

# Dry Eye Disease - Pipeline Insight, 2021

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## Abstracts

This report can be delivered to the clients within 2-3 business days

DelveInsight's, "Dry Eye Disease – Pipeline Insight, 2021," report provides comprehensive insights about 50+ companies and 50+ pipeline drugs in Dry Eye Disease 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

### Dry Eye Disease Understanding

#### Dry Eye Disease: Overview

Dry eye is a condition in which a person doesn't have enough quality tears to lubricate and nourish the eye. Tears are necessary for maintaining the health of the front surface of the eye and for providing clear vision. Dry eye is a common and often chronic problem, particularly in older adults. With each blink of the eyelids, tears spread across the front surface of the eye, known as the cornea. Tears provide lubrication, reduce the risk of eye infection, wash away foreign matter in the eye and keep the surface of the eyes smooth and clear. Dry eyes can occur when tear production and drainage are not in balance. People with dry eyes either do not produce enough tears or their tears are of a poor quality: Inadequate amount of tears, Poor quality of tears. People with dry eyes may experience irritated, gritty, scratchy or burning eyes; a feeling of something in their

eyes; excess watering; and blurred vision. Dry eyes can be diagnosed through a comprehensive eye examination. Testing with emphasis on the evaluation of the quantity and quality of tears produced by the eyes may include: patient history, external examination, evaluation of eyelids. Treatments for dry eyes aim to restore or maintain the normal amount of tears in the eye to minimize dryness and related discomfort and to maintain eye health. Dry eyes can be a chronic condition, but a doctor of optometry can prescribe treatment to keep your eyes healthy and comfortable and to prevent your vision from being affected. The primary approaches used to manage and treat dry eyes include adding tears using over-the-counter artificial tear solutions, conserving tears, increasing tear production, and treating the inflammation of the eyelids or eye surface that contributes to the dry eyes.

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

## Dry Eye Disease Emerging Drugs Chapters

This segment of the Dry Eye Disease 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.

## Dry Eye Disease Emerging Drugs

### OC-01: Oyster Point Pharma

OC-01, a highly selective nicotinic acetylcholine receptor (nAChR) agonist, is being developed as a preservative-free nasal spray to treat the signs and symptoms of dry eye disease. The parasympathetic nervous system, the “rest and digest” system of the body, controls tear film homeostasis partially via the trigeminal nerve which is accessible within the nose. Additionally, in preclinical models, it has been shown that OC-01 (varenicline) nasal spray may have the potential to modulate the amount of selected proteins, peptides, antibodies, hormones, enzymes or cytokines secreted from the lacrimal gland into the tear film and onto the ocular surface. The U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for OC-01 (varenicline) nasal spray for the treatment of signs and symptoms of dry eye disease. The Prescription Drug User Fee Act (PDUFA) target action date for OC-01 (varenicline) nasal spray is October 17, 2021.

### Reproxalap: Aldeyra Therapeutics

By inhibiting RASP, which are elevated in a variety of inflammatory diseases, reproxalap represents a novel mechanism for diminishing ocular inflammation in dry eye disease. In a number of clinical trials, reproxalap demonstrated consistent statistically significant and clinically relevant activity. Additionally, reproxalap, if approved, has added the potential of being the only product that may be able to effectively treat dry eye disease, uniquely addressing the needs of the large underserved population that suffers from this disease. The drug is being evaluated in Phase III clinical trial to treat dry eye disease.

### RGN-259: ReGenTree

RegeneRx drug candidate, RGN-259, is the subject of two Phase III clinical trials in the U.S. for patients with dry eye syndrome and neurotrophic keratopathy (an orphan indication). ReGenTree is a U.S. joint venture company owned by GtreeBNT Co., Ltd, and RegeneRx Biopharmaceuticals, Inc., specifically to develop RGN-259 in both the U.S. and Canada for ophthalmic indications. ReGenTree licensed the rights to RGN-259 from RegeneRx in 2015. ReGenTree reports Positive Results from ARISE-3 Clinical Trial Using RGN-259 to treat Dry Eye Syndrome.

### HL036: HanAll Biopharma

HL036, also known as Tanfanercept, is a new biological drug that can treat dry eye syndrome, which causes eye surface damage, irritation and foreign body sensation caused by the lack of tears or excessive evaporation. It has a new mechanism of inhibiting TNF $\alpha$  that causes inflammation in the eye. The company has been conducting the phase 3 clinical trial at 12 medical institutions in the U.S. through Ora, a local contract research organization.

### NOV03: Novaliq

NOV03 (100% perfluorohexyloctane) is the first drug developed to treat dry eye disease (DED) associated with Meibomian gland dysfunction in a highly effective way. NOV03 prevents excessive tear evaporation and has the ability to restore tear film balance. The investigational drug has a unique mode-of-action: It stabilizes the lipid layer for hours to protect the tear film and has the ability to penetrate the Meibomian glands. In a Phase II study, NOV03 met its primary sign endpoint of improvement of total corneal fluorescein staining over control at eight weeks with high statistical significance (p < 0.001). Further product details are provided in the report.....

### Dry Eye Disease: Therapeutic Assessment

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

### Major Players in Dry Eye Disease

There are approx. 50+ key companies which are developing the therapies for Dry Eye Disease. The companies which have their Dry Eye Disease drug candidates in the most advanced stage, i.e. Preregistration include, Oyster Point Pharma.

### Phases

DelveInsight's report covers around 50+ 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

Dry Eye Disease 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.

Dry Eye Disease: Pipeline Development Activities

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

Dry Eye Disease Report Insights

Dry Eye Disease Pipeline Analysis

Therapeutic Assessment

Unmet Needs

Impact of Drugs

Dry Eye Disease 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 Dry Eye Disease drugs?

How many Dry Eye Disease drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Dry Eye Disease?

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

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

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Dry Eye Disease Key Products

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