

Menkes Disease Market Report 2034: Epidemiology, Pipeline Therapies, Latest FDA, EMA, PDMA Approvals by DelveInsight

Menkes Disease companies are Cyprium Therapeutics, Sentyln Therapeutics, and others.

LAS VEGAS, NEVADA, UNITED STATES, June 13, 2024 /EINPresswire.com/ -- DelveInsight's "Menkes Disease Market Insights, Epidemiology, and Market Forecast-2034" report offers an in-depth understanding of the Menkes Disease, historical and forecasted epidemiology as well as the Menkes Disease market trends in the United States, EU4 (Germany, Spain, Italy, France) the United Kingdom and Japan.



To Know in detail about the Menkes Disease market outlook, drug uptake, treatment scenario and epidemiology trends, Click here; [Menkes Disease Market Forecast](#)

Recent advancement in the Menkes Disease Market:

In 2021, Sentyln and Cyprium reported positive results from a safety and efficacy analysis of data integrated from two completed pivotal studies in patients with Menkes disease treated with CUTX-101. A rolling submission of the CUTX-101 New Drug Application (NDA) to the FDA is ongoing, with expected completion in 2024. Menkes disease is a rare X-linked pediatric disease caused by gene mutations of copper transporter ATP7A, and currently, there is no FDA-approved treatment for it and its variants. However, CUTX-101 (copper histidinate), a subcutaneous injectable formulation, has been granted Fast Track designation by the FDA for the treatment of patients with classic Menkes disease who have not shown significant clinical progression. Clinical data from a Phase 1/2 study showed improvements in neurodevelopmental outcomes and survival when early initiation with CUTX-101 was used in patients with Menkes disease.

Some of the key facts of the Menkes Disease Market Report:

The Menkes Disease market size is anticipated to grow with a significant CAGR during the study period (2020-2034).

In 2023, the Menkes Disease market size was highest in the US among the Seven Major Markets (7MM), totaling approximately USD 7 million, with expectations for further growth by 2034. The entire market, primarily consisting of Standard of Care treatments, reached about USD 7.9 million in 2023 across the 7MM.

The diagnosed prevalence of Menkes Disease is projected to increase due to advancements in genetic testing, heightened awareness, improved survival rates, genetic predisposition, expanded screening practices, and environmental factors.

In 2023, the US accounted for the largest share of diagnosed Menkes Disease cases in the 7MM, comprising 54% of the total, followed by Japan at approximately 11%. Among European nations, France had the highest number of cases, making up around 9% of the total cases in the 7MM. Despite the steady rise in Menkes Disease prevalence, which saw approximately 177 diagnosed cases reported in the 7MM in 2023, there remains a notable gap in approved therapies specifically tailored for its treatment.

Key Menkes Disease Companies: Cyprium Therapeutics, Sentyln Therapeutics, and others

Key Menkes Disease Therapies: CUTX-101, and others

In 2023, the total market size of Menkes disease across the Seven Major Markets (7MM) reached approximately USD 7.9 million, with forecasts indicating an increase during the period from 2024 to 2034.

The market in the 7MM is expected to grow steadily with a constant compound annual growth rate (CAGR), driven by heightened awareness of the disease, improved diagnostic capabilities, and the introduction of emerging targeted therapies for Menkes disease.

Within the EU4 and the UK, France held the largest market share at 27% in 2023, while Spain had the smallest share at 12%.

The treatment market in the 7MM currently lacks approved targeted therapies for Menkes Disease. However, with the anticipated launch of CUTX-101 by 2025, the market is poised for positive growth.

The Menkes Disease market is expected to surge due to the disease's increasing prevalence and awareness during the forecast period. Furthermore, launching various multiple-stage Menkes Disease pipeline products will significantly revolutionize the Menkes Disease market dynamics.

Menkes Disease Overview

Menkes disease is a fatal infantile neurodegenerative disorder inherited in an X-linked manner. It arises from mutations in the ATP7A gene, crucial for copper transport throughout the body. The condition's progression leads to a rapid decline in the quality of life (QoL) for affected individuals, with increasing severity of symptoms and outcomes.

Newborns with Menkes disease may exhibit seizures, low muscle tone, abnormalities in blood vessel structure, and multiple organ defects. The mortality rate among patients is exceptionally high, making the experience profoundly distressing for parents and families.

Comprehensive support, both financial and emotional, is crucial for families grappling with this

devastating condition. Counseling should be provided to families, addressing the current situation and the potential for the disease to recur within the family.

Menkes Disease Epidemiology

The epidemiology section provides insights into the historical, current, and forecasted epidemiology trends in the seven major countries (7MM) from 2020 to 2034. 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.

According to our assessment, in 2023, there were an estimated nearly 177 diagnosed prevalent cases of Menkes Disease in the Seven Major Markets (7MM), with expectations for an increase by 2034. The United States reported the highest number of cases.

