India

Neutral *(no change)*

Highlighted Companies

Laurus Labs

REDUCE, TP Rs294, Rs400 close

ImmunoACT, a company in which Laurus Labs has a 33.86% stake, got approval for India's first CAR-T cell therapy.

Summary Valuation Metrics

P/E (x)	Mar22-A	Mar23-A	Mar24-F
Laurus Labs	26.06	27.29	43.42

P/BV (x)	Mar22-A	Mar23-A	Mar24-F
Laurus Labs	6.43	5.34	5

Dividend Yield	Mar22-A	Mar23-A	Mar24-F
Laurus Labs	0.4%	1%	0.5%

Pharmaceuticals

CAR-T: A new-age cancer therapy

- We had written on ImmunoACT's CAR-T cell therapy in earlier reports. India's first CAR-T received the nod on 13 Oct 2023. Laurus has a 33.86% stake in it.
- The therapy uses the human immune system to fight cancer. Many companies across the globe are in this field, and it is also a hot area for M&A activity.
- The global CAR-T cell therapy market is projected to touch US$88.52bn by 2032F, as per Precedence Research.

ImmunoACT gets nod for India's first CAR-T cell therapy

Laurus Labs acquired a 33.86% stake in ImmunoACT with an investment of Rs1.26bn. The company paid Rs460m to acquire a 26.62% stake in ImmunoACT in 2021, and an additional Rs800m to increase its stake to 33.86% in 2023. ImmunoACT used these funds to ramp up its manufacturing capacity for T-cell therapy and commercialize the product. ImmunoACT has now received approval for India's first CAR-T cell therapy on 13 Oct 2023. Even though there are multiple companies in this area globally, in India, ImmunoACT and Immuneel are the only two companies that are working in this field. Immuneel's therapy is still in the development phase. This will be of advantage to ImmunoACT, as it will be first to market the therapy and will have virtually no competition in India for the first few years. Based on a study, India has a market size of 20,000-40,000 patients per year for this therapy and according to media reports, ImmunoACT is planning to charge around Rs3-4m for this product. This is approximately 90% less than the cost of CAR-T cell therapies approved in the US.

CAR-T cell therapy market is growing despite its high price

The cost of CAR-T cell therapy can touch US$0.5m, even though there are currently six US Food and Drug Administration (US FDA)-approved CAR-T cell therapies. In contrast, chemotherapy costs US$150,000, which is approximately 3x less expensive than CAR-T cell therapy. Due to this reason, it is used only in high-risk cancers and relapse. However, due to its specialized mechanism and high efficacy, the market is experiencing good growth. The global CAR-T cell therapy market is projected to touch US$88.52bn by 2032F, with a noteworthy CAGR of 29.8% over 2023-32F. Six therapies that are approved in the US market had an annual revenue of US$2.51bn in 2022. Owing to the large market size and high reward multiple, pharmaceutical and biotechnology companies are active in this field.

CAR-T cell therapy uses a patient's own immune cells to fight cancer

T-cells are an important part of the human immune system that kill infected and unhealthy cells. In CAR-T cell therapy, these cells are engineered using a virus to identify the cancer cells and kill them. As it specifically targets cancer cells, the therapy has fewer side effects than chemotherapy and a higher efficacy too. Currently, this therapy is only available for different types of blood cancers, but work is going on to develop it for solid tumours as well.

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CAR-T cell therapy – NextGen cancer treatment

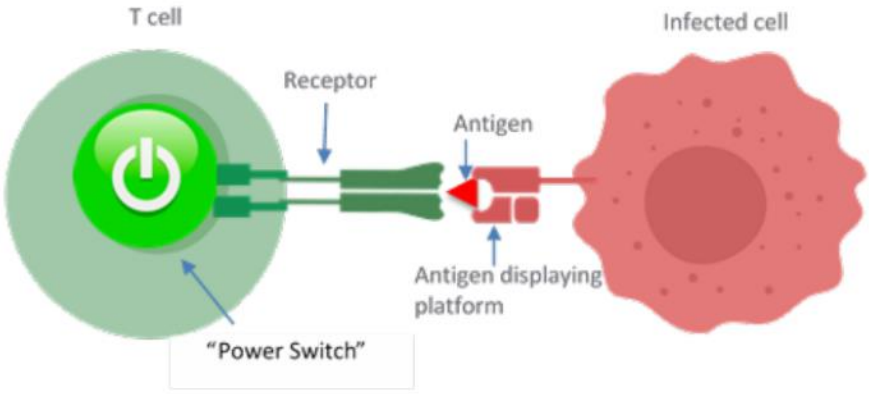
The how, what, and why of CAR-T cell therapy

