MARKET ANALYSIS OF CAR-T CELL THERAPY

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of Master of Business Administration (MBA)

in

Hospital and Health

Management By

Dr Sheegul Kaushik (1194)

Under the Supervision &

Guidance of

Dr. Arindam Das

2022

MARKET ANALYSIS OF CAR-T CELL THERAPY

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of Master of Business Administration (MBA)

in

Hospital and Health

Management By

Dr Sheegul Kaushik (1194)

Under the Supervision &

Guidance of

Dr. Arindam Das

2022

DECLARATION

I hereby declare that this dissertation titled Market research for CAR-T cell therapy is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Dr. Sheegul Kaushik

CERTIFICATE

This is to certify that Dr. Sheegul Kaushik in partial fulfillment of the requirements for the award of the degree of MBA Hospital and Health Management from the IIHMR University, Jaipur has successfully completed her/his internship at D Cube Analytics during March 22, 2022, to June 19, 2022.

Ms. Shipra Kohli

(Manager- D Cube Analytics)

CERTIFICATE

This is to certify that dissertation titled "Market Analysis of CAR-T cell therapy" is a record of the research work undertaken by Dr. Sheegul Kaushik in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Dr. Arindam Das

Faculty Guide
IIHMR University, Jaipur

Date

Dr. Mahender Kumar

School Dean
IIHMR University, Jaipur

Date

Acknowledgement

I would like to acknowledge my sincere regards to all mighty, my parents, family members, teachers, and my guides throughout the MBA curriculum, without their constant support this dissertation would not be possible.

I would like to pay sincere regards to my faculty guide Dr. Arindam Das for his constant guidance and motivation during my dissertation. Secondly, I want to express gratitude towards my industry mentor Ms. Shipra Kohli and Mr. Shivang Gupta, for the best learning opportunity ever, any student can get.

I want to express my sincere gratitude towards great teachers whom I crossed my path past two years- Dr. Alok Mathur, Dr. PR Sodani, Dr. Anshuman Sewda, Dr. Seema Mehta, Dr. Piyusha Majumdar, Dr. Goutam Sadhu, Dr Dhirendra, Dr. Veena, Dr. Arindam, Dr. Susmit Jain, and Dr. Anoop Khanna.

I want to express my gratitude to university academics department to efficiently manage my classes in the most difficult Covid times.

At last, I want to say Cheers! To all my dear batchmates for completing MBA with flying colors and lifelong relationships that we have nurtured during past two years.

Best regards,

Dr. Sheegul Kaushik

Contents

i. List of figures

ii. List of tables:

iii. Abbreviations

CAR	Chimeric antigen receptor
CAR-T	Chimeric antigen receptor T cells
WBC	White blood cells
ALL	Acute lymphoblastic leukaemia
CLL	Chronic lymphoblastic leukaemia
AML	Acute myeloid leukaemia
CML	Chronic myeloid leukaemia
CMML	Chronic monomyelocytic leukaemia
LLS	Leukaemia and lymphoma society
USD	US dollars
CAGR	Compound annual growth rate
PAP	
FDA	Food and drug administration
BCMA	B-cell maturation antigen
DLBCL	Diffuse large B-cell Lymphoma

1. Introduction

1.1 The Chimeric Antigen Receptor - T cell therapy (CAR-T)

The term "CAR-T cell therapy" refers to a method of treatment in which immune system cells (T-Cells) are modified in a lab such that they attack cancer cells. These so-called "T-cells" are drawn directly from the patient's blood. In the lab, T-cells have a gene linked to them that interacts with a particular protein on the cancer cell of the patient. The CAR receptor is this one (chimeric antigen receptor). These CAR-T cells, which have been generated in a sizable laboratory, are administered into patients. Studies for the treatment of other types of cancer are still ongoing, but this CAR-T cell therapy is used to treat a specific blood malignancy.

CAR-T (chimeric antigen receptor) cells can be used to treat T cells. T cells, the body's immune cells, are altered in labs to fight cancer and eradicate cancer cells with the aid of CAR-T cell therapy (chimeric antigen receptor). Since CAR-T cell therapy includes changing the genes inside T cells to help them attack cancer cells, it is also known as cell-based gene therapy.

T-cells from the patient's blood are altered in a lab by adding genes for a receptor (CAR) that enables the T-cells to bind to a particular cancer cell antigen. Patients receive these CAR-T cells, or modified T cells, back. Each CAR is designed for a particular type of cancer antigen since various malignancies have distinct antigens. Some lymphomas and leukemias have cancer cells that express the CD19 antigen. When used to treat cancer cells that have the antigen CD-19 attached, CAR-T cell treatments are ineffective against cancer cells that do not.

1.1.1. Process for starting CAR T-cell therapy

Process for getting a CAR-T cell therapy is long procedure which can take upto a several weeks.

1.1.2. Collection of the T cells:

The specific type of blood cells, white blood cells or the WBCs which contain the T cells (acting as a defence mechanism for the body and fights against different infections

and diseases) are first removed from the patient's blood with a procedure called Leukapheresis, a process, is used to first remove the specific type of blood cells, white blood cells or the WBCs, from the patient's blood. These WBCs contain T lymphocytes, which operate as a defence mechanism for the body and fight against many infections and disorders. Two IV lines are required for this operation because one line draws blood from the patient, separates the white blood cells from the blood, and then returns the patient's blood through the other line. A central venous catheter is a unique kind of IV line that incorporates both IV lines.

The patient must lie down or sit still during this operation, which could last up to two or three hours. Patients may occasionally experience tingling or numbness during this operation because it can lower the patient's calcium levels; in cases when the calcium levels are severely lowered, a muscle spasm may result. The doctor or nursing staff must keep a close eye on the patient throughout this process. When these kinds of situations arise, calcium can be replaced by administering it orally or intravenously.

1.1.3. Preparation of "CAR-T cells"

A patient's T-cells are isolated and delivered to the lab as the white blood cells are drawn out of them. These T-cells are modified in the lab by the addition of the appropriate Chimeric Antigen Receptor genes (CAR). An ordinary T-cell becomes a CAR-T cell as a result of this process. These CAR-T cells are multiplied in the lab with the aid of in-vitro. Once more, it may take many weeks for this operation to produce the necessary amount of cells for this therapy.

