Hemophilia Market Assessment, By Type [Hemophilia A, Hemophilia B, Hemophilia C], By Treatment [On-demand Treatment, Prophylactic Treatment], By Drug Class [Clotting Factors, Monoclonal Antibodies, Antidiuretic Drugs, Antihemorrhagic Drugs, Aminocaproic Acid, Antifibrinolytic Agents], By Therapy [Replacement Therapy, Immune Tolerance Induction (ITI) Therapy, Gene Therapy], By Distribution Channel [Hospital Pharmacies, Retail Pharmacies, Specialty Centers], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

Global hemophilia market is projected to witness a CAGR of 5.50% during the forecast period 2024-2031, growing from USD 13.11 billion in 2023 to USD 20.12 billion in 2031. The market demand for hemophilia is anticipated to thrive drastically in the forecast years due to rising prevalence and the growing interest of investors and market players.
Hemophilia is a very rare genetic disorder where blood clotting gets impeded due to the lack of blood clotting factors present in the body. The foremost incidence of this disease takes place among males because this is an X-linked recessive disorder. Further catalyzed by developments in the therapy areas used for the treatment of hemophilia, a paradigm shift towards targeted and combination therapy, and a higher diagnosis rate on account of rising awareness, the market for hemophilia therapeutics will probably boom at a faster rate during the forecast period, with the growing disease burden of this disease. Further, this growth is complemented by significant initiatives taken by the government to eradicate hemophilia by approving the products used in treating hemophilia, whether it be pharmaceuticals or therapies. In April 2024, Pfizer Inc. stated that it received approval from the U.S. Food and Drug Administration for BEQVEZ (fidanacogene elaparvovec-dzkt) to treat adults with moderate to severe

hemophilia B. It includes those who currently use FIX prophylaxis therapy, have had life-threatening hemorrhages, repeated, serious spontaneous bleeding episodes, or do not have neutralizing antibodies to AAVRh74var capsid as indicated by an FDA-approved test. BEQVEZ is a one-time treatment that might enable people with hemophilia B to make FIX themselves, as opposed to now, receiving regular intravenous infusions of FIX several times a week or month.

High Disease Burden of Hemophilia to Drive Market Growth

The global disease burden is relatively high and rising. Inheritance patterns, consanguinity, and an increasing diagnosis rate contribute to the high prevalence. Usually, a high disease burden and high demand for therapeutic products lead to higher diagnosis prevalence. As the disease burden of hemophilia increases, the demand for the hemophilia market is expected to rise. Awareness and diagnosis increase with the rise in prevalence, giving rise to the development of technologies for treatment, genetic engineering, and recombinant factor concentrates. These innovations improve patient outcomes and fuel market growth as they find widespread acceptance. Global initiatives, including the World Federation of Hemophilia and the World Health Organization (WHO), are ongoing to reduce the disease burden and create adequate awareness. For instance, if one looks at the results of the Annual Global Survey by the World Federation of Hemophilia published in October 2023, the total number of identified patients with hemophilia globally was 257,146 compared to 241,535 in 2020, thus increasing 6.46% over two years.

Advancements in Gene Therapy to Lead to Market Growth

Advancements in gene therapy are significantly driving market growth in the hemophilia market. Recent clinical trials utilizing adeno-associated viral (AAV) vectors have demonstrated stable and long-term expression of these factors, leading to significant reductions in spontaneous bleeding and the need for regular infusions. The market is further bolstered by biopharmaceutical companies' ongoing research and development efforts, which are focused on optimizing gene delivery methods and improving treatment efficacy. In June 2023, BioMarin Pharmaceutical Inc. announced that the United States Food and Drug Administration (FDA) approved ROCTAVIAN (valoctocogene roxaparvovec-rvox) gene therapy for the treatment of adults with severe hemophilia A. This type of hemophilia is characterized by congenital factor VIII (FVIII) deficiency with FVIII activity less than 1 IU/dL and without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test. The one-time, single-dose infusion is the first approved gene therapy for severe hemophilia A in the United States. Also, ROCTAVIAN was first approved by the European Medicines Agency in August 2022.

