

Cryopyrin-associated Periodic Syndromes (CAPS) - Market Insights, Epidemiology, and Market Forecast - 2030

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Abstracts

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DelveInsight's 'Cryopyrin-associated Periodic Syndromes (CAPS) - Market Insights, Epidemiology and Market Forecast—2030' report delivers an in-depth understanding of the CAPS, historical and forecasted epidemiology as well as the CAPS market trends in the United States.

The CAPS market report provides current treatment practices, emerging drugs, CAPS market share of the individual therapies, current and forecasted CAPS market size from 2017 to 2030 in the United States. The Report also covers current CAPS treatment practice/algorithm, market drivers, market barriers and unmet medical needs to curate best of the opportunities and assesses underlying potential of the market.

Geography Covered

The United States

Study Period: 2017–2030

Cryopyrin-associated Periodic Syndromes (CAPS): Disease Understanding and Treatment Algorithm

Overview

Cryopyrin-associated Periodic Syndromes (CAPS) is a group of auto-inflammatory as well as known autosomal dominant disorder that is believed to be caused by owing to mutations in the NLRP3 gene encoding a protein called cryopyrin. NLRP3 is a part of the inflammasome protein. For initiation of the innate inflammatory response, inflammasome activation is needed. Other CAPS also cause mutations in NLRP3, which in turn leads to the overproduction of Interleukin beta-1 (IL-1?) CAPS and basically comprises of three diseases that vary with the severity and the system they are involved in. The mode of inheritance is autosomal dominant with variable penetrance (means only one copy of the gene from one parent is sufficient enough to cause this medical condition).

CAPS comprises a group of three disorders, varying with their severity and the organs they tend to affect upon the onset, namely Neonatal Onset Multisystem Inflammatory Disease (NOMID), also called as Chronic Inflammatory Neurological Cutaneous Articular Syndrome (CINCA), Familial cold auto inflammatory syndrome (FCAS) and Muckle–Wells syndrome (MWS). NOMID is the most severe form of CAPS, along with episodic fever and chills, is accompanied by other associated symptoms like Central Nervous System Inflammation fever bouts (beginning in infancy), followed by rash flare-ups, and elevated joint pain and red eyes. On the other hand, MWS is an intermediate form of CAPS. In this case, symptoms like frequent rashes starts in infancy or early adolescence. Occasional fever, joint pain, frequent conjunctivitis, gradual hearing loss, and amyloidosis are symptoms of MWS. FCAS, also known as familial cold urticaria is the mildest form of CAPS with fever and other symptoms, the onset of rash flares begins in early childhood or occasionally in early childhood in all FCAS patients. Hearing loss and Amyloidosis renal disease is rare in FCAS patients. The symptoms and severity of CAPS vary by disease, but some of the sign include, inflammation in multiple organs, hive-like rash, periodic fever and flare-ups, headache, bulging eyes, blindness, hearing loss, vomiting, joint pain, swelling etc. Other symptoms that are specific to one type of disease include, hive-like rash on exposure to cold or other environmental triggers in FCAS and in MWS, symptoms may come and go.

Cryopyrin-associated Periodic Syndromes (CAPS) Diagnosis

Diagnosis of CAPS is based on clinical manifestations and on laboratory findings revealing generalized leukocytosis and neurophilia along with others elevated acute phase reactants (C reactive protein and serum amyloid A). Some of the laboratory tests that are used include, genetic testing that recognizes differences in chromosomes, genes, or proteins. Skin Biopsy of the rash, eye examination, hearing tests, imaging tests, etc.

Cryopyrin-associated Periodic Syndromes (CAPS) Treatment

In order to treat a rare disease such as CAPS, several anti-inflammatory medications, immunosuppressants, and antihistamines have been tested to regulate the signs and symptoms seen in CAPS. These include, methotrexate, cyclosporine, azathioprine, cyclophosphamide, and tumor necrosis factor blockers but they have all been unsuccessful. In recent years, research has shown that biologic drugs targeting interleukin-1 are effective in treating CAPS. Anakinra, rilonacept, and canakinumab are included in these IL-1 inhibitors. These three drugs are FDA approved and majorly contributes in treating CAPS's patients. It is essential to take these therapies for life, but it will encourage children to lead near-normal lives. Some therapies may also include physical therapy, joint alignment medication splints, and NSAIDs, symptom-lowering corticosteroids, or methotrexate. Surgery can correct deformities in the joint.

CAPS Epidemiology

The CAPS epidemiology division provides the insights about historical and current CAPS patient pool and forecasted trend for United States. It helps to recognize the causes of current and forecasted trends by exploring numerous studies and views of key opinion leaders. This part of the DelveInsight report also provides the diagnosed patient pool and their trends along with assumptions undertaken.