1.1.4. Infusion of the CAR-T cells:

CAR-T cells can be administered to the patient in need once a sufficient quantity have been produced in the lab. Cancer patients are called in a few weeks prior to receiving CAR-T cells; during this time, they receive chemotherapy to reduce the quantity of other immune cells because CAR-T cells are also foreign substances that could trigger the body's defence mechanisms. Therefore, chemotherapy is administered before this treatment in order to prevent wasting the CAR-T cells that will be put into the patient's body. Because CAR-T cells still require some cancer cells to assault, the chemotherapy being employed at this time is not very potent.

1.2. Some of the approved CAR- T cell therapy along the years.

The US Food and Drug Administration is in charge of approving CAR-T cell treatments. Over the years, they have approved about six CAR-T cell therapies from various businesses. CAR-T cell therapies are only normally utilised after a patient has tried several other therapy options that have failed, according to a set of guidelines that have previously been established for their usage. It is never the initial treatment option..

Some of the examples of approved CAR-T cell therapies:

Axicabtagene ciloleucel, also known as axi-cel (Yescarta)
Brexucabtagene autoleucel, also known as brexu-cel (Tecartus)
Lisocabtagene maraleucel, also known as liso-cel (Breyanzi)
Idecabtagene vicleucel, also known as ide-cel (Abecma)
Ciltacabtegene autoleucel, also known as cilta-cel (Carvykti)

Many clinical trials are going on find treatment for other types of cancers.

1.2.1. Different diseases in which CAR-T cell therapy is used:

There have been about six CAR-T cell treatments licenced by the US Food and Drug Administration since 2017. For the treatment of blood malignancies, including lymphomas, some types of leukaemia, and multiple myeloma, all approved medicines are available.

1.2.2. Top companies producing CAR-T cell therapy:

- There are several companies producing CAR-T cell therapy, there is a list of 250 companies, some of which are mentioned below.

AbbVie Inc.,	Adaptimmune Therapeutics PLC.,
Amgen, Inc.,	Atara Biotherapeutics, Inc.,
Aurora Biopharma, Inc.,	Autolus Therapeutics PLC.,
Bellicum Pharmaceuticals, Inc.,	bluebird bio,
BioAtla LLC.,	Carina Biotech,
CARsgen Therapeutics, Ltd.,	CARTherics,
Celgene,	Cellectis, Celularity,
Celyad SA,	Creative Biolabs,
DiaCarta, Inc.,	Endocyte, Inc.,
F1 Oncology, Inc.,	Fate Therapeutics Inc.,
Gilead, Humanigen, Inc.,	Immune Therapeutics, Inc.,
Intrexon, Corp.,	Juno Therapeutics, Inc.,
Kite Pharma, Inc.,	Lion TCR Pte Ltd.,
MaxCyte, Inc.,	Mesoblast, Ltd.,
Minerva Biotechnologies Corp.,	Mustang Bio, Inc.,
Novartis AG	Oxford BioMedica PLC.,
PeproMene Bio Inc.,	Pfizer, Inc.,
Posedia Therapeutics Inc.,	Precision Biosciences, Inc.,
ProMab Biotechnologies Inc.,	Servier Oncology,
Sorrento Therapeutics, Inc.,	TC Biopharm Ltd.,
Tessa Therapeutics Pte Ltd.,	TILT Biotherapeutics Ltd.,
Tmunity Therapeutics Inc.,	TrakCel Ltd.,
Xyphos,	ZIOPHARM Oncology, Inc.,

Table 1. List of all the companies producing CAR-T cell therapy

2. Review of literature

In the twenty-first century, CAR-T cell therapy has proven a game-changing method of treating serious illnesses like leukaemia, multiple myeloma, and lymphomas. **Even though** CAR T cell therapy is still in its early phases of development, recent clinical trials have revealed that anti-CD19 CAR-T cell infusions completely remitted advanced B cell malignancies in a number of patients. All forms of blood cancer are collectively referred to as leukaemia, which is further broken down into the following subtypes:

- acute lymph0cytic leukaemia (ALL), and chronic lymph0cytic leukaemia (CLL),
- acute myel0id leukaemia (AML),
- chronic myel0id leukaemia (CML),
- and chronic mon0myelocytic leukaemia (CMML)
- Hodgkin's lymph0ma is one type of lymphoma.
- Non-Hodgkin lymphoma (NHL)

2.1 Epidemiology of leukaemia and Lymphomas:

- • The leukaemia and lymphoma society (LLS) estimates that 54,025 children and adults in the United States under the age of 25 have leukaemia, lymphoma, myeloma, or myelodysplastic syndromes and are either living with them or in remission.
- Leukemia and lymphoma accounted for 40 percent out of all cancer types among under the age of 20 between 2013 and 2017.
- Leukemia and lymphoma have an age-adjusted incidence rate of 8 per one lakh in under the age of 20. (Leukaemia, 5 and lymphoma, 3).

Author	Title	Methodology	Findings
Drew A. Wells, Jenna Summerlin, Zachery Halford,	A Review of CAR T-Cell Therapies Approved for the Treatment of Relapsed and Refractory B-Cell Lymphomas	Literature review	With historically high response rates in patients who had had extensive pretreatment and had few other treatment options, numerous cutting-edge CAR T-cell treatments have emerged on the market since 2017. There are currently few small, single-arm, open-label clinical trials that can be compared head-to-head.
Richard P. Harrison, Ezequiel Zylberberg, Simon Ellison, Bruce L. Levine,	Chimeric antigen receptor–T cell therapy manufacturing: modelling the effect of offshore production on aggregate cost of goods,	Literature review	CAR-T cell treatment can be produced using either offshore manufacturing or autologous manufacture. Both approaches present unique logistical and supply chain difficulties. A new kind of manufacturing procedure is being offered to the market that can increase feasibility while lowering manufacturing costs and logistical problems. Some businesses, including Novartis and Gilead, who manufacture CAR-T cell treatment in scaled-up settings, are headed in this way. This novel approach is referred to as the "allogenic production model."
Heine, R., Thielen, F. W., Koopmanschap, M., Kersten, M. J., Einsele, H., Jaeger, U., Sonneveld, P., Sierra, J.,	Health Economic Aspects of Chimeric Antigen Receptor T-cell Therapies for Haematological Cancers: Present and Future		Although CAR-T cell treatments, both present and future, show promise in the treatment of haematological tumours, the cost for patients to receive this therapy is very high. Some nations are still having trouble paying for pre- and post-operative treatment, and occasionally they receive inadequate reimbursement. The financial strain on healthcare systems will rise with the expansion of the indication, which will have an

