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Fabry Disease Market (By Treatment, Route of Administration, Product, End-User, Country Analysis), Key Company Profiles, Product Portfolio, Pipeline Product Analysis, Recent Developments and Market Dynamics – Global Forecast (2025 – 2030)

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Abstracts

The global Fabry disease treatment market was valued at US$ 2.22 Billion in 2024, and is predicted to reach US$ 3.86 Billion by 2030. Fabry disease is a rare genetic disorder caused by a deficiency or malfunction of the enzyme alpha-galactosidase A (?-GAL A). This enzyme is essential for the breaking down a type of fat called globotriaosylceramide (GL-3 or Gb3) in the body's cells. In the absence of sufficient functional ?-GAL A, Gb3 accumulates in various tissues, particularly affecting blood vessels, kidneys, heart, and the nervous system. Over time, this buildup leads to progressive, multisystem damage. The primary goal of Fabry disease treatment is to minimize the buildup of globotriaosylceramide (Gb3) in the body, relieve associated symptoms, slow or prevent the progression of organ damage, and ultimately improve the patient’s quality of life. The growing prevalence of Fabry disease, coupled with rising awareness and the escalating need for precise and effective therapies, such as enzyme replacement substrate reduction, chaperone treatments, and substrate reduction therapy to stabilize individuals from suffering disease, are driving the market growth.

Recent Developments

> In February 2025, UniQure Biopharma announced the completion of enrollment in the first cohort of the Phase I/IIa trial of AMT-191. Additionally, the Independent Data Monitoring Committee (IDMC) reviewed safety data from the initial two patients enrolled in the first cohort.

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In December 2024, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to EXG110, a new gene therapy for Fabry disease.

In October 2024, Sangamo Therapeutics announced alignment with the FDA on an accelerated approval pathway for isaralgagene civaparvovec in Fabry disease, with a BLA submission expected in the second half of 2025.

In August 2023, the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved ELFABRIO for long-term ERT in adult patients with a confirmed diagnosis of Fabry disease in Great Britain.

By Treatment: Global Fabry Disease Market and Forecast – Key Takeaways

The enzyme replacement therapy (ERT) dominates the Fabry disease market, as it is the standard of care for managing Fabry disease. The rising prevalence of Fabry disease has directly increased the demand for ERT, with more patients gaining access to treatment due to improved diagnostic methods.

Chaperone treatment is gaining traction in the Fabry disease market landscape. The Galafold (migalastat) by Amicus Therapeutics is the first oral chaperone therapy approved for adult patients with specific GLA gene mutations. Galafold is approved in more than 40 countries around the world, including the U.S., EU, U.K., and Japan.

The substrate reduction therapy works in Fabry disease by inhibiting the activity of the GCS enzyme, which prevents the formation of GL-1 and the production of Gb3, the alpha-galactosidase substrate. Substrate reduction therapy effectively addresses the enzyme deficiency associated with Fabry disease, thereby mitigating its impact.

By Route of Administration: Global Fabry Disease Market and Forecast – Key Takeaways

The intravenous route dominates the Fabry disease market owing to its high efficacy in delivering enzyme replacement therapy (ERT) for Fabry disease. The clinical trials have consistently shown the superiority of intravenous ERT in

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stabilizing Fabry disease symptoms over long durations.

Oral route offers a convenient way of administering treatments, which is particularly advantageous for patients who require long-term therapy. Oral route reduces the anxiety of patients & improves the overall treatment experience, contributing to better patient satisfaction & treatment continuation.

By Product: Global Fabry Disease Market and Forecast – Key Takeaways

Since its introduction by Sanofi, Fabrazyme has established itself as the standard of care for managing Fabry disease. Fabrazyme continues to hold a substantial share of the global Fabry disease market, supported by strong regulatory approvals, broad geographic availability, and widespread clinical acceptance.

Elfabrio (PRX-102) was developed through a strategic partnership between Chiesi Farmaceutici and Protalix BioTherapeutics. Elfabrio is poised to capture significant market share by appealing to both treatment-naive individuals and those who have encountered resistance or reduced benefit from existing therapies.

Galafold (migalastat) by Amicus Therapeutics is the first oral chaperone therapy approved for adult patients with specific GLA gene mutations. Galafold provides a more patient-friendly and personalized approach to long-term disease management, particularly appealing to those seeking freedom from intravenous infusions.

Replagal gained widespread adoption in Europe and Asia, where it became a mainstay therapy in managing Fabry disease, particularly in patients seeking long-term enzyme replacement with a well-established safety profile.

By End User: Global Fabry Disease Market and Forecast – Key Takeaways

Hospitals end user segment dominates the Fabry disease treatment market, largely because of the high level of expertise involved in treating this rare genetic disorder. Hospitals increasingly serve as critical hubs for advancing Fabry disease treatment through active participation in clinical trials and

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strategic collaborations with research institutions.