1. CAR-T cell therapy is an immunotherapy. It uses the T-cells that are found in our adaptive immune system.
2. In this therapy, the patient's T-cells are extracted from the bone marrow. After this, they are genetically edited by scientists in a laboratory to identify the cancer cells. The genetically modified cells are then multiplied in a bioreactor. The new pool of T-cells is injected in the patient, where they kill the cancer cells.
3. Currently, it is used to treat different types of blood cancers like lymphoma and leukaemia, but clinical trials and research is going on to adapt it for the treatment of solid tumours. It is primarily used for treatment of patients who have relapsed or are suffering from high-risk cancers.
4. The therapy has a higher efficacy and fewer side effects when compared with conventional cancer treatments like chemotherapy.

T-cells are brave warriors of the human immune system »

1. The immune system creates an army of T-cells that patrol our body to look for signs of infection and other diseases. They inspect suspicious cells and when they find an abnormal one, they immediately attack it, while taking care that there is limited damage to the healthy cells.
2. **T-cells have protein receptors on their surface that latch on to antigens.** Antigens are protein fragments that can be found on the surface of cells. When a T-cell latches on to an antigen that can only be found on a diseased cell, **it turns on and releases toxic chemicals that damage the diseased cell.** It also recruits other immune helper cells to the area.

Figure 1: T-cells have receptors that latch on to antigens on infected cells - this turns on an attack that kills the infected cells



SOURCE: CANCER RESEARCH INSTITUTE, INCRED RESEARCH, COMPANY REPORTS

The game of evasion between cancer cells and immune cells »

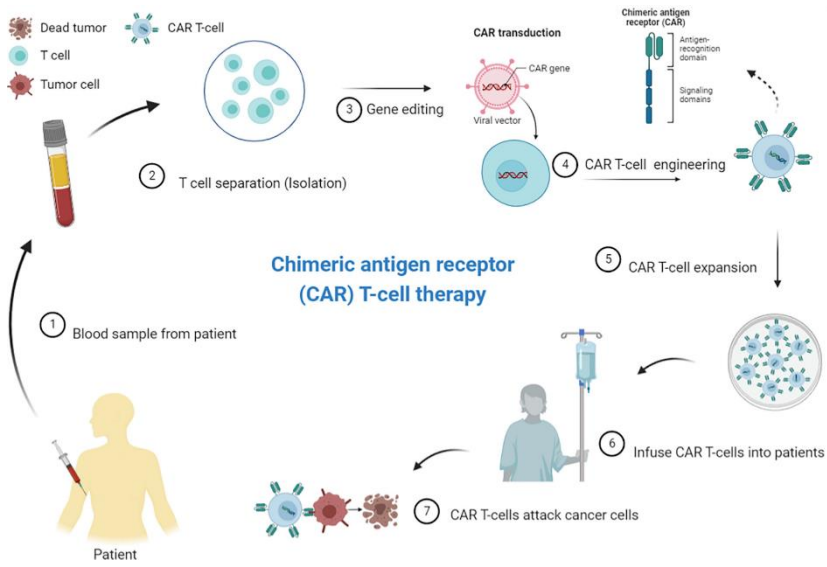
Like other diseased cells, T-cells also want to kill cancer cells. However, sometimes cancer cells cheat the T-cells in one of the below-mentioned ways:

1. Disguising themselves as healthy cells.
2. By producing so many antigens on their surface that the T-cells are stymied and cannot mount an effective attack.
3. Finding ways to turn off the immune attack against them.

CAR-T cell therapy is an effective way to combat evasive cancer cells

1. CAR-T cell therapy is one way to win over the deception of cancer cells. Thousands of patients' own T-cells are collected in a process similar to blood donation.
2. The T-cells are reprogrammed using a modified and inactive virus that cannot cause any disease but can introduce genetic information to the T-cells. The T-cells are reprogrammed so that they produce special receptors called chimeric antigen receptors (CARs) on their surface.
3. These newly engineered CAR-T cells are grown in a laboratory and millions of them are infused back into the patient. **The new receptors enable the CAR-T cells to latch onto a specific antigen on a patient's tumour cells and destroy them.**

Figure 2: The process of CAR-T cell therapy: T-cells are collected from the patient, genetically edited to attack cancer cells, and introduced back into the patient where they recognize and kill cancer cells