Smand, C., & Uyl-de Groot, C. A. (2021).			immediate impact on patients' ability to access this course of therapy.
Cade Hildreth	CAR-T Cell Companies Proliferate: List of CAR-T Companies Worldwide	Literature review	There are numerous businesses that manufacture CAR-T cell treatment. The medicines Kymriah, Yescarta, Tecartus, Breyanzi, and Abecma were among those that made the way for the approval of CAR-T cell therapy and are most commonly prescribed.
	Global CAR-T Cell Therapy Market - Market Size, Forecasts, Trials & Trends, 2022.	Literature review	The following CAR T-cell therapies have been commercially available since the first historic CAR-T approvals in 2017: Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel), and Abecma (idecabtagene vicleucel). Amounts raised in financing rounds by CAR-T startups are getting close to $4 billion, while staggering $2 billion is provided through CAR-T industry alliances.
	Pharma Companies in Europe | Updated 2021	Literature review	22 percent of all pharmaceutical sales worldwide are made in Europe. Half of the biotech companies in Europe are located in France, Germany, and the UK, which has a complicated biotech environment. Sanofi Roche Pharmaceuticals, Bayer AG, and Nordic Group are a few of the well-known companies in the sector.
	Europe CAR T cell Therapy Market Analysis | 2022 to 2027	Literature review	Due to extensive research and development and joint efforts of government cost of treatment has reduced.

			Germany is predicted to grow faster than any other country in the region, however some of these factors include development taking place over a shorter period of time and increased hospital and research centre investment.
	CAR T-cell Therapy Market Insights, 2021-2031	Literature review	Market segmentation of CAR-T cell therapy is done on following factors, Indications, End user, product type, region. Market value for CAR-T cell therapy is 21.8 Billion USD, with a CAGR of 30.6% for 2021- 2031.

3. Methodology

3.1 Type of study: a descriptive cross-sectional study

3.2 Research question:

- What are the CAR-T cell treatment market trends?

3.3 Research objective:

- To comprehend the CAR-T cell therapy market's size.
- To comprehend market trends and developments for CAR-T cell therapy.
- To comprehend the CAR-T cell therapy market's competition.
- To comprehend the cost of CAR-T therapy for a patient.
- To determine the industry's market size and CAGR.

3.4 Methodology:

3.4.1. Inclusion criteria: Pharmaceutical Companies producing CAR-T cell therapy all over the world. Selection of top five companies from the list for further research.

3.4.2. Exclusion criteria: Pharmaceutical companies which were not producing CAR-T cell therapy.

- Historical data analysis: Using previously generated reports from different portals are being used.
- A thorough secondary research is conducted using different platforms like:
    - Clinical trial databases: Clinical trials.gov, clinical trials registry platform
    - Scientific publications: PubMed, High wire press
    - Product launch announcements: Google news
    - Market research reports: Polaris market research, PR newswire, pharmaceutical technology, etc.

- **Market segmentation:** Based on Indication of the therapy, End User, Product type and region.
- **Porter's five forces** of the market, highlighting the five forces which are mainly responsible for driving the market.
- **Competitor analysis** of the top five companies.

4. Results

The CAR-T cell therapy market was estimated at USD 1970 globally in 2021 and is anticipated to increase at a CAGR of 32 percent over the following five years. In this sort of therapy, the body's T-cells are altered to become CAR-T cells, which oversee eliminating cancerous cells from the body (predominantly blood cancers). The source of T cells is patient's blood these cells are processed in labs, these are then known as CAR-T cells since they are linked to a particular kind of antigen.

Along with the expansion of the biotechnology and life sciences industries for the purpose of treating cancer with CAR-T cells, this industry has experienced consistent growth throughout time (chimeric antigen receptors). The market for CAR-T cell therapy has grown because of several factors, including an increment in PAPs (patient assistance programmes), increment in government efforts to raise cancer awareness, an increment in the total number of cancer cases worldwide, and research and development initiatives from major corporations. Due to the market's rapid expansion, it became necessary to manufacture the therapy in-house; as a result, some businesses have begun to invest in production facilities.

This therapy is gaining popularity because of people being more conscious of the importance of preserving their health and the growing need for high-quality medical care. Due to the significant rise in disease prevalence and incidence, people have begun investing in products that will help them stay healthy and active. The pharmaceutical manufacturing companies, which were formerly concentrated on producing various products, are now concentrating on working with healthcare services to encourage more research and development of cutting-edge therapies, medications, and instruments for identifying and treating different diseases.

Approximately 100 medical facilities in the United States are now providing CAR-T cell therapy, primarily in inpatient settings, though there is a growing trend to provide this treatment in outpatient settings as well.

The CAR-T cell treatment process is pricey. One patient's treatment can cost a healthcare professional up to $1 million. Cancer treatments, including CAR-T cell therapy, are covered by insurances like Medicare and Medi-aid. The amount that a patient must pay varies depending on their unique situation, including their insurance

coverage preference and their eligibility for Medicare. Healthcare professionals assist patients when they suggest this therapy, and the hospital's financial support helps them grasp their unique situation.

Additional research is being done in this therapy, and the findings thus far are promising. More than 85% of patients with ALL demonstrated a complete cure of the disease immediately following the disease, while 60% survived cancer-free for 12 months following treatment, according to research. The industry is still very concerned with production and manufacturing, and efforts have been made to find ways to produce in greater quantities so that patients can obtain treatment more quickly and for less money. To treat solid tumours like breast cancer and lung cancer, some researchers are working on novel understandings for this therapy. Research and development is in progress to lengthen the duration ,that these cells can fight cancer, as well as to lessen the negative effects of the treatment.

