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United States T-Cells Therapy Market Assessment, By Modality [Research, Commercialized], By Therapy Type [CAR T-Cell Therapy, T-Cell Receptor-based, Tumor-Infiltrating Lymphocytes-based], By Indication [Hematologic Malignancies, Solid Tumors, Others], By End-user [Hospitals, Cancer Treatment Centers], By Region, Opportunities and Forecast, 2016-2030F

https://marketpublishers.com/r/UC6BD5B93B56EN.html
Date: February 2025
Pages: 117
Price: US$ 3,300.00 (Single User License)
ID: UC6BD5B93B56EN

Abstracts

United States T-cells therapy market size was valued at USD 1.01 billion in 2022 and is expected to reach USD 4.6 billion in 2030, with a CAGR of 20.96% for the forecast period between 2023 and 2030F. Increasing cancer incidences, rising demand for personalized cancer treatments, and growing number of FDA approvals for T-cell therapies has driven the demand for T-cells therapy. T-cell therapy is a highly customized form of cancer treatment, as it involves using the patient's immune system to fight cancer. Patients with cancer are increasingly demanding personalized treatments that are tailored to their tumor biology.

The prevalence of cancer and other diseases is increasing due to numerous factors including aging population, the increasing prevalence of obesity, and the rising rates of environmental exposure to carcinogens. The FDA has recently approved several T-cell therapies for cancer and other diseases. It has increased T-cell therapy availability for patients, boosting the market growth. One of the key drivers of this market's development is the approval and commercialization of CAR-T (Chimeric Antigen Receptor T-cell) therapies. CAR-T therapies have shown remarkable results in treating certain types of leukemia and lymphoma, leading to FDA approvals, and expanded clinical applications. These therapies involve genetically modifying a patient's T-cells to target specific cancer cells, resulting in highly targeted and potent anti-cancer

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responses.

Increasing Advancement in Research and Development

Research and development are crucial for the advancement of T-cell therapy. The United States has a significant advantage, as it is home to some of the world's leading research institutions and pharmaceutical companies. These companies are investing heavily in T-cell therapy research, driving the market. Additionally, the FDA discovered an improved environment to approve T-cell therapies for use in the United States, which has boosted the market. The regulatory environment for T-cell therapy is favorable, which has encouraged more companies to invest in this area. The FDA's expedited review process for breakthrough therapies has helped speed up the approval process for T-cell therapies, contributing to market growth.

The first bispecific BCMA-directed CD3 T-cell engager, teclistamab-cqyv (Tecvayli, Janssen Biotech, Inc.), received accelerated approval from the FDA in October 2022 for the treatment of adult patients with relapsed or refractory multiple myeloma who had received at least four prior lines of therapy, including proteasome inhibitors, immunomodulatory drugs, and anti-CD38 monoclonal antibodies.

Rising Prevalence of Cancer

The most common cause of death in the United States is cancer. Asbestos, tobacco smoke, alcohol, aflatoxin (a food contaminant), arsenic (a drinking water contaminant), and biological carcinogens like infections from specific viruses, bacteria, or parasites as well as unhealthy lifestyle choices are the reasons for this. Also, physical carcinogens like ultraviolet and ionizing radiation are the reasons for cancer. The American Cancer Society estimates that in 2023, more than 1,958,310 cases of cancer may occur in the country and around 6,09,820 ca sualties are likely to occur in the same year.

According to the Leukemia and Lymphoma Society, 34,920 new myeloma cases were anticipated to be diagnosed in the United States in 2021 (19,320 men and 15,600 females), and an estimated 138,415 people in the U.S. live with the disease. In addition, 61,090 Americans will receive a leukemia diagnosis in 2021, while anticipating that 397,501 Americans are currently suffering from the disease.

Rapid Expansion in Clinical Trial Activity

Clinical trial activity in the United States T-Cells therapy market is experiencing rapid

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expansion, signaling a promising era in the field of healthcare. T-Cells therapy is a groundbreaking approach in treating various diseases, especially cancer, which has gained significant momentum in recent years. Chimeric Antigen Receptor T-cell therapies have demonstrated remarkable efficacy in previously untreatable cancers, fostering immense optimism within the medical community. FDA's proactive stance in streamlining regulatory processes and expediting approvals for T-Cells therapies has encouraged pharmaceutical companies, research institutions, and startups to invest in innovative trials.

AUTO1, a novel medication from Autolus Therapeutics plc, is conducting a phase I trial to treat adult acute lymphoblastic leukemia. AUTO1, a CD19 CAR T-cell-containing experimental cell therapy, is intended to overcome clinical safety and activity constraints associated with existing CD19 CAR T-cell therapies on April 26, 2023.

Advancement in CAR T-cell Therapy

According to an update from the American Society of Clinical Oncology (ASCO) published in June 2021, cancer cells are known to evade detection by the body's immune system. However, due to CAR T-cell treatment, some cancer cells can be more susceptible to detection and elimination. CAR T-cell treatment will, therefore, be in high demand during the next few years because of the predicted rise in cancer patients. Chimeric antigen receptor T-cells have undergone genetic engineering to develop a synthetic T-cell receptor for use in immunotherapy. It alters a person's immune system, increasing its capacity to combat long-term illnesses like cancer and other conditions.

The treatment of adult patients with relapsed or refractory multiple myeloma who have already attempted four or more prior lines of therapy, the FDA authorized ciltacabtagene autoleucel (CarvyktiTM) in March 2022.

Impact of COVID-19

The COVID-19 pandemic has considerably influenced the market for T-cell therapies. According to a November 2021 article in PubMed, recipients of T-cell therapy were thought to have an elevated risk of experiencing negative outcomes from COVID-19 because of their severely immunocompromised state brought on by prior lymphodepletion immunochemotherapy and side effects specific to T-cell therapy, such as B-cell depletion, hypogammaglobulinemia, and cytopenias. These results show that the COVID-19 pandemic considerably decreased the number of patients receiving T-cell therapy, which impacted the demand for T-cell therapy. However, research and

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development activities have resumed, and patient visits have increased because of the release of vaccinations and the easing of lockdown restrictions, indicating that the industry is anticipated to grow significantly.

Key Players Landscape and Outlook

The T-cell therapy market is competitive, with several international and global companies. The major players are utilizing a variety of growth tactics to improve their market presence, including mergers, acquisitions, partnerships, agreements, collaborations, new product launches, and geographic expansions.

In November 2022, The FDA approved Caribou Biosciences, Inc.'s Investigational New Drug (IND) application for CB-011, a genome-edited allogeneic anti-BCMA CAR-T cell therapy with immune cloaking. The company is a leading clinical-stage CRISPR genome-editing biopharmaceutical company.

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