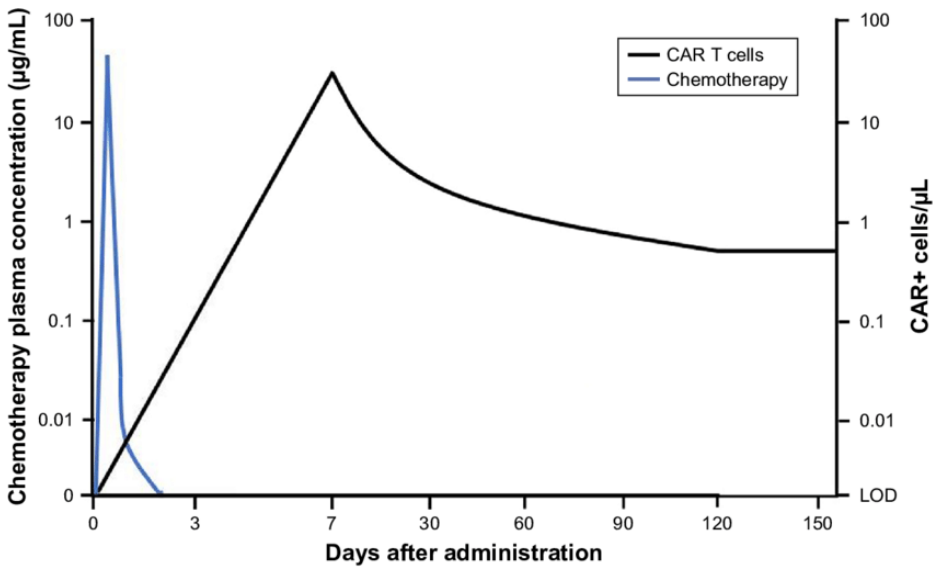
SOURCE: INCRED RESEARCH, COMPANY REPORTS

CAR-T cell therapy: a quantum leap in cancer treatment

1. Until the 1950s, tumour growth was treated via methods such as surgery, radiotherapy, hyperthermia, or other traditional methods. It was next to impossible to treat a cancer that had spread. Chemotherapy heralded a new era in cancer treatment by allowing treatments of such cancers. However, even with chemotherapy, there is a high rate of remission, and it has lasting side effects like nausea, hair loss, headache, and muscle damage.
2. In the year 2017, the US FDA approved the first two CAR-T cell therapies, and over a dozen therapies have been developed or are currently being developed. CAR-T cell therapies are used as a second-line treatment. **The current CAR-T cell therapies aim at treating leukaemia, lymphoma, and other types of blood cancers that were mostly incurable earlier.**
3. CAR-T cell therapy was developed with an aim of providing the patient with the potential of long-term remission and even a cure. As they target the cancer cells effectively, they are more **effective, have fewer side effects, and provide long-term protection**. Moreover, only one session of CAR-T cell therapy is needed, while chemotherapy requires multiple sessions. For example, in one study, CAR-T cell therapy was able to achieve **complete remission in 83% of the patients with relapsed or refractory acute lymphoblastic leukaemia**. CAR-T cell therapy has also been shown to be effective against some types of lymphoma, such as diffuse large B-cell lymphoma (DLBCL). In one study, CAR-T cell therapy was able to achieve

complete remission in 52% of patients with relapsed or refractory DLBCL.

Figure 3: CAR T-cell therapy has a longer lasting effect than chemotherapy



SOURCE: NATURE, INCRED RESEARCH, COMPANY REPORTS

Global market landscape for CAR-T cell therapy

With such high-priced models, does CAR-T cell therapy have any room for growth?