A patient must pay a very high price for this therapy, and there are additional pharmacological costs that must be covered, making the cost of the entire course of treatment very high. Pre-infusion procedures may involve bridging therapy and chemotherapy that depletes lymphocytes. The operation typically takes between 15 to 33 days, but in circumstances where the administration is delayed, it may take up to two months. The average time for the procedure also increases as a result of drug shortages and administrative delays. Patients with chronic illnesses may need some form of supporting care, which eventually adds to their financial burden.

5. Discussion:

5.1. Timeline for "CAR-T cell therapy" development:

Immune cells offered mice cancer protection in 1960.

This year, researchers made history by proving for the first time that these cells can stop cancer in mice.

T-cell ancestry was found in 1961.

An Immunologist found that the thymus gland oversees manufacturing "T-Cells," a part of the body's immune system.

In 1973, a bone marrow transplant was performed to treat cancer.

MSK researchers employed bone marrow stem cells from an unrelated donor to replenish a patient's blood cells after intensive chemotherapy. Cancerous cells were eliminated from T cells delivered from a donor to a patient or receiver. The first immunotherapy to be successful was this one.

Infiltrating lymphocytes were first utilised to treat cancer in 1986.

Patients with cancer were treated at the National Cancer Institute using lymphocytes that infiltrate tumours. After being removed from a tumour and expanded in a lab, the lymphocytes were returned to the patient in large quantities. This shown that even in its advanced stages, cancer may be fought off by a patient's own immune cells.

In 1992, Michel Sadelain, an immunologist and PhD candidate at MIT, began the genetic engineering of T cells. He created retroviral vectors, which he then introduced into T cells to strengthen them as cancer-fighting cells. In 1993 first CARs were developed

An Immunologist Zelig Eshhar of the Weizmann Institute in Israel genetically modified T-cells with the first chimeric molecule, which is a portion of an antibody connected to or infused with a portion of T-cell receptor. Even though these antigens were technologically advanced and clinically effective, they were unable to stay in the human body.

In 1994 T cells that were specific to an antigen were employed in humans.

When researchers at MSK discovered how to extract virus-specific T-cells for the use in stem cell transplantation, the area of genetic engineering had already advanced. These cells helped avoid post-transplant infections and malignancies brought on by viruses in the patients, and they also helped prevent the potentially fatal graft versus host disease.

In 1998 A necessary boost in the field was shown by Co-stimulation.

This year, researchers produced a significant finding that allowed modified T-cells to remain active and persistent in the human body with the aid of the co-stimulatory molecule CD28. This discovery helped pave the way for the development of a new generation of CARs.

In 2002 Development of CAR T cells which were first effective result

Prostate cancer antigen was the target of the first successful CAR-T cell therapy, which was created by a team of MSK researchers. The ability of the second generation of CAR-T cells to live, grow, and kill the prostate cancer cell in the lab showed the viability of the CAR-T cell therapy.

In 2003 following the 1st -generation CAR-T cells a 2nd generation CARs which were built to target CD-19.

Prior to this advancement, Dr. Sadelain and his colleagues published a report demonstrating the ability of human CD-19 guided CAR-T cells to eradicate leukaemia cells in the same mouse model. For the first time, CD-19's efficacy was demonstrated. The genetically modified tools were then changed to employ CD-19 after that.

In 2009 The method of developing CD19 CARs was published

The production of CD19 antigens cells, which were intended infused in children suffering from chemo-refractory leukaemia, was thoroughly described in a publication shared. The manufacturing procedure and the efficiency of the cells were demonstrated in this publication.

In 2013 Results of the clinical trials for CAR-T leukaemia were published.

Renier Brentjens, a physician-scientist at MSK, and colleagues presented the outcomes of clinical studies using CD-19 infused cells in adults with ALL in humans.

In 2014 CARs were designated as "breakthrough therapy" by FD

The FDA awarded CD-19 guided CAR-T cells a breakthrough designation, signalling the field's advancement in science and medicine.

A Mesothelin-directed CAR was created in 2014.

A MSK physician-scientist published a study on the outcomes of CARs that were created to recognise an antigen on solid tumours called mesothelin. Since solid tumours do not produce CD-19, a different strategy was used.

In 2015 Development of Armoured CARs was done

A study on the effectiveness of CARs designed to recognise antigen on the researchers at MSK are working on a new sort of ovarian cancer therapy that they have dubbed "armoured CARs." These CAR-T cells are designed to create additional molecules called "armed CARs."

In 2017 CRISPR'd (Genome editing tool) CARs built

According to several investigations by researcher, the CRISPR genome editing technology can be utilised to insert the CAR into a genetically precise site for better functioning.

In 2017 FDA approves First CARs

The FDA has approved CD-19 guided CAR-T cells for the treatment of relapsed, refractory acute lymphoblastic leukaemia in adolescents and young adults.

5.2 Market size for the CAR-T cell therapy:

After 2018, the CAR-T cell treatment market began to expand. With a CAGR of more than 45%, the 2019 global market size for CAR-T cell treatment was anticipated to be approximately 480 million USD (Research Corridor, 2022). Since then, the market has continued to grow, reaching a value of 588.99 million USD in 2020. (CAR T-Cell Therapy Market Size, Share, Trends, Growth & Forecast, 2022). Despite the fact that the market had been experiencing growth, the Covid-19 pandemic struck the world in 2020, disrupting logistics for the entire market. By 2021, the global market had grown to 1965.8 million USD with a CAGR of 63.82 percent (CAR-T Cell Therapy Market | 2022-29 | Share, Size, Industry Report, 2022).

The market for CAR-T cell treatment has seen a rise in CAGR throughout the years, reaching 63.82 percent.

Year	Market size (million USD)	CAGR (%)
2019	480 million USD	45%
2020	589.99 million USD	31.16%
2021	1965.8 million USD	63.82%

Table 2: Market size and CAGR along the years.

