

Argininosuccinic Aciduria Market - A Global and Regional Analysis: Focus on Type and Region - Analysis and Forecast, 2025-2035

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Abstracts

The global argininosuccinic aciduria market is witnessing significant growth driven by the increasing prevalence of inherited metabolic disorders, advancements in newborn screening programs, and the availability of novel therapeutic interventions.

Argininosuccinic aciduria (ASA) is a rare autosomal recessive urea cycle disorder caused by a deficiency of the enzyme argininosuccinate lyase (ASL), leading to the accumulation of ammonia and argininosuccinic acid in the blood. Early diagnosis and prompt treatment are essential to prevent neurological complications and hyperammonemia-associated toxicity. Rising awareness among clinicians and patients regarding rare genetic disorders and the development of enzyme replacement and gene therapy approaches are supporting the growth trajectory of the argininosuccinic aciduria market.

The argininosuccinic aciduria market is expanding due to improved diagnostic precision through tandem mass spectrometry, next-generation sequencing (NGS) and the increasing adoption of rare disease genetic testing panels for early identification of metabolic abnormalities. Early-onset cases are typically more severe, requiring lifelong dietary management and ammonia-scavenging drugs, whereas late-onset cases present with milder symptoms, creating differentiated treatment needs. Companies are actively developing therapeutics that address enzyme deficiency and optimize nitrogen excretion pathways, reducing the frequency of metabolic crises. Additionally, healthcare infrastructure improvements in rare disease management, coupled with increased government support for orphan drug approvals, are enhancing access to treatment across developed regions such as the U.S., U.K., Germany, and Japan.

Despite positive market developments, the argininosuccinic aciduria market faces

challenges including limited curative options, high treatment costs, and dependency on lifelong dietary and pharmacological management. The small patient pool and the complexity of clinical trials for rare diseases also restrict commercial scalability. However, the market continues to benefit from advancements in gene therapy platforms, such as adeno-associated viral (AAV) vector-based delivery systems, which hold potential for long-term correction of ASL deficiency. Pharmaceutical and biotech firms are collaborating with academic research institutions to accelerate translational research and clinical validation of innovative therapeutic modalities.

The competitive landscape of the argininosuccinic aciduria market is shaped by a blend of established pharmaceutical players and emerging biotech innovators. Companies such as Glenmark Pharmaceuticals Inc., Amgen, Zevra Therapeutics, Inc., Evox Therapeutics, Swedish Orphan Biovitrum AB (publ), Immedica Pharma, and Winhealth Pharma are focusing on expanding their rare metabolic disorder portfolios through partnerships, acquisitions, and clinical research. These firms are actively involved in developing small-molecule therapies, enzyme replacement candidates, and gene therapy platforms targeting argininosuccinic aciduria and related urea cycle disorders.

Looking ahead, the global argininosuccinic aciduria market is expected to witness steady growth over the forecast period. Increasing funding for orphan drug research, ongoing clinical trials for ASL gene therapy, and improved reimbursement pathways for rare disease treatments will significantly influence market expansion. Technological integration in genetic testing, coupled with the development of precision medicine initiatives, is anticipated to further enhance diagnosis and management.

Market Segmentation:

Segmentation 1: by Type

Early Onset

Late Onset

Segmentation 2: by Region

North America

Europe

Asia-Pacific

Rest-of-the-World

The Argininosuccinic Aciduria Market is expected to maintain growth through a combination of improved diagnostic approaches, enhanced therapeutic innovation, and supportive regulatory frameworks. With growing global awareness and early detection programs, the market is positioned to evolve toward curative and long-term disease management solutions.

Contents

Executive Summary
Scope and Definition
Market/Product Definition
Inclusion and Exclusion
Key Questions Answered
Analysis and Forecast Note

1. GLOBAL ARGININOSUCCINIC ACIDURIA MARKET: INDUSTRY ANALYSIS

1.1 Market Overview and Ecosystem
1.2 Epidemiological Analysis
1.3 Key Market Trends
 1.3.1 Impact Analysis
1.1 Pipeline Analysis
1.2 Patent Analysis
 1.2.1 Patent Filing Trend (by Country)
 1.2.2 Patent Filing Trend (by Year)
1.3 Regulatory Landscape
1.4 Ongoing Clinical Trials
1.5 Market Dynamics
 1.5.1 Overview
 1.5.2 Market Drivers
 1.5.3 Market Restraints
 1.5.4 Market Opportunities