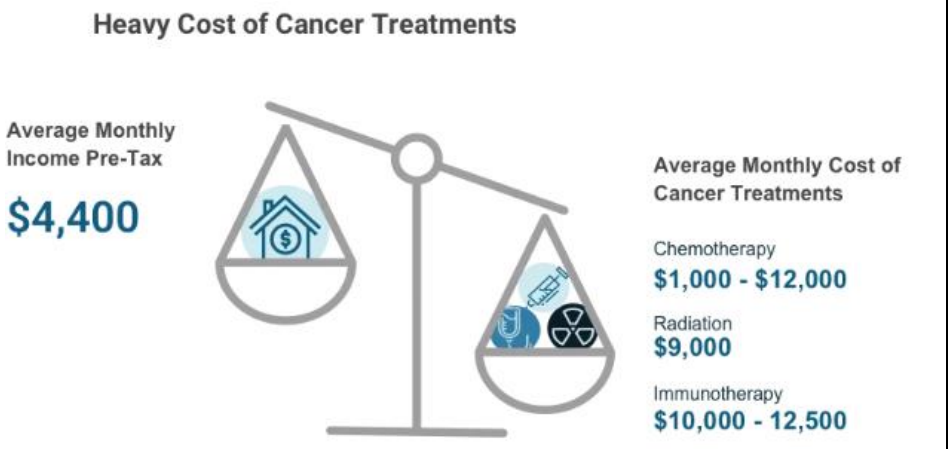
1. Six CAR-T cell therapies have been approved in the US from 2017 till now. They are: Kymriah, Yescarta, Tecartus, Breyanzi, Abcema and Carvykti. Despite the presence of multiple options, the cost of these therapies can touch US$500,000.
2. Due to high prices, there is a resistance to use CAR-T cell therapy. It is used only when no other treatment options are available, or the cancer is high risk. The first preference is more economical treatments like chemotherapy and radiotherapy.
3. Despite the high prices and resistance, CAR-T cell therapy market was valued at US$3.82bn in 2022 and is expected to grow to a valuation of US$88.52bn by 2032F. Owing to the large market size and high reward, multiple pharmaceutical and biotechnology companies across the globe are active in this area, and it is a hot field for merger and acquisition or M&A activity.

CAR-T therapy prices touch the moon ➤

1. In 2017 and 2018, Novartis's Kymriah and Gilead's Yescarta were approved by the US FDA for use after showing ground-breaking results in relapsed/refractory B-cell malignancies. After that, four additional treatments were approved. However, despite its effectiveness, the technology is controversial because of its high price.
2. Owing to the high cost, CAR-T cell therapy is used as a treatment option only when the cancer is high risk or no other treatment option is available. In comparison to the **US$500,000 cost of CAR-T cell therapy, the total cost of chemotherapy for a patient with relapsed or refractory follicular lymphoma is US$155,000** (see Fig. 4).
3. Along with the acquisition cost of the product itself, the cost of procedure and facility costs add to the final product cost. **The cost of acquisition of CAR-T cell therapy lies in the range of US$373,000-475,000 per infusion**, and this excludes the extra procedures and facility costs.
4. Moreover, this therapy needs to be done in a hospital, which adds an additional cost of US$79,466-85,267. The other barrier is that after the administration of CAR-T therapy, patients can have an adverse reaction called

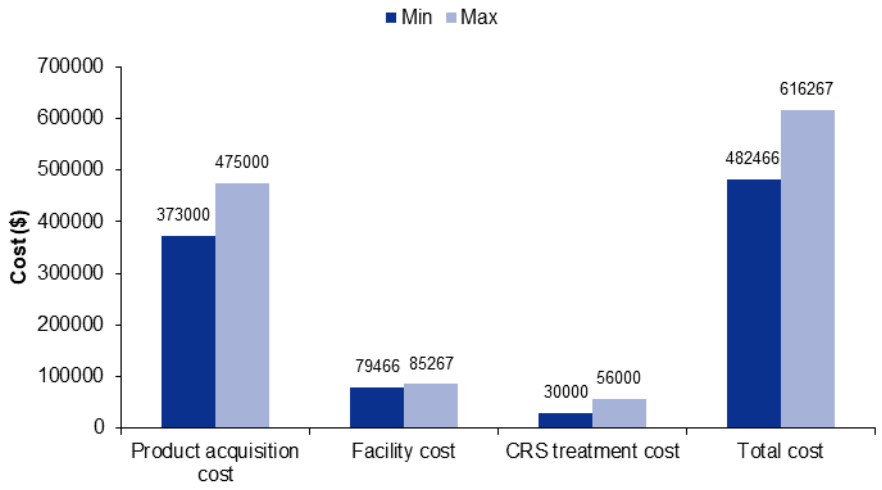
cytokine release syndrome (CRS). CRS is an immune response that can negatively affect any organs including cardiovascular, respiratory, gastrointestinal, hepatic, renal, haematological, and nervous systems, and can be lethal to cancer patients. CRS treatment costs can fall between US$30,000-56,000 per patient. This makes **the total cost of CAR-T cell therapy to touch US$500,000** for patients with CRS (see Fig. 5).