Key Findings

In the year 2017, the total prevalent case of CAPS was 650 cases in the United States which are expected to grow during the study period, i.e., 2017–2030.

The disease epidemiology covered in the report provides historical as well as forecasted CAPS epidemiology [segmented as Total Prevalent Cases of CAPS, Total Diagnosed Cases of CAPS, Age-specific Prevalent cases of CAPS, Type-specific Prevalent Cases of CAPS, Severity-specific Prevalent Cases of CAPS and Treated cases of CAPS] in the United States from 2017 to 2030.

CAPS Drug Chapters

The drug chapter segment of the CAPS report encloses the detailed analysis of CAPS marketed drugs and pipeline drugs. It also helps to understand the CAPS clinical trial details, expressive pharmacological action, agreements and collaborations, approval

and patent details, advantages and disadvantages of each included drug and the latest news and press releases.

CAPS Approved Drugs

Kineret (Anakinra): Amgen/ Swedish Orphan Biovitrum

Kineret (anakinra) is a recombinant, non-glycosylated form of the human interleukin-1 receptor antagonist (IL-1Ra). In January 2013, the US Food and Drug Administration (FDA) approved Kineret for the treatment of NOMID. Kineret was the first and only FDA-approved therapy treatment for NOMID, the most severe form of CAPS.

Ilaris (Canakinumab): Novartis

Ilaris (Canakinumab), previously known as ACZ885, is a recombinant, human anti-human-IL-1 β monoclonal antibody that belongs to the IgG1/ γ 1 isotype subclass. In June 2009, the US FDA approved Ilaris (canakinumab) for the treatment of children and adults with CAPS, which includes a number of rare but life-long auto-inflammatory disorders with debilitating symptoms and limited treatment options. The FDA granted priority review to Ilaris based on its potential to meet an important clinical need for patients with CAPS.

Arcalyst (Riloncept): Regeneron Pharmaceuticals

Riloncept, formerly known as IL-1 TRAP, is a targeted inhibitor of interleukin-1 (IL-1), the key driver of inflammation in CAPS. Riloncept is a dimeric fusion protein consisting of the ligand-binding domains of the extracellular portions of the human interleukin-1 receptor component (IL-1RI) and IL-1 receptor accessory protein (IL-1RAcP) linked in-line to the Fc portion of human IgG1. Arcalyst is used to treat adults and children 12 years of age and older with CAPS, including FCAS and MWS. In February 2008, the US FDA approved Arcalyst (riloncept) an interleukin-1 blocker, for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older.

Note: Detailed Current therapies assessment will be provided in the full report of CAPS

CAPS Emerging Drugs

ATI-450 (Aclaris Therapeutics)

ATI-450 formerly known as CDD-450 is an investigational drug which is a unique p38^γ MAPK–MK2 pathway selective inhibitor used to expose the function of this protein complex in inflammasome priming signals. Notably, ATI-450 is as efficacious as global p38^γ MAPK inhibitors in decreasing inflammation in disease models. CAPS and the most severe form of the disease, NOMID result from dysregulated inflammasome generating elevated systemic levels of the cytokine IL-1 β .

In August 2017, Aclaris Therapeutics, announced that it has acquired Confluence Life Sciences—a privately held biotechnology company focused on the discovery and development of kinase inhibitors to treat inflammatory and immunological disorders and cancer. The issued U.S. patents covering ATI-450, are expected to expire in 2034 and other issued patents covering different MK2 signaling pathway inhibitors are expected to expire in 2031 and 2032.

Note: Detailed emerging therapies assessment will be provided in the final report.

CAPS Market Outlook

Key Findings

The CAPS market size in the US is expected to change during the study period 2017–2030. The therapeutic market of CAPS in the US was USD 36 million in 2017 which is expected to increase during study period (2017–2030).

CAPS Pipeline Development Activities

The drugs which are in pipeline include:

ATI-450: Aclaris Therapeutics

Note: Detailed emerging therapies assessment will be provided in the final report.

CAPS Drugs Uptake

Among the approved therapies, Canakinumab is dominating the current market owing to well-established efficacy and safety profile, rapid and sustained response, and a significantly less-frequent dosing schedule (i.e., once every eight weeks).

Access and Reimbursement Scenario in CAPS Therapies

The high-cost of rare disease drugs usually have a limited impact on budget due to the small number of eligible patients being prescribed the drug. Several rare disease therapies have been approved by the US FDA in the past few years. From a patient perspective, health insurance and payer coverage guidelines surrounding rare disease treatments restrict broad access to these treatments, leaving only a small number of patients who can bypass insurance and pay for products on their own. Insured patients in the United States are typically granted access to rare disease drugs. This is due to several factors, including about half of rare diseases affecting children, which makes management difficult, without coverage after approval.

