

# Exocrine Pancreatic Insufficiency (EPI) – Pipeline Insight, 2020

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## Abstracts

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DelveInsight's, "Exocrine Pancreatic Insufficiency (EPI) – Pipeline Insight, 2020," report provides comprehensive insights about 5+ companies and 5+ pipeline drugs in Exocrine Pancreatic Insufficiency 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

### Exocrine Pancreatic Insufficiency Understanding

#### Exocrine Pancreatic Insufficiency (EPI): Overview

Exocrine pancreatic insufficiency (EPI) is a condition characterized by deficiency of the exocrine pancreatic enzymes, resulting in the inability to digest food properly, or maldigestion. The exocrine pancreas produces three main types of enzymes: amylase, protease, and lipase. Under normal physiologic conditions, the enzymes (specifically, lipase) break undigested triglycerides into fatty acids and monoglycerides, which are then solubilized by bile salts (see Pathophysiology). Because the exocrine pancreas retains a large reserve capacity for enzyme secretion, fat digestion is not clearly impaired until lipase output decreases to below 10% of the normal level. Exocrine

pancreatic insufficiency is associated with certain diseases and conditions that affect the pancreas. Chronic pancreatitis (CP) is the most common cause of Exocrine pancreatic insufficiency in adults. Over the course of years the inflammation can lead to irreversible damage to the pancreas, including the cells that secrete pancreatic digestive enzymes and the cells that produce insulin leading to diabetes.

## Symptoms

The most common symptom of PEI is fatty stools (steatorrhea). Steatorrhea occurs when the digestive system is unable to absorb dietary fats. Instead, these fats pass through the intestinal tract with waste products. The stools tend to be oily, large, pale, very foul-smelling, and often float in toilet water and stay in the toilet bowl, even after flushing. Individuals with steatorrhea sometimes experience fecal incontinence or oily leakage. Intestinal gas and bloating can also occur from the fermentation of undigested food in the colon. Many individuals with PEI will experience nutritional deficiencies, especially of fat-soluble vitamins such as A, D, E, and K, since they are not taking in enough fats to help absorb these vitamins.

## Diagnosis

The symptoms of PEI are often similar to other gastrointestinal illnesses, which can make diagnosis difficult. Blood tests: These can include the following:

Complete blood count (CBC)

Antigliadin and antiendomysial antibodies

## Stool tests

Determination of fecal elastase and chymotrypsin (2 proteases produced by the pancreas) can be used to try to distinguish between pancreatic causes and intestinal causes of malabsorption.

## Treatment

Treatment for EPI includes dietary management, lifestyle changes (i.e., decrease in alcohol consumption and smoking cessation), and pancreatic enzyme replacement therapy.

Lifestyle modifications (eg, avoidance of fatty foods, limitation of alcohol intake, cessation of smoking, and consumption of a well-balanced diet)

Vitamin supplementation (primarily the fat-soluble vitamins A, D, E, and K)

Pancreatic enzyme replacement therapy (PERT), which is the therapeutic mainstay

## Exocrine Pancreatic Insufficiency Emerging Drugs Chapters

This segment of the Exocrine Pancreatic Insufficiency 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.

## Exocrine Pancreatic Insufficiency Emerging Drugs

### MS1819: AzurRx BioPharma/Mayoly-Spindler

MS1819, a recombinant lipase derived from the yeast *Yarrowia Lipolytica*, is in development for the treatment of exocrine pancreatic insufficiency (EPI) associated with chronic pancreatitis (CP) and cystic fibrosis (CF). Early Phase Ib data in EPI patients treated with MS1819 showed a favorable safety profile and encouraging preliminary signals of efficacy. AzurRx is currently conducting a Phase IIa trial of MS1819 for the treatment of exocrine pancreatic insufficiency (EPI) associated with chronic pancreatic pancreatitis (CP). The study is being performed at four sites in Australia and New Zealand with a target enrollment of 12-15 patients. In addition to assessing safety, AzurRx is evaluating four escalating dose increments of MS1819, with the aim of elucidating the optimal treatment dose to be taken into subsequent registration trials in EPI patients with chronic pancreatitis (CP) and cystic fibrosis (CF).

Further product details are provided in the report

## Exocrine Pancreatic Insufficiency: Therapeutic Assessment

This segment of the report provides insights about the different Exocrine Pancreatic

Insufficiency drugs segregated based on following parameters that define the scope of the report, such as:

### Major Players in Exocrine Pancreatic Insufficiency

There are approx. 5+ key companies which are developing the therapies for Exocrine Pancreatic Insufficiency. The companies which have their Exocrine Pancreatic Insufficiency drug candidates in the mid to advanced stage, i.e. phase III and Phase II include, AzurRx BioPharma, Inc., Abbott, Digestive Care, Inc. etc.

### Phases

DelveInsight's report covers around 5+ 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

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

Exocrine Pancreatic Insufficiency 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

Intramuscular

Intravenous

Molecule Type

Products have been categorized under various Molecule types such as

Recombinant proteins

Pancreatic enzymes

Product Type

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

### Exocrine Pancreatic Insufficiency: Pipeline Development Activities

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

### Report Highlights

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

August 2020: First patients enrolled in phase 2b trial testing MS1819 for Exocrine Pancreatic Insufficiency in CF. The OPTION 2 trial aims to evaluate the safety, tolerability, and efficacy of MS1819 compared to current standard of care, porcine (from pigs) enzyme replacement therapy. Recruitment is currently open at four U.S. locations with plans to expand to 15 locations in the U.S. and Europe.

## Exocrine Pancreatic Insufficiency Report Insights

Exocrine Pancreatic Insufficiency Pipeline Analysis

Therapeutic Assessment

Unmet Needs

Impact of Drugs

## Exocrine Pancreatic Insufficiency 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 Exocrine Pancreatic Insufficiency drugs?

How many Exocrine Pancreatic Insufficiency drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Exocrine Pancreatic Insufficiency?

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

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

### Key Players

Digestive Care, Inc.

AzurRx BioPharma, Inc.

Abbott

Orlando Health, Inc.

Chiesi Farmaceutici

### Key Products

Pancrelipase

MS1819

## Contents

Introduction

Executive Summary

Exocrine Pancreatic Insufficiency: 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

Exocrine Pancreatic Insufficiency – DelveInsight's Analytical Perspective

In-depth Commercial Assessment

Exocrine Pancreatic Insufficiency companies' collaborations, Licensing, Acquisition  
-Deal Value Trends

Exocrine Pancreatic Insufficiency Collaboration Deals

Company-Company Collaborations (Licensing / Partnering) Analysis

Company-University Collaborations (Licensing / Partnering) Analysis

Mid Stage Products (Phase II)

Comparative Analysis

Recombinant lipase: AzurRx BioPharma/Mayoly-Spindler

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....

Pre-clinical and Discovery Stage Products

Comparative Analysis

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....



Inactive Products

Comparative Analysis

Exocrine Pancreatic Insufficiency Key Companies

Exocrine Pancreatic Insufficiency Key Products

Exocrine Pancreatic Insufficiency- Unmet Needs

Exocrine Pancreatic Insufficiency- Market Drivers and Barriers

Exocrine Pancreatic Insufficiency- Future Perspectives and Conclusion

Exocrine Pancreatic Insufficiency Analyst Views

Exocrine Pancreatic Insufficiency Key Companies

Appendix

## List Of Tables

### LIST OF TABLES

Table 1 Total Products for Exocrine Pancreatic Insufficiency

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 Exocrine Pancreatic Insufficiency

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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