Figure 4: CAR T-cell therapy prices are significantly higher than conventional treatments



SOURCE: US BUREAU OF LABOR STATISTICS, INCRED RESEARCH, COMPANY REPORTS

Figure 5: The cost of CAR-T therapy is US$373,000-475,000 per infusion; after the addition of facility cost and CRS treatment cost, the total cost of the therapy is approximately US$500,000



SOURCE: INCRED RESEARCH, COMPANY REPORTS

Growth despite astronomical prices ➤

1. There has been an increase in adoption of CAR-T cell therapy due to its added advantages over traditional therapies which has, in turn, contributed to market growth. A rise in the prevalence of childhood cancer, an increase in knowledge about CAR-T cell therapy, rise in demand for effective cancer treatments, and favourable reimbursement policies in some economies are the key factors that are driving forward the growth of the CAR-T cell therapy market. Owing to the contribution of the above-mentioned factors, the CAR-T cell therapy market grew to a size of **US$3.82bn in 2022**.
2. The CAR-T cell therapy market is segmented in the following categories based on the drug type and antigen:
    a) Brexucabtagene autoleucel (MCL)
    b) Axicabtagene ciloleucel (DLBCL)

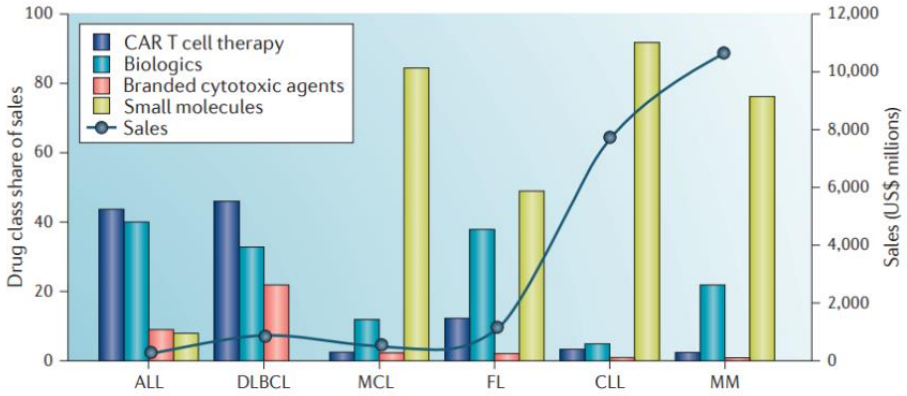
c) Tisagenlecleucel (ALL)

d) Others (FL, CLL, MM)

Axicabtagene ciloleucel (Yescarta), a drug by Gilead, had the majority share in the market in 2022, and is expected to grow further in the coming years (see Fig. 6). Yescarta's active ingredient is effective against follicular lymphoma and diffuse large B-cell lymphoma, which has helped propel its growth in the projected period. **Gilead's Yescarta sales increased by 29%, and it generated a quarterly revenue of US$380m.**

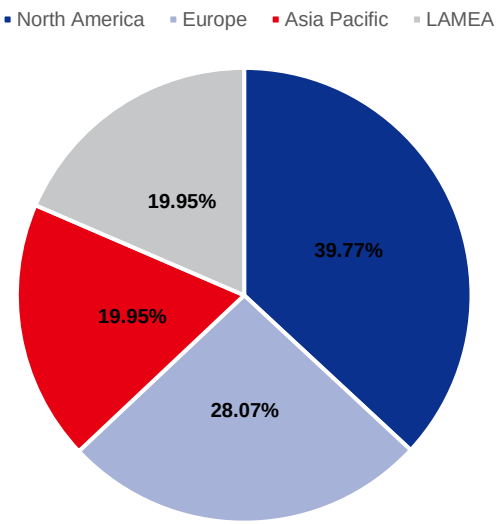
3. So far, six CAR-T cell therapies have been approved in the US market: Kymriah, Yescarta, Tecartus, Breyanzi, Abecma and Carvykti. Even though the revenue share of the US market is the highest among all geographies, China is leading in terms of clinical trials and innovation (see Figs. 7 and 8).

