



ImmunoACT



Accessible & Affordable
Cutting-Edge Research
Transforming Ideas to Reality

A fighting chance to achieve remission

- NexCAR19 is a prescription drug for treating specific relapsed or refractory B-cell Non-Hodgkin's Lymphomas and B-cell Acute Lymphoblastic Leukaemia when other standard treatments have been unsuccessful.
- NexCAR19 is a **CAR-T Cell Therapy**. It involves **genetically modifying your body's T-cells** in a controlled laboratory setting, and then **re-infusing the modified T-cells**, which are empowered to identify & destroy certain cancerous B-cells.



Humanized by Us.
Personalized for You.



Disclaimer: NexCAR19 is administered only at ImmunoACT's Partner Hospitals. To find one closest to you that will safely and properly administer the therapy, visit our website by scanning the QR code linked here.

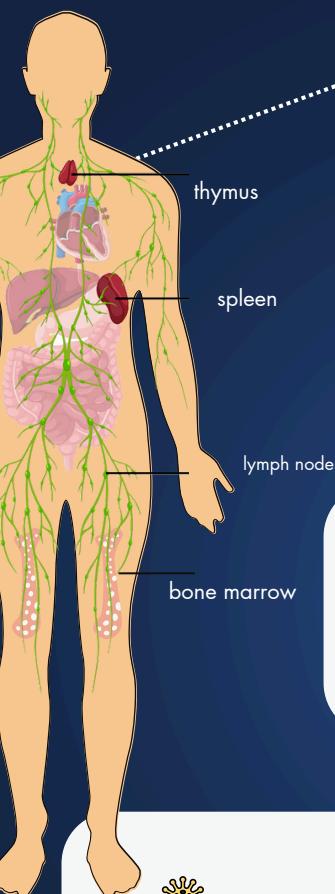
This brochure is for representative purposes only. Treatment with NexCAR19 must be carried out only as per a licensed haematologist/medical oncologist. Ask your haematologist or medical oncologist about NexCAR19 for the treatment of your B-cell leukaemia or lymphoma. To verify that your treatment is being conducted at an ImmunoACT Partner Hospital, ask for the official NexCAR19 Informed Consent Form.





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How does it work?



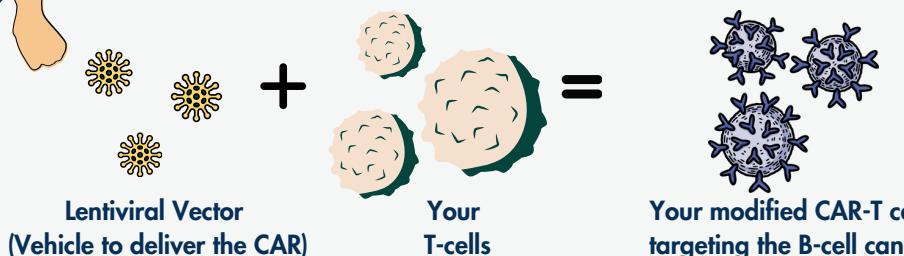
T-cells are naturally made by your body, as an advanced defence against viruses and cancer cells. As they mature, they develop specific connectors (receptors) to target key signals on cancer cells.



However, cancers are able to escape the inbuilt defence mechanism of T-cells which can result in survival of cancer cells and a further increase in tumour burden.



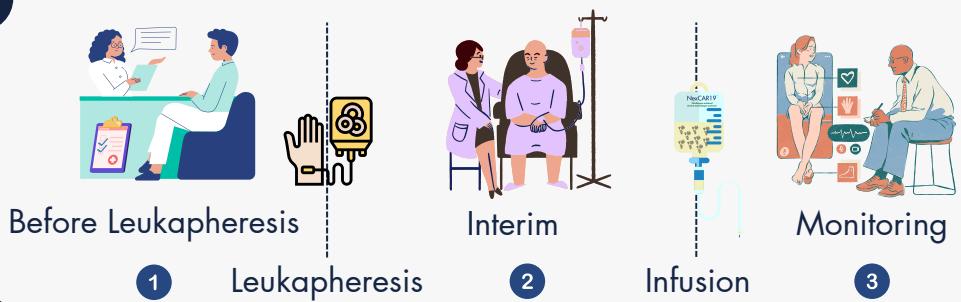
CAR-T cell
CD19 is a protein that is commonly present on the surfaces of certain B-cell cancers. Our scientists designed unique proteins called Chimeric Antigen Receptors (CARs) which are delivered by a vehicle to your T-cells, so that they can target and bind to CD19.