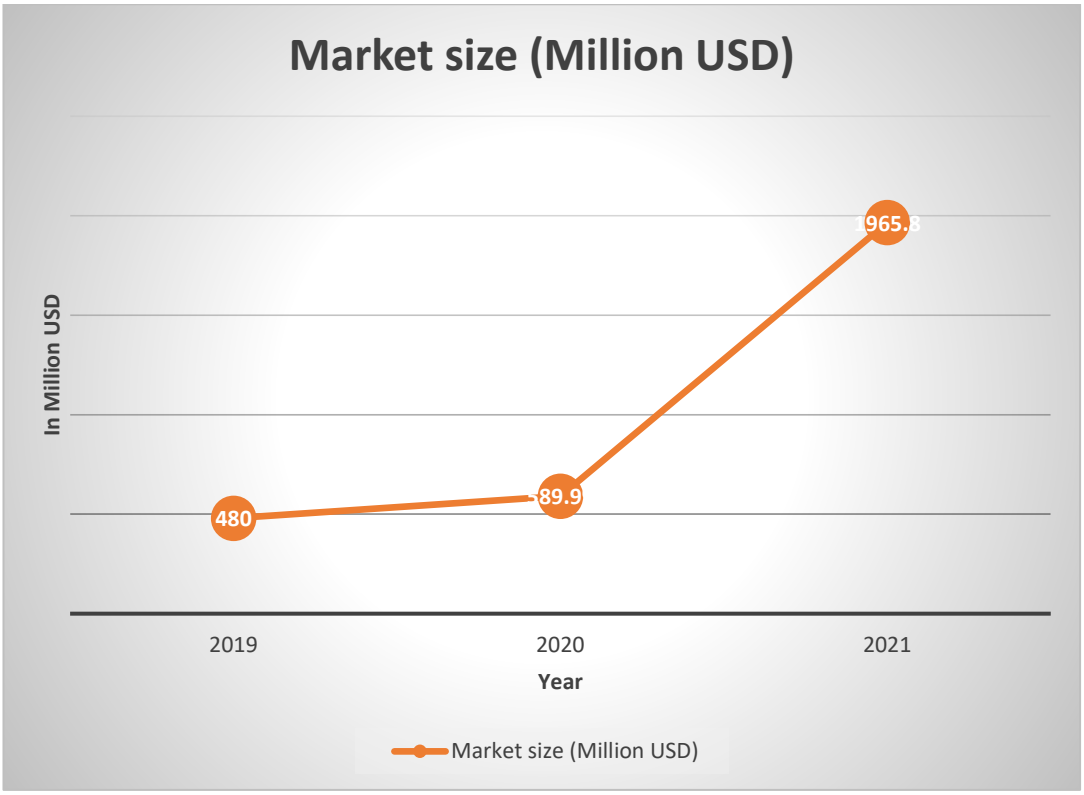


Fig. 1 Growth of market for global CAR-T cell therapy.

The graph illustrates the rising trend of the global market for CAR-T cell treatment, which was reported to be 480 million USD in 2019 with a CAGR of 45 percent and rose to 589.99 million USD with a CAGR of 31.16 percent in 2020. Despite the pandemic, the market size for 2021 was the largest at 1965.3 million USD, with a CAGR of 63.82 percent.

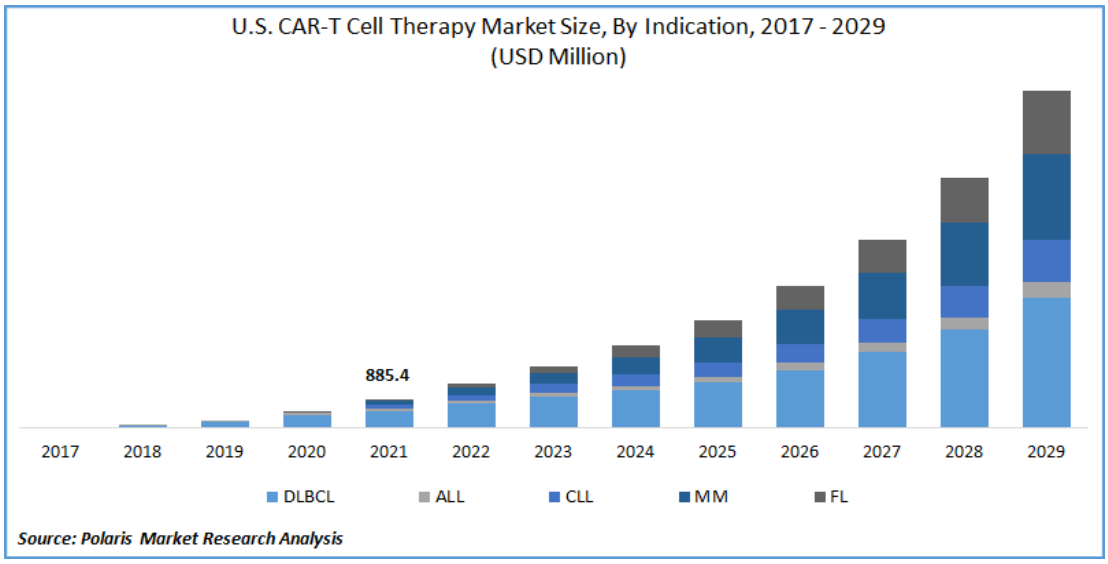


Fig. 2 Growth of US market for CAR-T cell therapy over the years.

5.3 Market segmentation:

Fig 3. Market segmentation for the therapy

- This treatment market is segmented using the following four categories:
- • By target antigen: The diverse surface antigens, such as CD-19, BCMA (B-cell maturation antigen), as well as certain other antigens, determine the target antigen for CAR-T cell treatment.

- • By indicators/diseases: this cell therapy has been shown to be beneficial in treating a variety of blood cancers, while additional research is showing that it is also effective in treating solid tumours.

• By region: The global market for CAR-T cell treatment is split up into various areas. North American region, European region, Asia Pacific, and the rest of the world are separated from it.

