primary Hyperoxaluria pipeline landscape is provided which includes the disease overview and Primary Hyperoxaluria treatment guidelines. The assessment part of the report embraces, in depth Primary Hyperoxaluria 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, Primary Hyperoxaluria 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 Primary Hyperoxaluria R&D. The therapies under development are focused on novel approaches to treat/improve Primary Hyperoxaluria.

Primary Hyperoxaluria Emerging Drugs Chapters

This segment of the Primary Hyperoxaluria 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.

Primary Hyperoxaluria Emerging Drugs

Oxabact: OxThera

To address Primary Hyperoxaluria (PH), OxThera has taken a bacterial strain isolated from the human gut and developed a live biotherapeutic product candidate. *Oxalobacter formigenes* is an anaerobe, non-pathogenic bacterium which exclusively uses oxalate as the energy source. Administration of the bacteria at pharmacological doses to PH patients is hypothesized to promote active, incremental secretion of oxalate into the gut where it is subject to degradation and enteric elimination. This highly innovative approach reroutes oxalate elimination to the gut, thereby reducing the high oxalate burden on the kidneys. Oxabact is being evaluated in Phase III stage of development for the treatment of Primary Hyperoxaluria.

DCR-PHXC: Dicerna Pharmaceuticals

Nedosiran (formerly referred to as DCR-PHXC) is the only RNAi drug candidate in development for primary hyperoxaluria (PH) types 1, 2 and 3 and is Dicerna's most advanced product candidate utilizing the proprietary GalXC™ RNAi technology platform. Nedosiran is designed to inhibit the lactate dehydrogenase (LDH) enzyme – an enzyme that catalyzes the final step in a common pathway resulting in oxalate overproduction in patients with PH1, PH2 and PH3. Dicerna is evaluating the safety and efficacy of nedosiran in Phase III clinical trial in patients with all known forms of PH as part of its PHYOX clinical development program. In November 2014, Arbutus signed a licensing and collaboration agreement with Dicerna Pharmaceuticals, Inc., to utilize the proprietary LNP delivery technology exclusively in Dicerna's primary hyperoxaluria type 1 (PH1) development program.

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

Primary Hyperoxaluria: Therapeutic Assessment

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

Major Players in Primary Hyperoxaluria

There are approx. 8+ key companies which are developing the therapies for Primary Hyperoxaluria. The companies which have their Primary Hyperoxaluria drug candidates in the most advanced stage, i.e. Phase III include, OxThera.

Phases

DelveInsight's report covers around 8+ 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

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

Oral

Parenteral

Intravenous

Subcutaneous

Topical

Molecule Type

Products have been categorized under various Molecule types such as

Monoclonal Antibody

Peptides

Polymer

Small molecule

Gene therapy

Product Type

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

Primary Hyperoxaluria: Pipeline Development Activities

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

Primary Hyperoxaluria Report Insights

Primary Hyperoxaluria Pipeline Analysis

Therapeutic Assessment

Unmet Needs

Impact of Drugs

Primary Hyperoxaluria 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 Primary Hyperoxaluria drugs?

How many Primary Hyperoxaluria drugs are developed by each company?

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

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Primary Hyperoxaluria 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 Primary Hyperoxaluria and their status?

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

Contents

- Introduction
- Executive Summary
- Primary Hyperoxaluria: Overview
 - Causes
 - Mechanism of Action
 - Signs and Symptoms
 - Diagnosis
 - Disease Management
- Pipeline Therapeutics
 - Comparative Analysis
- Therapeutic Assessment
 - Assessment by Product Type
 - Assessment by Stage and Product Type
 - Assessment by Route of Administration
 - Assessment by Stage and Route of Administration
 - Assessment by Molecule Type
 - Assessment by Stage and Molecule Type
- Late Stage Products (Phase III)
 - Comparative Analysis
- Oxabact: OxThera
 - Product Description
 - Research and Development
 - Product Development Activities
- Drug profiles in the detailed report.....
- Mid Stage Products (Phase II)
 - Comparative Analysis
- Stiripentol: Biocodex
 - Product Description
 - Research and Development
 - Product Development Activities
- Drug profiles in the detailed report.....
- Preclinical stage products
 - Comparative Analysis
- CHK-336: Chinook therapeutics
 - Product Description
 - Research and Development
 - Product Development Activities

Drug profiles in the detailed report.....

Inactive Products

Comparative Analysis

Primary Hyperoxaluria Key Companies

Primary Hyperoxaluria Key Products

Primary Hyperoxaluria- Unmet Needs

Primary Hyperoxaluria- Market Drivers and Barriers

Primary Hyperoxaluria- Future Perspectives and Conclusion

Primary Hyperoxaluria Analyst Views

Primary Hyperoxaluria Key Companies

Appendix

List Of Tables

LIST OF TABLES

Table 1 Total Products for Primary Hyperoxaluria

Table 2 Late Stage Products

Table 3 Mid Stage Products

Table 4 Early Stage Products

Table 5 Pre-clinical & Discovery Stage Products

Table 6 Assessment by Product Type

Table 7 Assessment by Stage and Product Type

Table 8 Assessment by Route of Administration

Table 9 Assessment by Stage and Route of Administration

Table 10 Assessment by Molecule Type

Table 11 Assessment by Stage and Molecule Type

Table 12 Inactive Products

List Of Figures

LIST OF FIGURES

Figure 1 Total Products for Primary Hyperoxaluria

Figure 2 Late Stage Products

Figure 3 Mid Stage Products

Figure 4 Early Stage Products

Figure 5 Preclinical and Discovery Stage Products

Figure 6 Assessment by Product Type

Figure 7 Assessment by Stage and Product Type

Figure 8 Assessment by Route of Administration

Figure 9 Assessment by Stage and Route of Administration

Figure 10 Assessment by Molecule Type

Figure 11 Assessment by Stage and Molecule Type

Figure 12 Inactive Products

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