Among European countries in 2023, France had the largest diagnosed prevalent population of Menkes Disease at 26%, followed closely by Germany and the UK at 24%. Conversely, Spain had the lowest diagnosed prevalent population at 11% in the same year.

In 2023, Japan accounted for approximately 19 diagnosed prevalent cases of Menkes Disease.

Menkes Disease Epidemiology Segmentation:

The Menkes Disease market report proffers epidemiological analysis for the study period 2020–2034 in the 7MM segmented into:

Total Prevalence of Menkes Disease

Prevalent Cases of Menkes Disease by severity

Gender-specific Prevalence of Menkes Disease

Diagnosed Cases of Episodic and Chronic Menkes Disease

Download the report to understand which factors are driving Menkes Disease epidemiology trends @ [Menkes Disease Epidemiology Forecast](#)

Menkes Disease Drugs Uptake and Pipeline Development Activities

The drugs uptake section focuses on the rate of uptake of the potential drugs recently launched in the Menkes Disease market or expected to get launched during the study period. The analysis covers Menkes Disease 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 Menkes Disease 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.

Menkes Disease Therapies

CUTX-101

Menkes Disease Key Companies

Cyprium Therapeutics, Sentyln Therapeutics

Discover more about therapies set to grab major Menkes Disease market share @ [Menkes Disease Treatment Landscape](#)

Menkes Disease Emerging Drugs Profile:

CUTX-101: Cyprium Therapeutics/Sentyln Therapeutics

CUTX-101 is currently being investigated for the treatment of Menkes disease and related disorders. It has not yet received approval as a safe and effective treatment from the US FDA or any other regulatory bodies. However, it is accessible through an Expanded Access Protocol, allowing collection of additional safety and efficacy data that could support future product approval and broader availability to Menkes disease patients.

The drug has received several designations from the FDA, including Breakthrough Therapy, Fast Track, Rare Pediatric Disease, and Orphan Drug Designations. Additionally, the European Medicines Agency granted it Orphan Drug Designation. In December 2023, Cyprium completed the transfer of its proprietary rights and FDA-related documents for the CUTX-101 Copper Histidinate product candidate for Menkes disease treatment to Sentyln Therapeutics, Inc. Sentyln is currently engaged in a rolling submission of a New Drug Application (NDA) to the FDA for CUTX-101, with completion expected in 2024.

Menkes Disease Market Outlook

Disorders affecting copper balance are now recognized across all stages of life. Their understanding and connection to human disease have evolved over decades, beginning with the identification of a degenerative condition in lambs born to sheep grazing on copper-deficient pastures. This journey extends to the recognition of infants suffering from a progressive neurodegenerative disorder marked by epileptic seizures, developmental regression, failure to thrive, and distinct hair abnormalities, which led to its colloquial name, kinky hair disease.

The development of Menkes disease is rapid and unpredictable, often necessitating urgent

medical intervention. Unfortunately, the prognosis for these patients is bleak; without access to therapies like copper histidine or other copper replacement treatments, survival rarely exceeds 3.5 years. Current management of Menkes disease primarily revolves around standard of care practices, including off-label use of copper supplements (such as copper histidine or copper chloride), antiepileptic medications, L-threo-dihydroxyphenylserine, and other supportive therapies.

Advancements in therapeutic strategies are paving the way for new treatments in Menkes disease, such as CUTX-101, among others, currently in development.

CUTX-101 appears to be the most promising candidate in the clinical pipeline for Menkes disease. Anticipated approval of this emerging therapy is expected to positively impact the market, establishing it as a leading treatment option in a field where no other therapies have yet gained approval. We foresee that the approval of new therapies and increased awareness regarding early disease screening will significantly drive market growth.

Scope of the Menkes Disease Market Report:

Study Period: 2020–2034

Coverage: 7MM [The United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan]

Key Menkes Disease Companies: Cyprium Therapeutics, Sentyln Therapeutics, and others

Key Menkes Disease Therapies: CUTX-101, and others

Menkes Disease Therapeutic Assessment: Menkes Disease current marketed and Menkes Disease emerging therapies

Menkes Disease Market Dynamics: Menkes Disease market drivers and Menkes Disease market barriers

Competitive Intelligence Analysis: SWOT analysis, PESTLE analysis, Porter's five forces, BCG Matrix, Market entry strategies

Menkes Disease Unmet Needs, KOL's views, Analyst's views, Menkes Disease Market Access and Reimbursement

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Related Reports:

Menkes Disease Pipeline

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

Menkes Disease Epidemiology

DelveInsight's 'Menkes Disease Epidemiology Forecast to 2034' report delivers an in-depth understanding of the disease, historical and forecasted Menkes Disease epidemiology in the 7MM, i.e., the United States, EU5 (Germany, Spain, Italy, France, and the United Kingdom), and Japan.

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