2. GLOBAL ARGININOSUCCINIC ACIDURIA MARKET, BY TYPE, \$MILLION, 2024-2035

2.1 Early Onset
2.2 Late Onset

3. GLOBAL ARGININOSUCCINIC ACIDURIA MARKET, BY REGION, \$MILLION, 2024-2035

3.1 North America
 3.1.1 Market Dynamics
 3.1.2 Market Sizing and Forecast

3.1.3 North America Argininosuccinic Aciduria Market, by Country

3.1.3.1 U.S.

3.2 Europe

3.2.1 Market Dynamics

3.2.2 Market Sizing and Forecast

3.2.3 Europe Argininosuccinic Aciduria Market, by Country

3.2.3.1 U.K.

3.2.3.2 France

3.2.3.3 Germany

3.2.3.4 Italy

3.2.3.5 Spain

3.3 Asia-Pacific

3.3.1 Market Dynamics

3.3.2 Market Sizing and Forecast

3.3.3 Asia-Pacific Argininosuccinic Aciduria Market, by Country

3.3.3.1 Japan

3.3.3.2 China

3.3.3.3 South Korea

3.3.3.4 Australia

3.3.3.5 India

3.4 Rest-of-the-World

3.4.1 Market Dynamics

3.4.2 Market Sizing and Forecast

4. GLOBAL ARGININOSUCCINIC ACIDURIA MARKET, COMPETITIVE LANDSCAPE AND COMPANY PROFILES

4.1 Competitive Landscape

4.1.1 Mergers and Acquisitions

4.1.2 Partnership, Alliances and Business Expansion

4.1.3 New Offerings

4.1.4 Regulatory Activities

4.1.5 Funding Activities

4.2 Company Profiles

4.2.1 Glenmark Pharmaceuticals Inc.

4.2.1.1 Overview

4.2.1.2 Top Products / Product Portfolio

4.2.1.3 Top Competitors

4.2.1.4 Target Customers/End-Users

- 4.2.1.5 Key Personnel
- 4.2.1.6 Analyst View
- 4.2.2 Amgen
 - 4.2.2.1 Overview
 - 4.2.2.2 Top Products / Product Portfolio
 - 4.2.2.3 Top Competitors
 - 4.2.2.4 Target Customers/End-Users
 - 4.2.2.5 Key Personnel
 - 4.2.2.6 Analyst View
- 4.2.3 Zevra Therapeutics, Inc.
 - 4.2.3.1 Overview
 - 4.2.3.2 Top Products / Product Portfolio
 - 4.2.3.3 Top Competitors
 - 4.2.3.4 Target Customers/End-Users
 - 4.2.3.5 Key Personnel
 - 4.2.3.6 Analyst View
- 4.2.4 Evox Therapeutics
 - 4.2.4.1 Overview
 - 4.2.4.2 Top Products / Product Portfolio
 - 4.2.4.3 Top Competitors
 - 4.2.4.4 Target Customers/End-Users
 - 4.2.4.5 Key Personnel
 - 4.2.4.6 Analyst View
- 4.2.5 Swedish Orphan Biovitrum AB (publ)
 - 4.2.5.1 Overview
 - 4.2.5.2 Top Products / Product Portfolio
 - 4.2.5.3 Top Competitors
 - 4.2.5.4 Target Customers/End-Users
 - 4.2.5.5 Key Personnel
 - 4.2.5.6 Analyst View
- 4.2.6 Immedica Pharma
 - 4.2.6.1 Overview
 - 4.2.6.2 Top Products / Product Portfolio
 - 4.2.6.3 Top Competitors
 - 4.2.6.4 Target Customers/End-Users
 - 4.2.6.5 Key Personnel
 - 4.2.6.6 Analyst View
- 4.2.7 Winhealth Pharma
 - 4.2.7.1 Overview

4.2.7.2 Top Products / Product Portfolio

4.2.7.3 Top Competitors

4.2.7.4 Target Customers/End-Users

4.2.7.5 Key Personnel

4.2.7.6 Analyst View

5. RESEARCH METHODOLOGY

List Of Figures

LIST OF FIGURES

Figure: Argininosuccinic Aciduria Market (by Scenario), \$Million, 2024, 2030, and 2035

Figure: Global Argininosuccinic Aciduria Market, 2024 and 2035

Figure: Global Argininosuccinic Aciduria Market Key Trends, Impact Analysis

Figure: North America Argininosuccinic Aciduria Market, \$Million, 2024-2035

Figure: Europe Argininosuccinic Aciduria Market, \$Million, 2024-2035

Figure: Asia-Pacific Argininosuccinic Aciduria Market, \$Million, 2024-2035

Figure: Rest-of-the-World Argininosuccinic Aciduria Market, \$Million, 2024-2035

List Of Tables

LIST OF TABLES

Table: Market Snapshot

Table: Market Dynamics

Table: Global Argininosuccinic Aciduria Market (by Type), \$Million, 2024-2035

Table: Global Argininosuccinic Aciduria Market (by Region), \$Million, 2024-2035

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