Bullous Keratopathy Market Report 2032: Epidemiology Data, Therapies, Latest FDA, EMA, PDMA Approvals by DelveInsight

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LAS VEGAS, NEVADA, UNITED STATES, April 3, 2024 /EINPresswire.com/ -- DelveInsight's "Bullous Keratopathy Market Insights, Epidemiology, and Market Forecast-2032" report offers an in-depth understanding of the Bullous Keratopathy, historical and forecasted epidemiology as well as the Bullous Keratopathy market trends in the United States, EU4 (Germany, Spain, Italy, France) the United Kingdom and Japan.

To Know in detail about the Bullous Keratopathy market outlook, drug uptake, treatment scenario and epidemiology trends, Click here; Bullous Keratopathy Market Forecast

Some of the key facts of the Bullous Keratopathy Market Report:

The Bullous Keratopathy market size is anticipated to grow with a significant CAGR during the study period (2019-2032).
The occurrence of bullous keratopathy has been increasing in the US due to the increase in etiologies of bullous keratopathy. The major etiologies include Fuchs endothelial corneal dystrophy, cataract surgery, and glaucoma surgery.
Advancements in understanding corneal endothelium function and epithelial cell regeneration have developed pharmacological and less invasive surgical techniques like DSAEK and DMEK. Further, advanced diagnostic techniques like slit-lamp examination and ultrasound biomicroscopy have improved bullous keratopathy diagnosis.
The current treatment regime is symptomatic. Medications such as lubricating eye drops, hyperosmotic medicines, antiglaucoma, steroids, ointments, or bandage contact lenses are used to alleviate symptoms.
In severe cases, especially where vision is significantly impaired and quality of life is affected, corneal transplantation (keratoplasty) is considered.
The major concern in understanding the market for bullous keratopathy is a lack of recent epidemiology studies and a paucity of evidence to validate interventions used in daily managing bullous keratopathy. No diagnostic or clinical guidelines for bullous keratopathy are available in the US, EU4 and the UK, and Japan.
Fusing various technologies like magnetic nanoparticles and iPS cells to develop novel

treatments will facilitate the effective delivery and retention of therapeutic agents at the target site.
In 2022, the market size of bullous keratopathy was highest in the US among the 7MM countries, accounting for approximately USD 7.7 million. It is expected to increase by 2032.
Although corneal transplant surgeries are often used, they carry inherent risks, including rejection, infection, and graft failure, and are associated with high costs. Moreover, there is a lack of cornea donors.
Emerging therapy VYZNOVA (neltependocel) will create a positive shift in the US, EU, and Japan markets of bullous keratopathy. This allogeneic cell therapy is a human corneal endothelial cell therapy formulated as a solution for the intracameral route of administration and launched in Japan in March 2023.
Other assets, including Trefoil Therapeutics' TTHX1114 (NM141), Emmecells' EO2002, and Cellusions' CLS001, are in their early development phase.
TTHX1114 (NM141) is an engineered form of fibroblast growth factor-1 protein (FGF-1) designed to increase the half-life of the FGF-1 molecule and to stimulate the proliferation and migration of corneal endothelial cells in pseudophakic bullous keratopathy patients.
With no approved treatment in the US and EU, limited application of corneal transplant, and significant risk of rejections, there is a window of opportunity for pharma companies to develop pharmacological therapies.
Key Bullous Keratopathy Companies: Cellusion, Emmecell, Trefoil Therapeutics, and others
Key Bullous Keratopathy Therapies: TTHX1114 (NM141), EO2002, and others
The Bullous Keratopathy epidemiology based on gender analyzed that Males are slightly more affected in the case of Bullous Keratopathy
The Bullous Keratopathy market is expected to surge due to the disease's increasing prevalence and awareness during the forecast period. Furthermore, launching various multiple-stage Bullous Keratopathy pipeline products will significantly revolutionize the Bullous Keratopathy market dynamics.

Bullous Keratopathy Overview

Keratopathy, stemming from the words "kera" for cornea and "pathy" for disease, refers to various conditions affecting the cornea, each with diverse underlying causes and mechanisms. It can arise from ocular or systemic conditions and encompasses multiple types, including bullous keratopathy.

Bullous keratopathy presents as the formation of small fluid-filled vesicles, or bullae, in the cornea due to endothelial dysfunction. Initially, endothelial trauma occurs, leading to progressive stromal and epithelial swelling. Epithelial swelling eventually results in bullae formation, hence the term bullous keratopathy.

Also known as pseudophakic bullous keratopathy (PBK) or pseudophakic corneal edema (PCE) in certain contexts, this condition specifically affects individuals who have undergone cataract surgery and received an intraocular lens (IOL) implant. Its hallmark is the appearance of fluid-

filled blisters on the cornea, causing discomfort, blurred vision, and other visual impairments. Bullous keratopathy typically arises from damage to the corneal endothelium, the innermost layer of cells responsible for maintaining corneal clarity and regulating fluid balance.