Figure 6: 2026 sales forecast for different therapeutics in each class and market share for relapsed blood cancer (CAR-T cell therapy has captured majority share in drug class sales for lymphoblastic leukemia (ALL) and diffuse large B cell lymphoma (DBCL)



SOURCE: INCRED RESEARCH, COMPANY REPORTS

Figure 7: Regional Market Share – 2022 (North America has the highest market share in CAR-T cell therapy among all geographies)



SOURCE: INCRED RESEARCH, COMPANY REPORTS

Figure 8: Even though the US has the highest market share, China has the greatest number of clinical trials going on for CAR-T cell therapy

SOURCE: INCRED RESEARCH, COMPANY REPORTS

Big or small, every pharma player wants a piece of the CAR-T pie ➤

1. There has been a substantial increase in the number of clinical trials being held and the patents being filed for CAR-T cell therapy. From small start-ups to big multibillion-dollar pharma giants, CAR-T has spread across the healthcare field globally (see Fig. 9 and Fig. 10).
2. Vigorous mergers and acquisitions are going on in this area. **Celgene acquired Juno Therapeutics for US$9bn, and Gilead acquired Kite Pharma for US$11.9bn** (Fig. 11).
3. The high revenue and success of the six approved CAR-T cell therapies in the US further encouraged companies across the globe to venture into this area (Fig. 12).
4. All the above-mentioned activities will result in a meteoric rise in the CAR-T cell therapy market. It is **projected to touch US$88.52bn by 2032, with a noteworthy CAGR of 29.8% over 2023-32** (see Fig.13).

Figure 9: Pharmaceutical and biotechnology companies active in CAR-T cell therapy based on patent activity

- Bubble size = patent volumes between 2010 and 2021
- Application diversity and geographic reach scores are normalised and ranked on a scale between 0 and 1

SOURCE: INCRED RESEARCH, COMPANY REPORTS

Figure 10: Global companies that have CAR-T cell therapy products which are currently marketed, under regulatory process or under development

Company	Therapy	Diesease	Development	Country	Market Cap of Company (USD)
Abbvie	CLBR001	B-cell malignancies	Phase I	USA	260.26 billion
Alaunos Therapeutics	Library TCR-T cell Therapy	Lung cancer	Phase I	USA	69.52 million
Allogene	ALLO-501A	Allogenic, Large B-cell Lymphoma	Phase II	USA	528.02 million
Amgen	AMG 119	Treatment of small-cell lung cancer	Phase I	USA	141.79 billion
Atara Biotherapeutics	ATA2271	Solid tumours	Phase I	USA	141.54 million
Autolus Limited	Obe-cel	Adult B-cell acute lymphoblastic leukemia (ALL)	Phase I	USA	401.20 million
Bristol-Myers Squibb	Abecma	Relapsed and refractory multiple myeloma	Marketed	USA	117.87 billion
CARsgen Therapeutics	Zevor-cel	Relapsed and refractory multiple myeloma	BLA	China	600.16 million
Cellectis	UCART22	Allogenic, B-cell leukemia and lymphoma	Phase I/II	France	77.49 million
Celularity	CYCART-19	B-cell malignancies	Development	USA	39.70 million
Celyad Oncology	CYAD-01	Acute lymphoblastic leukemia, diffuse large B-cell lymphoma	Phase II	Belgium	19.79 million
Fate Therapeutics	FT576 (iNK)	Multiple Myeloma	Phase I	USA	184.31 million
Gilead Sciences	Yescarta	Large B-cell Lymphoma	Marketed	USA	93.08 billion
Janssen Biotech (owned by J&J)	Carvykti	Relapsed and refractory multiple myeloma	Marketed	USA	379.59 billion
JW Therapeutics	Relma-cel	Large B-cell Lymphoma	Marketed	China	108.00 million
Mustang Bio	MB-106	Relapsed or refractory large B-cell lymphoma	Phase I/II	USA	16.25 million
Nanjing Legend Biotech	CARTITUDE-4	Multiple Myeloma	Phase III	China	12.26 billion
Novartis	Kymriah	B-cell acute lymphoblastic leukemia, Diffuse large B-cell lymphoma, follicular lymphoma	Marketed	Switzerland	223.60 billion
Posieda Therapeutics	P-BCMA-ALL01	Relapsed and refractory multiple myeloma	Phase I	USA	214.95 million
Takeda	TAK-940	Relapsed or Refractory B-cell Malignancies	Phase I	Japan	48.58 billion

SOURCE: INCRED RESEARCH, COMPANY REPORTS

Figure 11: Mergers and acquisitions that have taken place in the CAR-T cell therapy space.