• By key players: A small number of companies that manufacture and distribute CAR-T cell treatment control the majority of the market. Following are a few of the major players:

- **Celgene Corporation,**
- **Gilead Sciences,**
- **Inc., Cellectis,**
- **Servier Laboratories,**
- **Pfizer Inc., and Mereck KGaA are a few examples such companies.**

5.3.1. Targeted audience for CAR-T cell therapy market are:

- Market makers,
- Suppliers of raw materials,
- Research consultants
- Retailers, wholesalers, and suppliers
- Regional and local government entities as well as research organisations
- Investment research companies

5.4 Porter's five forces model

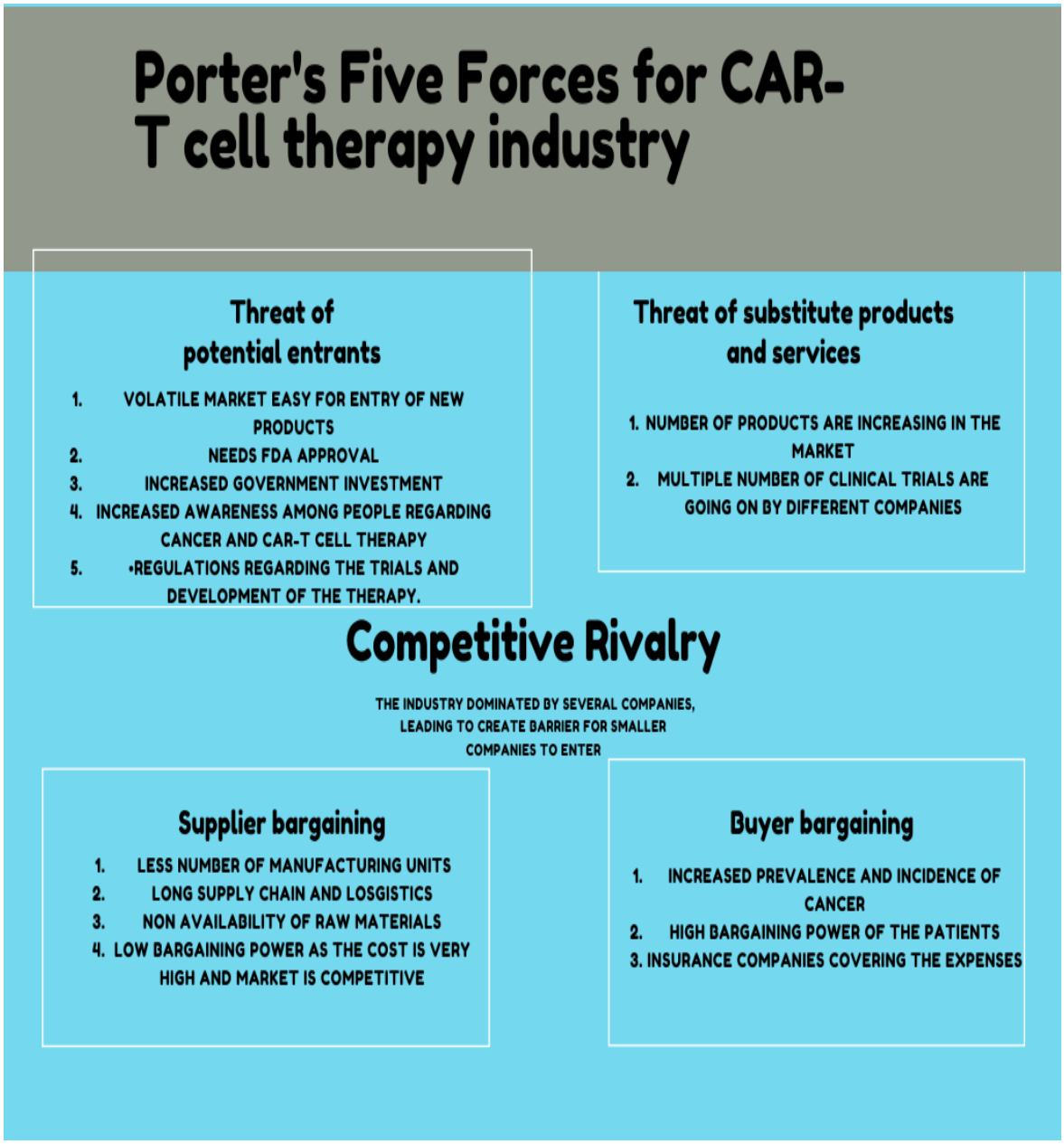


Fig. 4 Porter's five forces model for CAR-T cell therapy.

5.5 Financial burden of the therapy on a patient:

Cost of five approved therapy by different companies for a single shot. (The construct all the different brands are same i.e., anti-CD-19-4-1BB-CD3z)

Therapy and manufacturer	Cost per shot (USD)
Tisagenlecleucel (Kymirah) Novartis	ALL- $475,000, B-cell lymphoma- $373,000
Axicabtageneciloleucel (Yescarta) Kite pharma	$399,000
Lisocabtagenemaraleucel (Breyanzi) Bristol Myers Squibb	$410,300
Brexucabtangencartoleucel (Tecartus) Kite pharma	$399,000
Idecabtagenevicleucel (Abecma) Bristol Myers Squibb/ Bluebird Bio.	$419,500