KOL-Views

To keep up with current market trends, we take KOLs and SME's opinion working in CAPS domain through primary research to fill the data gaps and validate our secondary research. Their opinion helps to understand and validate current and emerging therapies treatment patterns or CAPS market trend. This will support the clients in potential upcoming novel treatment by identifying the overall scenario of the market and the unmet needs.

Competitive Intelligence Analysis

We perform Competitive and Market Intelligence analysis of the CAPS Market by using various Competitive Intelligence tools that includes – SWOT analysis, PESTLE analysis, Porter's five forces, BCG Matrix, Market entry strategies etc. The inclusion of the analysis entirely depends upon the data availability.

Scope of the Report

The report covers the descriptive overview of CAPS, explaining its causes, signs and symptoms, pathophysiology and currently available therapies.

Comprehensive insight has been provided into the CAPS epidemiology and treatment in the US.

Additionally, an all-inclusive account of both the current and emerging therapies

for CAPS is provided, along with the assessment of new therapies, which will have an impact on the current treatment landscape.

A detailed review of CAPS market; historical and forecasted is included in the report, covering drug outreach in the US.

The report provides an edge while developing business strategies, by understanding trends shaping and driving the global CAPS market.

Report Highlights

In the coming years, CAPS market is set to change due to the rising awareness of the disease and incremental healthcare spending across the world; which would expand the size of the market to enable the drug manufacturers to penetrate more into the market.

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

Major players are involved in developing therapies for CAPS. Launch of emerging therapies, will significantly impact the CAPS market.

A better understanding of disease pathogenesis will also contribute to the development of novel therapeutics for CAPS.

Our in-depth analysis of the pipeline assets across different stages of development, different emerging trends and comparative analysis of pipeline products with detailed clinical profiles, key cross-competition, and launch date along with product development activities will support the clients in the decision-making process regarding their therapeutic portfolio by identifying the overall scenario of the research and development activities.

CAPS Report Insights

Patient Population

Therapeutic Approaches

CAPS Pipeline Analysis

CAPS Market Size and Trends

Market Opportunities

Impact of upcoming Therapies

CAPS Report Key Strengths

11-Years Forecast

US Coverage

CAPS Epidemiology Segmentation

Key Cross Competition

Highly Analyzed Market

Drugs Uptake

CAPS Report Assessment

SWOT Analysis

Current Treatment Practices

Unmet Needs

Pipeline Product Profiles

Conjoint Analysis

Market Attractiveness

Market Drivers and Barriers

Key Questions

Market Insights:

What was the CAPS Market share (%) distribution in 2017 and how it would look like in 2030?

What would be the CAPS total market size as well as market size by therapies across the US during the study period (2017–2030)?

What are the key findings pertaining to the market across the United States (2017–2030)?

At what CAGR, the CAPS market is expected to grow in the US during the study period (2017–2030)?

What would be the CAPS market outlook across the US during the study period (2017–2030)?

What would be the CAPS market growth till 2030 and what will be the resultant market size in the year 2030?

How would the market drivers, barriers and future opportunities affect the market dynamics and a subsequent analysis of the associated trends?

CAPS patient types/pool where unmet need is more and whether emerging therapies will be able to address the residual unmet need?

How emerging therapies are performing on the parameters like efficacy, safety, route of administration (RoA), treatment duration and frequencies on the basis of their clinical trial results?

Among the emerging therapies, what are the potential therapies which are expected to disrupt the CAPS market?

Epidemiology Insights:

What is the disease risk, burden and unmet needs of the CAPS?

What is the historical CAPS patient pool in the United States?

What would be the forecasted patient pool of CAPS in the United States?

What will be the growth opportunities in the United States with respect to the patient population pertaining to CAPS?

At what CAGR the population is expected to grow in the United States during the study period (2017–2030)?

What are the various recent and upcoming events which are expected to improve the diagnosis of CAPS?

Current Treatment Scenario and Emerging Therapies:

What are the current options for the treatment of CAPS?

What are the current treatment guidelines for the treatment of CAPS in the US?

How many companies are developing therapies for the treatment of CAPS?

How many therapies are developed by each company for the treatment of CAPS?

How many emerging therapies are in mid stage, and late stage of development for the treatment of CAPS?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the CAPS therapies?

What are the recent novel therapies, targets, mechanisms of action and technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for CAPS and their status?

What are the key designations that have been granted for the emerging therapies for CAPS?

What is the global historical and forecasted market of CAPS?

Reasons to buy

The report will help in developing business strategies by understanding trends shaping and driving the CAPS market.

To understand the future market competition in the CAPS market and insightful review of the key market drivers and barriers.

Organize sales and marketing efforts by identifying the best opportunities for CAPS in the US.

Identification of strong upcoming players in market will help in devising strategies that will help in getting ahead of competitors.

Organize sales and marketing efforts by identifying the best opportunities for CAPS market.

To understand the future market competition in the CAPS market.

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