Acquirer	Target	Deal Value (USD)	Date Announced
Bristol-Myers Squibb	Celgene	74bn	20/11/2019
Gilead Sciences	Kite Pharma	11.9bn	28/08/2017
Celgene	Juno Therapeutics	9bn	22/01/2018
Gilead Sciences	Forty Seven	4.9bn	02/03/2020
Amgen	Teneobio	2.5bn	27/07/2021
Pfizer	Trillium Therapeutics	2.2bn	17/11/2021
Gilead Sciences	Tmunity Therapeutics	325m	22/02/2023
AstraZeneca	Neogene Therapeutics	320m	29/11/2022

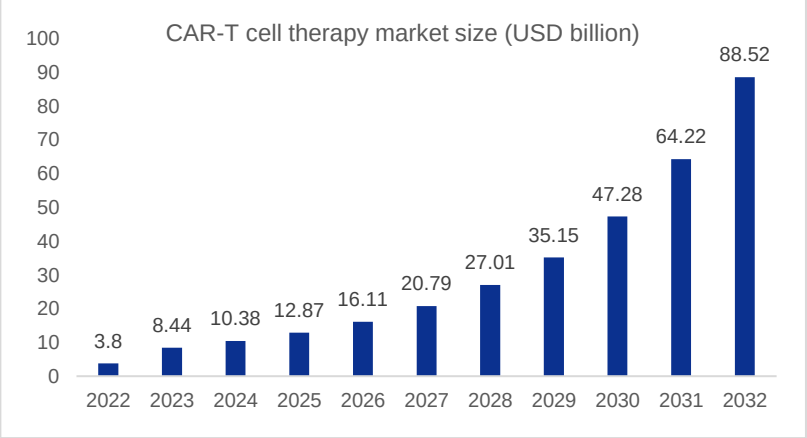
SOURCE: INCRED RESEARCH, COMPANY REPORTS

Figure 12: 2022 revenue of six US FDA approved CAR-T cell therapies

Product	Manufacturer	Revenue (USD)	Launch date
Yescarta	Gilead Sciences	1.16bn	18/10/2017
Kymriah	Novartis	536m	03/08/2017
Tecartus	Gilead Sciences	229m	24/07/2020
Abecma	Bristol Myers Squibb	297m	26/03/2021
Breyanzi	Bristol Myers Squibb	182m	05/02/2021
Carvykti	Johnson and Johnson	110m	28/02/2022

SOURCE: INCRED RESEARCH, COMPANY REPORTS

Figure 13: CAR-T cell therapy market is projected to touch a valuation of US$88.52bn in 2032



SOURCE: INCRED RESEARCH, COMPANY REPORTS

Landscape of India's CAR-T cell therapy market

Current standing of India in CAR-T cell therapy

1. Despite having a market size of 20,000-40,000 patients per year, there are only two companies active in this field - ImmunoACT and Immuneel. Immuneel is still in the development phase.
2. **We have written about CAR-T cell therapy and Laurus Labs' advances in this field in our previous** reports. **ImmunoAct has received the approval for the first CAR-T cell therapy in India. Laurus Labs has a 33.86% stake in ImmunoAct.**
3. ImmunoACT plans to offer the therapy at a cost which is 90% less than what is offered in the US market.

Two Indian biotechs in the race to grab a piece of the CAR-T pie ➤

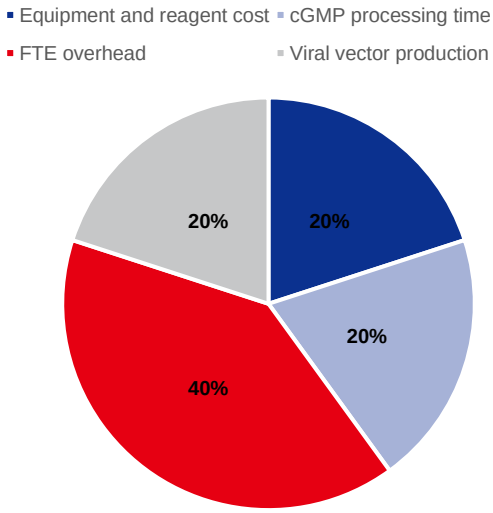
1. In 2019, Kiran Mazumdar, the founder of Biocon, announced that her company would be starting Immuneel, a start-up aiming to introduce CAR-T cell therapy in the Indian market. A year prior to that, ImmunoACT, a company focusing on CAR-T cell therapy, was started by an IIT-Bombay professor and his group. Both start-ups aim to provide a solution for the treatment of blood cancer.
2. Even though there are over 400 clinical trials currently going on globally, there is a complete gap in the Indian market. The two companies aim to fill the gap and serve the Indian market.
3. Along with filling in the gap due to the lack of global players, these two companies also aim to provide the therapy at a fractional cost compared to the currently approved therapies in the US market. Although Novartis's Kymiriah is used to treat children suffering from acute lymphoblastic lymphoma and Gilead's Yescarta is used to treat adults suffering from large B-cell lymphoma, each of them costs US$475,000 and US$373,000, respectively. Over **40% of the manufacturing of these therapies can be attributed to high skilled labour** (see Fig. 14) This will give both the Indian companies an advantage, and they aim for cutting-edge treatment at **Rs3-4 m** (US$50,000), approximately **90% less** than Kymiriah's and Yescerta's prices.
4. The initial goal is to serve the Indian market. Based on the extrapolation data from several hospitals, the market size for these therapies in India is approximately **20,000-40,000 patients** per year.
5. The long-term plan is to attract customers from across the globe, as both companies plan to offer the therapy at a fractional price compared to the global players. Despite the availability of six FDA-approved CAR-T cell therapies in the US, many patients have visited China and Israel to gain access to cheaper therapies.

