

Gene Therapy Market: New Product Approvals and Commercialization to Boost Market

Gene Therapy Market is driven by new product approvals, promising therapeutic outcomes of gene therapy, and high prevalence of non-Hodgkin Lymphoma.



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Transparency Market Research (TMR) has published a new report titled, "[Gene Therapy Market - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2018–2026](#)". According to the report, the global gene therapy market was valued at US\$ 17.0 Mn in 2017 and is projected to expand at a CAGR of 40.0% from 2018 to 2026. New product approvals, promising therapeutic outcomes of gene therapy, and high prevalence of non-Hodgkin Lymphoma are anticipated to drive the global market in the next few years. Europe is projected to dominate the global gene therapy market, followed by U.S., by the end of 2026. Potential unmet needs in the fields of oncology, rare genetic disorders in the U.S. and Europe, new product approvals and commercialization, and high clinical R&D budgets are likely to drive the gene therapy market in these regions during the forecast period. The gene therapy market in Rest of World is projected to expand at a significant CAGR during the forecast period. The high growth rate is attributed to the anticipated approval and commercialization of gene therapy products in developed countries such as Japan, Australia & New Zealand, GCC countries, and China, and high prevalence of non-Hodgkin Lymphoma and head and neck cancers.

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New product approvals & commercialization drives market

2016, 2017, and 2018 were key milestones in the history of the gene therapy market in the U.S. and Europe, as around four gene therapy products have been approved and commercialized. These products are currently in the infancy stage of commercialization, and have exhibited highly positive therapeutic outcomes. For instance, in May 2016, GlaxoSmithKline (GSK) gene therapy product, Strimvelis, received marketing approval for the treatment of patients with a very rare disease called ADA-SCID (Severe Combined Immunodeficiency, due to Adenosine Deaminase deficiency). Strimvelis is the first ex-vivo stem cell gene therapy to be approved in Europe for the

treatment of ADA-SCID. Furthermore, in August 2017, the USFDA approved Novartis AG's flagship gene therapy product, Kymriah, for the treatment of children and adults up to the age of 25 years affected with B-cell precursor acute lymphoblastic leukemia (ALL). Thus, recent approvals of gene therapy products in the U.S. and Europe for the treatment of various life threatening disorders is projected to fuel the gene therapy market during the forecast period.

Yescarta to be highest revenue generating gene therapy product

The report offers a detailed segmentation of the global gene therapy market based on different gene therapy products approved and commercialized. Based on product, the global gene therapy market has been segmented into Yescarta, Kymriah, Luxturna, Strimvelis, and Gendicine. Yescarta (Axicabtagene Ciloleucel) is a genetically modified autologous Chimeric Antigen Receptor T (CAR T) cell immunotherapy developed by Gilead Sciences, Inc. for the treatment of adult patients with relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL). It is the first CAR T therapy approved by the US FDA for the treatment of DLBCL. The Yescarta segment is projected to dominate the global gene therapy market by the end of 2026. Anticipated commercialization of Yescarta in Europe and other developed countries and increasing number of treatment centers are key factors that are likely to lead to the dominant share held by Yescarta by the end of 2026.

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Oncology segment to account for high market share

In terms of application, the global gene therapy market has been segmented into ophthalmology, oncology, and adenosine deaminase ?deficient severe combined immunodeficiency (ADA-SCID). The oncology segment is likely to account for a significant share of the market by the end of 2026. Oncology is a highly studied medical field in the clinical pipeline studies of gene therapy candidates. More than 60% of gene therapy clinical research studies are focused on oncology. The large share held by the oncology segment is attributed to the approval and commercialization of Yescarta and Kymriah, in the last one to two years, for the treatment of certain types of non-Hodgkin lymphoma in the U.S. and Europe. Furthermore, increase in demand for Gendicine in China for the treatment of head and neck cancers is projected to drive the segment during the forecast period.

Europe offers high incremental opportunity

The gene therapy market in Europe is projected to expand at a significant CAGR of 30.6% during the forecast period. Large number of patient population with refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL), promising therapeutic outcomes, rising demand for gene therapy treatment, and

increasing number of gene therapy treatment centers in Europe are key factors that are likely to fuel the gene therapy market in Europe. Moreover, different pricing models are being evaluated by payers and governments to enable access to high priced gene therapy products. This is likely to drive the demand for gene therapy products in Europe during the forecast period.

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Large number of clinical pipeline studies and significant investments in gene therapy to gain the first mover advantage

The global gene therapy market is highly consolidated, with very few global players accounting for a major share. Currently, only five companies; Gilead life Sciences Inc. Spark Therapeutic Inc., Novartis AG, Sibiono GeneTech Co. Ltd, and Orchard Therapeutics Limited offer gene therapy products in the market. Most biopharmaceutical companies have invested significantly in clinical R&D for the development of gene therapy products for different chronic and genetic disorders. Large number of gene therapy products are under different stages of clinical pipeline studies, and the number of gene therapy candidates is projected to rise consistently during the forecast period. For instance, according to the Journal of Gene Medicine, there were around 2,597 gene therapy candidates under clinical trials, as of 2017. Of the total clinical studies, around 65% of studies were focused on oncology, 11% of studies were focused on monogenetic field, 7% on infectious diseases and cardiovascular disease, each.

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