Retail pharmacies offer patients enhanced convenience, particularly for managing chronic treatments that no longer require in-hospital infusions. The approval of oral therapies like Amicus Therapeutics' Galafold has expanded the role of retail pharmacies in managing Fabry disease.

Online pharmacies segment is expected to experience significant growth over the forecast period due to advancements in digital health platforms and rising patient demand for convenience. The increasing penetration of internet and digital literacy, and expanding telemedicine services, are making it easier to reach rare disease medicines.

By Country: Global Fabry Disease Market and Forecast – Key Takeaways

The United States dominates the Fabry disease market owing to increasing disease awareness, ongoing innovation and the introduction of novel treatments, and a robust healthcare infrastructure. The key players in the United States Fabry disease treatment market including Sanofi, Amicus Therapeutics, and Protalix BioTherapeutics, among others, are actively involved in developing and providing therapies aimed at improving the quality of life for individuals with Fabry disease.

Germany is the leading market for Fabry disease treatments in Europe. Germany's commitment to research is evident through institutions like the German Center for Rare Diseases (DZNE), which actively participates in Fabry disease studies and clinical trials.

Italy's market is characterized by a strong presence of established therapies like Replagal, alongside the rapid adoption of newer treatments such as Galafold.

Japan's dominance is attributed to its robust healthcare infrastructure, early disease detection programs, and a strong regulatory framework that supports the availability and adoption of advanced therapies for rare diseases like Fabry disease.

iGATE Research report titled "Fabry Disease Market [By Treatment (Enzyme

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Replacement Therapy, Chaperone Treatment, Substrate Reduction Therapy, Others), By Route of Administration (Intravenous Route, Oral Route), By Product (Fabrazyme (Agalsidase beta), Elfabrio (Pegunigalsidase alfa), Replagal, Galafold (Migalastat)), By End-User (Hospitals, Retail Pharmacy, Online Pharmacy)], Country Analysis, Key Company Profiles, Product Portfolio, Pipeline Product Analysis, Recent Developments and Market Dynamics – Global Forecast (2025 – 2030)" provides a comprehensive assessment of the fast–evolving, high–growth Global Fabry Disease Market.

This 122 Pages report with 62 Figures and 8 Tables has been analyzed from 9 viewpoints:

1) Global - Fabry Disease Market and Forecast (2021 – 2030)
2) Global - Fabry Disease Market Share and Forecast (2021 – 2030)
3) By Treatment – Global Fabry Disease Market and Forecast (2021 – 2030)
4) By Route of Administration – Global Fabry Disease Market and Forecast (2021 – 2030)
5) By Product – Global Fabry Disease Market and Forecast (2021 – 2030)
6) By End User – Global Fabry Disease Market and Forecast (2021 – 2030)
7) By Country – Fabry Disease Market and Forecast (2021 – 2030)
8) Global Fabry Disease Market – Company Profiles
9) Global Fabry Disease Treatment – Market Dynamics

By Treatment: Global Fabry Disease Market and Forecast

1. Enzyme Replacement Therapy
2. Chaperone Treatment
3. Substrate Reduction Therapy
4. Others

By Route of Administration: Global Fabry Disease Market and Forecast

1. Intravenous Route
2. Oral Route

By Product: Global Fabry Disease Market and Forecast

1. Fabrazyme (Agalsidase beta)
2. Elfabrio (Pegunigalsidase alfa)
3. Replagal

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4. Galafold (Migalastat)

By End User: Global Fabry Disease Market and Forecast

- Hospitals
- Retail Pharmacy
- Online Pharmacy

By Country: Global Fabry Disease Market and Forecast

- United States
- Canada
- Mexico
- Germany
- France
- UK
- Italy
- Spain
- Japan
- China
- Australia
- Saudi Arabia
- UAE

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South Africa

Brazil

Argentina

Global Fabry Disease Market – Company Profile, Product Portfolio, Pipeline Analysis

1. Sanofi
2. Protalix Biotherapeutics
3. Amicus Therapeutics
4. Takeda Pharmaceutical
5. uniQure
6. AceLink Therapeutics
7. Sangamo Therapeutics
8. 4D Molecular Therapeutics
9. Greenovation Biopharmaceuticals
10. Idorsia

Data Sources

iGATE Research employs rigorous primary and secondary research techniques in developing distinctive data sets and research material for business reports. This report is built by using data and information sourced from Proprietary Information Database, Primary and Secondary Research Methodologies, and In house analysis by iGATE Research dedicated team of qualified professionals with deep industry experience and expertise.

Research Methodologies

Primary Research Methodologies: Questionnaires, Surveys, Interviews with Individuals, Small Groups, Telephonic Interview, etc.

Secondary Research Methodologies: Printable and Non–printable sources, Newspaper, Magazine and Journal Content, Government and NGO Statistics, white Papers, Information on the Web, Information from Agencies Such as Industry Bodies, Companies Annual Report, Government Agencies, Libraries and Local Councils and a large number of Paid Databases.

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