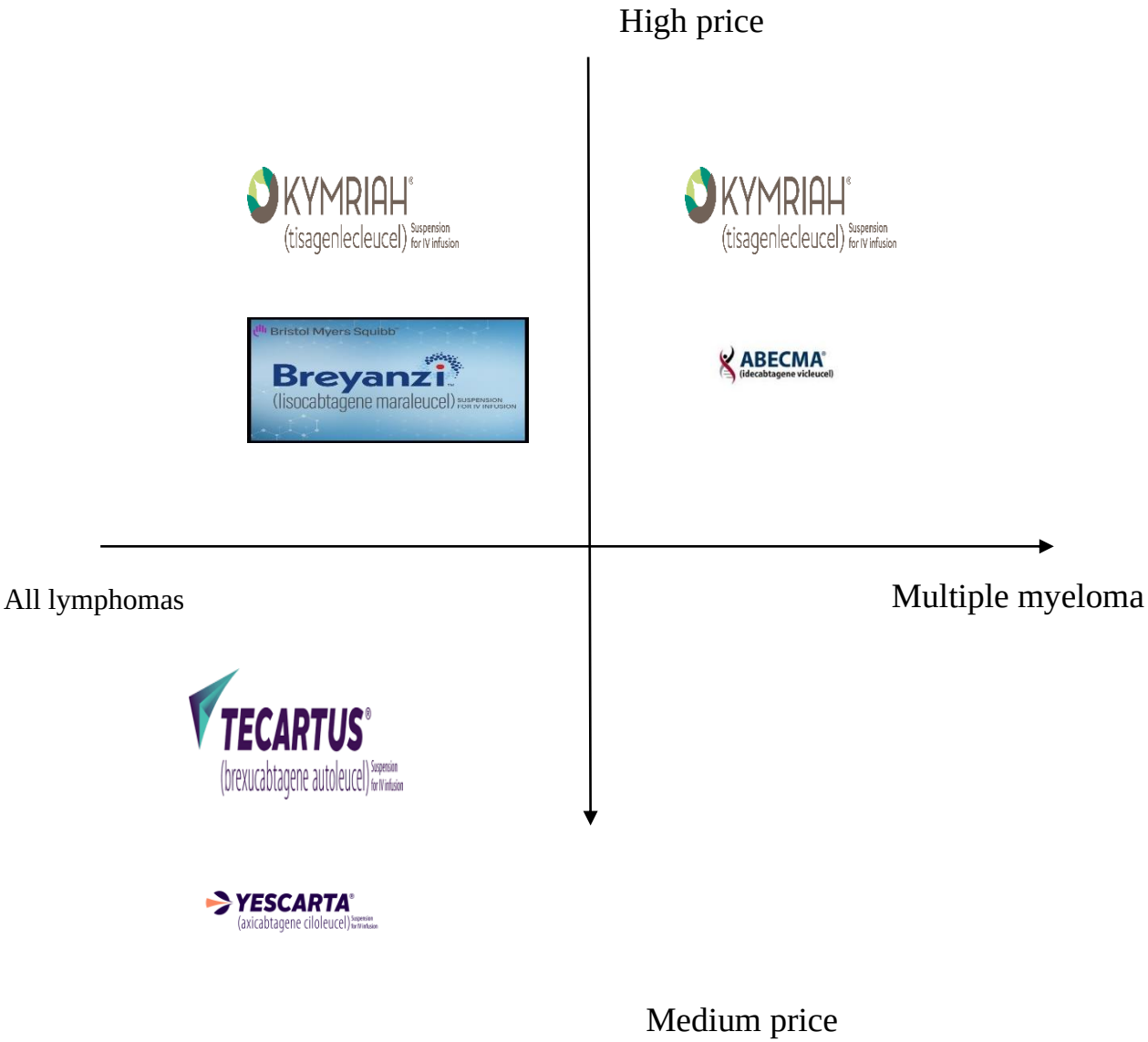
Table 3. Therapy manufacturer and the cost.

5.4.2 Other expenses linked to the process include: Direct expenditures for CAR-T cell therapy that are projected to be incurred by the typical patient in two healthcare settings.

Economic Inputs	Academic inpatient hospital	Non academic speciality oncology network
Drug costs	Value $ USD	
CAR-T cell	373,000	373,000
Lymphodepletion	1,578	1,578
Tocilizumab	4,368	4,368
Dexamethasone	2.5	2.5
Filgrastim	315	315
Procedure costs		
Radiology	76	22
EEG	445	330
ECG	656	239
Lumbar puncture	117	87
MRI	441	327
1-h chemotherapy administration	364	144
CAR-T cell administration	313	176
Facility costs		
ICU days	6546	6546
Inpatient days	2668	2668
Non-academic speciality oncology network visit	NA	76

Table 4 Prices connected with CAR-T cell therapy.

5.5. Competitor analysis



Reference: (CAR-T Cell Therapy Aka Miraculous Technology: Mapping the Market, Approved Therapies, Competitive Landscape, and Impact of COVID-19, 2022)

Fig 5. Competitor analysis for different products-based disease and their price ranges.

6. Conclusion

Genetic engineering and the field of cancer treatment have both benefited greatly from the development of this therapy. In B-cell malignant cancer that are refractory or relapsed, this therapy has shown some spectacular results. The important genetic alterations made for this therapy over the years have been discussed in this publication.

This study has provided a detailed account of the entire process, including the discovery of the medication, its development, effective survival, and FDA approval.

The CAR-T cell treatment market is expanding daily; nevertheless, a small number of dominant enterprises make it challenging for newer, smaller businesses to gain market share. Other factors, such as governmental laws, drug approval procedures, disruptions in the availability of raw materials, and a lack of numerous manufacturing facilities, also contribute to the introduction of new products to the market. The market has also seen a constant annual growth rate (CAGR). The market for the therapy has expanded since the first approval was received in 2017. Promising outcomes from treatment clinical trials, rising cancer incidence and prevalence, increased public awareness of cancer and its treatment, government grants for clinical trials, and vigorous research and development by businesses already operating in the market or attempting to do so are reasons for driving growth of market.

Study also illustrates the financial burden that a patient must endure for this treatment, including both the direct cost of the treatment and any indirect expenditures. This has shown to be a significant out-of-pocket expense because the insurance does not pay the full cost of the treatment.

According to the research done for this project, there are numerous steps that may be taken to lower the price of the treatment, including the cell therapy that is produced more quickly, allowing patients to spend less on supportive care. creation of internal manufacturing facilities at cancer hospitals or other specialised facilities. ensuring a continuous supply chain and logistics.