Several factors can contribute to bullous keratopathy, including conditions like Fuchs' endothelial dystrophy, various eye surgeries such as cataract or glaucoma surgery, eye trauma, and corneal transplantation. Prolonged wear of contact lenses is also implicated in damaging the corneal endothelium and triggering bullous keratopathy, as suggested by studies.

Bullous Keratopathy Epidemiology

The epidemiology section provides insights into the historical, current, and forecasted epidemiology trends in the seven major countries (7MM) from 2019 to 2032. It helps to recognize the causes of current and forecasted trends by exploring numerous studies and views of key opinion leaders. The epidemiology section also provides a detailed analysis of the diagnosed patient pool and future trends.

Bullous Keratopathy Epidemiology Insights:

In 2022, the total bullous keratopathy cases in FECD were approximately 79,250 in the 7MM, which is expected to increase by 2032.
Among the 7MM, the US accounted for the highest number of bullous keratopathy cases in the 7MM. Among total cases of bullous keratopathy, cataract surgery patients contributed to nearly 49.4% in the US, while Spain accounted for the least, making up 7.1% of the total bullous keratopathy cases in 2022.
In EU4 and the UK, out of total glaucoma surgery patients, 5,389 were affected by bullous keratopathy in 2022. The bullous keratopathy cases in glaucoma surgery patients are expected to increase by 2032.
In the US, there were around 77,896 cases of bullous keratopathy in 2022, and the cases are expected to increase by 2032.
Among EU4 and the UK, Germany contributed the highest number of bullous keratopathy cases (nearly 25,692), followed by France, Italy, the UK, and Spain in 2022.
In 2022, among the 7MM, Japan ranked fifth and contributed nearly 9% to the total bullous keratopathy cases.
Of the total cases of bullous keratopathy in Japan, around 87% of the cases were contributed by cataract surgery, while nearly 10% and 2% of the cases were contributed by glaucoma surgery and Fuchs endothelial corneal dystrophy, respectively, in 2022.
According to estimates based on DelveInsight's epidemiology model, bullous keratopathy affects more females than males. In EU4 and the UK, around 39% of males and 61% of females were affected by bullous keratopathy in 2022, and the cases are expected to increase during the forecast period.
In Japan, approximately 7,371 males and 10,306 females were affected by bullous keratopathy in 2022; the cases are expected to decrease by 2032.

Among the 7MM, the US accounted for the highest number of bullous keratopathy cases in corneal transplants. Of the total corneal transplant cases, around 28% were affected by bullous keratopathy in 2022.
In Japan, there were 2,322 corneal transplant cases in 2022, of which approximately 55% were affected by bullous keratopathy.

Bullous Keratopathy Epidemiology Segmentation:

The Bullous Keratopathy market report proffers epidemiological analysis for the study period 2019–2032 in the 7MM segmented into:

Total Prevalence of Bullous Keratopathy
Prevalent Cases of Bullous Keratopathy by severity
Gender-specific Prevalence of Bullous Keratopathy
Diagnosed Cases of Episodic and Chronic Bullous Keratopathy

Download the report to understand which factors are driving Bullous Keratopathy epidemiology trends @ Bullous Keratopathy Epidemiology Forecast

Bullous Keratopathy Drugs Uptake and Pipeline Development Activities

The drugs uptake section focuses on the rate of uptake of the potential drugs recently launched in the Bullous Keratopathy market or expected to get launched during the study period. The analysis covers Bullous Keratopathy market uptake by drugs, patient uptake by therapies, and sales of each drug.
Moreover, the therapeutics assessment section helps understand the drugs with the most rapid uptake and the reasons behind the maximal use of the drugs. Additionally, it compares the drugs based on market share.

The report also covers the Bullous Keratopathy Pipeline Development Activities. It provides valuable insights about different therapeutic candidates in various stages and the key companies involved in developing targeted therapeutics. It also analyzes recent developments such as collaborations, acquisitions, mergers, licensing patent details, and other information for emerging therapies.

Bullous Keratopathy Therapies

TTHX1114 (NM141)
EO2002
Bullous Keratopathy Key Companies
Cellusion, Emmecell
Trefoil Therapeutics

Discover more about therapies set to grab major Bullous Keratopathy market share @ Bullous Keratopathy Treatment Landscape