ImmunoACT vs. Immuneel ➤

- Immuneel aims to in-license the CAR-T cell therapy technology. After this, the company wants to work on the engineering aspects and multiply the T-cells under the cGMP production guidelines. The company wants to pass this platform on to hospitals operating with the 'fee for service model'. It will be run in an independent manner in individual hospitals, like the bone marrow stem cell transplant. This will shorten the time compared to the traditional approach of processing the cells at a centralized facility, and also reduce logistics and facility costs, thereby cutting Immuneel's manufacturing costs. ImmunoACT, on the other hand, is taking the traditional approach. The company will collect the T-cells from a patient, take them to a centralized facility, modify them, and then send them back to the hospital (see Fig. 15).

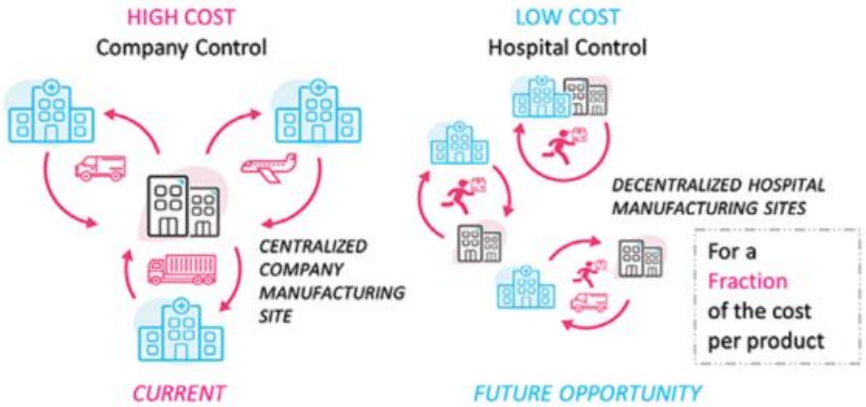
- Immuneel has raised funds through various pharma companies and major hospitals. Kiran Mazumdar and Apollo Hospitals have a stake in the company. ImmunoACT acquired seed funds from philanthropic organizations. Later, Laurus Labs acquired a 33.83% stake in the company for Rs1.26bn. ImmunoACT used these funds to commercialize its product and ramp up the manufacturing capacity.
- ImmunoACT has a head start when compared with Immuneel. It has been incubating at IIT-B since 2013. While Immuneel's CAR-T is still under development, **ImmunoACT received approval for the first CAR-T cell therapy on 13 Oct 2023**. Along with showing efficacy in clinical trials, ImmunoACT has also demonstrated in the labs that its therapy kills 100% of cancer cells with the antigen that the T-cells are targeting.
- ImmunoACT has the potential to dominate the Indian market, as it is the first to market and, in its initial years, it can capture the entire Indian market as there is no competition. Moreover, the company has developed expertise in the technology in India and built a network with hospitals, which will play to its advantage. Overall, this approval is a huge potential opportunity for ImmunoACT and also for Laurus Labs, which has a 33.83 % stake in ImmunoACT.

Figure 14: CAR-T manufacturing cost break-up



SOURCE: INCRED RESEARCH, COMPANY REPORTS

Figure 15: Company control (ImmunoACT) vs. hospital control (Immuneel's proposed method)



SOURCE: INCRED RESEARCH, COMPANY REPORTS

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