References

- LLP, D., 2022. *Comprehensive Analysis of 250+ Key Companies Developing 250+ Novel CAR-T Therapies: DelveInsight*. [online] GlobeNewswire Newsroom. Available at: <https://www.globenewswire.com/news-release/2021/04/21/2213788/0/en/Comprehensive-Analysis-of-250-Key-Companies-Developing-250-Novel-CAR-T-Therapies-DelveInsight.html#:~:text=Key%20companies%20developing%20CAR%2DT,.%2C%20CARTherics%2C%20Celgene%2C%20Cellectis> [Accessed 14 June 2022].
- Nair, R. and Westin, J., 2022. *CAR T-Cells*.
- Alabanza, L., Pegues, M., Geldres, C., Shi, V., Wiltzius, J., Sievers, S., Yang, S. and Kochenderfer, J., 2022. *Function of Novel Anti-CD19 Chimeric Antigen Receptors with Human Variable Regions Is Affected by Hinge and Transmembrane Domains*
- Lls.org. 2022. *Childhood and Adolescent Blood Cancer Facts and Statistics | Leukemia and Lymphoma Society*. [online] Available at: <https://www.lls.org/facts-and-statistics/childhood-and-adolescent-blood-cancer-facts-and-statistics> [Accessed 14 June 2022].
- Cancer.org. 2022. *Leukemia*. [online] Available at: <https://www.cancer.org/cancer/leukemia.html> [Accessed 14 June 2022].
- ltd, R., 2022. *Global CAR-T Cell Therapy Market - Market Size, Forecasts, Trials & Trends, 2022*. [online] Researchandmarkets.com. Available at: <https://www.researchandmarkets.com/reports/5331298/global-car-t-cell-therapy-market-market-size> [Accessed 14 June 2022].
- Franchise, P. and Europe, P., 2022. *Pharma Companies in Europe | Updated 2021 list of PharmaAdda*. [online] Pharmaadda.in. Available at: <https://www.pharmaadda.in/pharma-companies-in-europe> [Accessed 14 June 2022].
- Polarismarketresearch.com. 2022. *CAR-T Cell Therapy Market | 2022-29 | Share, Size, Industry Report*. [online] Available at: <https://www.polarismarketresearch.com/industry-analysis/CAR-T-Cell-Therapy-Market> [Accessed 24 June 2022].

- Verified Market Research. 2022. *CAR T-Cell Therapy Market Size, Share, Trends, Growth & Forecast*. [online] Available at: <https://www.verifiedmarketresearch.com/product/car-t-cell-therapy-market/>
- Research Corridor, h., 2022. *CAR T-Cell Therapy Market Size, Share, Growth, Industry Report to 2027*. [online] Researchcorridor.com. Available at: <https://www.researchcorridor.com/car-t-cell-therapy-market/#:~:text=The%20global%20CAR-T%20Cell%20Therapy%20market%20size%20was,This%20is%20predicted%20to%20uplift%20the%20market%20growth>
- Rebecca Borgert, B., 2022. *Improving Outcomes and Mitigating Costs Associated With CAR T-Cell Therapy*. [online] AJMC. Available at: <https://www.ajmc.com/view/improving-outcomes-and-mitigating-costs-associated-with-car-t-cell-therapy> [Accessed 25 June 2022].
- Memorial Sloan Kettering Cancer Center. 2022. *CAR T Cells: Timeline of Progress*. [online] Available at: <https://www.mskcc.org/timeline/car-t-timeline-progress#:~:text=2002%20%E2%80%94First%20effective%20CAR%20T,of%20CAR%20T%20cell%20therapy.> [Accessed 25 June 2022].
- DelveInsight Business Research. 2022. *CAR-T Cell Therapy aka Miraculous Technology: Mapping the Market, Approved Therapies, Competitive Landscape and Impact of COVID-19*. [online] Available at: <https://www.delveinsight.com/blog/car-t-cell-therapy-market-and-competitive-landscape> [Accessed 25 June 2022].
- MarketWatch. 2022. *CAR T Cell Therapy Market Report 2022 Industry Size, Market Status, Influencing Factors, Competition, SWOT Analysis, Outlook and 2031 Forecast*. [online] Available at: <https://www.marketwatch.com/press-release/car-t-cell-therapy-market-report-2022-industry-size-market-status-influencing-factors-competition-swot-analysis-outlook-and-2031-forecast-2022-05-06> [Accessed 25 June 2022].
- Zachery Halford, B., 2022. A Review of CAR T-Cell Therapies Approved for the Treatment of Relapsed and Refractory B-Cell Lymphomas. [online] The Journal of Hematology Oncology Pharmacy. Available at: <https://jhoponline.com/jhop-issue-archive/2022-issues/february-2022-vol-12-no-1/19290-a-review-of-car-t-cell-therapies-approved-for-the-treatment-of-relapsed-and-refractory-b-cell-lymphomas> [Accessed 14 June 2022].

- Doi.org. 2022. Redirecting. [online] Available at: <https://doi.org/10.1016/j.jcyt.2019.01.003> [Accessed 14 June 2022].
- Heine, R., Thielen, F., Koopmanschap, M., Kersten, M., Einsele, H., Jaeger, U., Sonneveld, P., Sierra, J., Smand, C. and Uyl-de Groot, C., 2022. Health Economic Aspects of Chimeric Antigen Receptor T-cell Therapies for Hematological Cancers: Present and Future.
- (CEO), C., 2022. The Meteoric Rise of CAR-T Cell Therapies: List of CAR-T Companies. [online] BioInformant. Available at: <https://bioinformant.com/car-t-companies-the-meteoric-rise-of-cellular-immunotherapies/#introduction> [Accessed 14 June 2022].
- ltd, R., 2022. Global CAR-T Cell Therapy Market - Market Size, Forecasts, Trials & Trends, 2022. [online] Researchandmarkets.com. Available at: <https://www.researchandmarkets.com/reports/5331298/global-car-t-cell-therapy-market-market-size> [Accessed 14 June 2022].
-
- Franchise, P. and Europe, P., 2022. Pharma Companies in Europe | Updated 2021 list of PharmaAdda. [online] Pharmaadda.in. Available at: <https://www.pharmaadda.in/pharma-companies-in-europe> [Accessed 14 June 2022].
- ltd, M., 2022. Europe CAR T cell Therapy Market Analysis | 2022 to 2027 | UK, Germany, Spain, Italy, Frane. [online] Market Data Forecast. Available at: <https://www.marketdataforecast.com/market-reports/europe-car-t-cell-therapy-market> [Accessed 14 June 2022].
- Transparencymarketresearch.com. 2022. CAR T-cell Therapy Market Insights, 2021-2031. [online] Available at: <https://www.transparencymarketresearch.com/car-t-cell-therapy-market.html> [Accessed 14 June 2022].