Bullous Keratopathy Market Insights

The total market size of bullous keratopathy in the 7MM was approximately USD 13.6 million in 2022 and is projected to increase during the forecast period (2023–2032).
The market size of bullous keratopathy in the US will increase at a CAGR of 13.3% due to increasing etiologies of the disease and the launch of the emerging therapy.
In 2022, the standard of care generated nearly USD 7.7 million in revenue in the US for bullous keratopathy, which is anticipated to decrease during the forecast period owing to the launch of emerging therapies.
Among EU4 and the UK countries, Germany accounted for the maximum market size of bullous keratopathy in 2022, while Spain occupied the bottom of the ladder.
Germany accounted for the second largest market of bullous keratopathy among the 7MM, taking around 27% share of EU4 and the UK market in 2022.
Japan accounted for the third largest market of bullous keratopathy among the 7MM, with a revenue of approximately USD 1.1 million in 2022, expected to increase during the forecast period.
In the US, VYZNOVA (neltependocel) is expected to enter by 2029, while in EU4 and the UK, it is estimated to launch by 2030.
In Japan, VYZNOVA (neltependocel) was launched in 2023 and is expected to attain a peak in its seventh year.

Bullous Keratopathy Market Outlook

The present treatment landscape for bullous keratopathy encompasses both pharmacological and surgical interventions. Medications like cell therapy, hypertonic saline drops, antibiotic and anti-inflammatory agents, antiglaucoma drugs, and lubricating drops are employed for symptomatic relief, particularly in the early stages of the disease. However, if medical management proves ineffective, surgical options are pursued.

Corneal transplantation stands as the primary treatment modality for bullous keratopathy, involving the replacement of damaged endothelium with healthy endothelium from a donor cornea to restore normal structure and function. While effective, visual recovery after transplantation may require time, with grafts typically sized between 7 to 7.5 mm to minimize complications such as astigmatism and secondary glaucoma.

A notable advancement in treatment occurred with the global approval of VYZNOVA, the first allogenic cell therapy for corneal endothelial disease, by PMDA in March 2023. This therapy provides a non-surgical alternative by utilizing fully differentiated corneal endothelial cells (CECs) from a single donor to treat bullous keratopathy. Cultured healthy cells are administered intracamerally to repopulate the cornea's endothelial layer, leading to a reduction in corneal

edema.

Additionally, the use of steroids is recommended to manage acute inflammation or postoperative uveitis following cataract surgery, with systemic L-cysteine demonstrating efficacy in promoting corneal edema remission during the postoperative period. Rho-kinase inhibitors like ripasudil and netarsudil have emerged as promising treatments for early endothelial decompensation, promoting endothelial cell proliferation and reducing the risk of corneal decompensation.

While corneal transplantation remains the gold standard, less invasive techniques like Descemet membrane endothelial keratoplasty (DMEK) and Descemet stripping automated endothelial keratoplasty (DSAEK) have revolutionized the transplant paradigm, offering alternatives to full-thickness transplantation.

Despite available treatments, limitations persist. Symptomatic relief is temporary, and corneal transplantation poses inherent surgical risks. However, the approval of VYZNOVA represents a significant milestone in providing non-surgical therapeutic options. Ongoing research into corneal endothelial regeneration holds promise for the development of novel therapies, but the current pipeline is limited, with VYZNOVA expected to be the sole drug launch in the forecast period for the US and EU markets.

Scope of the Bullous Keratopathy Market Report:

Study Period: 2019–2032
Coverage: 7MM [The United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan]
Key Bullous Keratopathy Companies: Cellusion, Emmecell, Trefoil Therapeutics, and others
Key Bullous Keratopathy Therapies: TTHX1114 (NM141), EO2002, and others
Bullous Keratopathy Therapeutic Assessment: Bullous Keratopathy current marketed and Bullous Keratopathy emerging therapies
Bullous Keratopathy Market Dynamics: Bullous Keratopathy market drivers and Bullous Keratopathy market barriers
Competitive Intelligence Analysis: SWOT analysis, PESTLE analysis, Porter’s five forces, BCG Matrix, Market entry strategies
Bullous Keratopathy Unmet Needs, KOL’s views, Analyst’s views, Bullous Keratopathy Market Access and Reimbursement

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Related Reports:

Bullous Keratopathy Pipeline

"Bullous Keratopathy Pipeline Insight, 2024" report by DelveInsight outlines comprehensive insights of present clinical development scenarios and growth prospects across the Bullous Keratopathy market. A detailed picture of the Bullous Keratopathy pipeline landscape is provided, which includes the disease overview and Bullous Keratopathy treatment guidelines.

Bullous Keratopathy Epidemiology

DelveInsight's 'Bullous Keratopathy Epidemiology Forecast to 2032' report delivers an in-depth understanding of the disease, historical and forecasted Bullous Keratopathy epidemiology in the 7MM, i.e., the United States, EU5 (Germany, Spain, Italy, France, and the United Kingdom), and Japan.

About DelveInsight

DelveInsight is a leading Healthcare Business Consultant, and Market Research firm focused exclusively on life sciences. It supports Pharma companies by providing comprehensive end-to-end solutions to improve their performance.

It also offers Healthcare Consulting Services, which benefits in market analysis to accelerate the business growth and overcome challenges with a practical approach.

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