Hemophilia A Segment to Dominate the Hemophilia Market Share

The dominance of Hemophilia A in the hemophilia treatment market can be attributed to several key factors. Hemophilia A accounts for approximately 74.16% of all hemophilia cases globally, making it the most prevalent type of genetic disorder. This significant patient population drives the demand for targeted therapies and treatments, ensuring that Hemophilia A remains the focal point for pharmaceutical companies and healthcare providers. As per the Annual Global Survey conducted by the World Federation of Hemophilia, published in October 2023, out of 257,146 identified hemophilia patients worldwide, 208,957 were suffering from hemophilia A while 42,203 were suffering from hemophilia B and the rest were suffering from unknown type. It indicates that hemophilia A is 4.9 times more prevalent than hemophilia B. Thus, the combination of high prevalence, continuous innovation in treatment, and substantial financial implications positions Hemophilia A as the leading segment in the hemophilia market.

North America to Dominate the Hemophilia Market Share

North America leads the hemophilia market due to several interrelated factors that improve treatment accessibility and innovation. The presence of established healthcare infrastructure, specialized hemophilia treatment centers, and significant financial support for research and development further bolsters market growth. Substantial government initiatives and funding have been directed toward gene therapy and other innovative treatments, improving patient outcomes and expanding treatment options. According to the Canadian Hemophilia Society, about 3,900 Canadians are affected by hemophilia A, and about 800 Canadians suffer from hemophilia B. Similarly, the data of the National Bleeding Disorders Foundation quotes that hemophilia occurs in approximately 1 in 5,617 live male births, resulting in 30,000-33,000 males with hemophilia in the United States.

Future Market Scenario (2024 - 2031F)

Favorable reimbursement and health insurance coverage for hemophilia treatment are shaping the future market growth of the hemophilia market. The growing popularity of health insurance, especially in developing countries, enables more patients to afford expensive hemophilia treatments. Reimbursement policies are expanding to include newer therapies, such as gene therapy for

hemophilia treatment. In November 2023, BioMarin Pharmaceutical Inc. reached an agreement with the German National Association of Statutory Health Insurance Funds (GKV-SV) regarding the reimbursement amount for ROCTAVIAN (valoctocogene roxaparvovec-rvox) for individuals with severe hemophilia A. It marks the first gene therapy for hemophilia to establish a set federal price in Germany. ROCTAVIAN provides value to patients and the German healthcare system as a one-time, single-dose therapy administered through an intravenous infusion lasting 3-4 hours, priced at USD 31,274.25 per vial.

Key Players Landscape and Outlook
The hemophilia market is primarily dominated by players such as Novo Nordisk A/S and Baxter International Inc. Market activity reported in recent years includes business agreements, collaborations, and regulatory approvals of products. The market fosters several smaller players as well, which operate through partnerships with other players to cater to a larger market.
In June 2024, 2seventy bio, Inc. announced the completion of an asset purchase agreement by Novo Nordisk A/S. Under the terms of the agreement, Novo Nordisk acquired the Hemophilia A program and the rights to 2seventy's in vivo gene editing technology outside of oncology and gene editing for autologous or allogeneic cell therapies to treat autoimmune disease. The 2seventy bio team currently involved in the program will join Novo Nordisk and continue to advance the technology.
In March 2024, ReciBioPharm AB entered into a collaboration agreement with GeneVentiv Therapeutics, Inc., a preclinical gene therapy company, to extend the development of a universal gene therapy for hemophilia based on adeno-associated virus (AAV). This therapy is reportedly the first of its kind designed to treat hemophilia patients with inhibitors. GeneVentiv's GENV-HEM (AAV8.FVa) is a single infusion, universal AAV-based gene therapy for all types of hemophilia. ReciBioPharm intends to expedite the development by leveraging its AAV manufacturing platform at its Watertown facility in Massachusetts.

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