We use a specially designed & patented, delivery vehicle - called a lentiviral vector - to genetically engineer your own T-cells, so that they will express Chimeric Antigen Receptors (CARs) that target CD19. Now that they are trained, your T-cells will find and destroy these cancer cells, using their inbuilt processes.

The Treatment Process

A step-by-step breakdown of your NexCAR19 treatment journey



1

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Treatment Consideration



NexCAR19 may be considered by your haematologist or medical oncologist if you are 15 years of age or older and were diagnosed with a B-cell Non-Hodgkin's Lymphoma or B-cell Acute Lymphoblastic Leukaemia and one of the following has occurred:

- Frontline treatment was not sufficient to achieve remission.
- Previous treatment failed to achieve any response or was followed by a relapse.
- Relapse occurred after a prior complete remission, or after a prior stem cell transplant.

Some of the clinical factors in choosing NexCAR19 as a potential option are:

- General fitness and the preserved function of critical organ systems in order to safely tolerate NexCAR19.
- The nature and progression of the disease, and the impact of prior treatments.
- Whether another treatment may have to be performed before or after the therapy, in order to achieve a durable response.

The Treatment Process



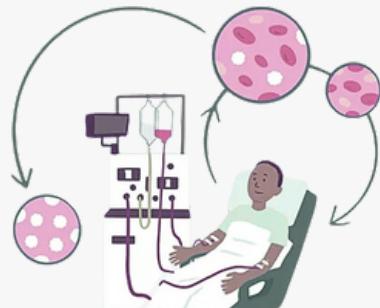
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Treatment Planning



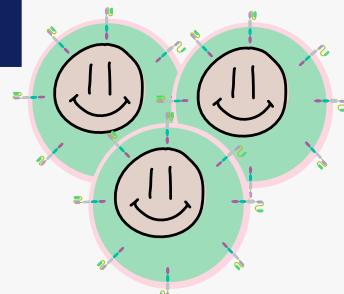
Based on the following factors, your treatment team will schedule a cell collection process called Leukapheresis.

- Existing burden of disease - If your disease burden is high, your treating physician might want to schedule the NexCAR19 treatment around another therapy to reduce this disease burden first.
- Timing of prior treatments - NexCAR19 is manufactured from your own T-cells. Certain prior immunotherapies or chemotherapies may negatively affect the quality & quantity of the T-cells. Your physician may accordingly schedule the collection of your cells & the administration of the treatment around these aspects, to get your best possible T-cells to fight your cancer.



Leukapheresis

T-cells apheresed in early treatment lines make stronger CAR-T cells!



- This is the process of collection of white blood cells, which is performed at the treatment centre/hospital.
- Leukapheresis is a day-care procedure, and usually requires 4-6 hours. It is recommended to wear loose-fitting clothing for the procedure.
- ImmunoACT processes the Leukapheresis sample within 24 hours. The hospital will inform you when manufacturing is proceeding.

The Treatment Process



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- After Leukapheresis, NexCAR19 is usually manufactured within 19 days.

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- In the Interim period, your physician may administer a Bridging Therapy to lower your disease burden.

Interim

- ~5 days before NexCAR19's infusion, you will start receiving a Conditioning Chemotherapy so that your body is ready for NexCAR19's infusion.

3

Infusion
&
Monitoring

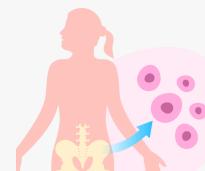
- You may be hospitalized for ~7-15 days to monitor and manage side effects, based on your physician's discretion.
- You may experience fever, muscle ache, dizziness, breathing difficulty, and tiredness within the first 2-3 weeks from Infusion. Alert your physician if you start exhibiting these symptoms. You may receive medications if required, to manage these symptoms. Monitor your handwriting periodically to check for potential neurotoxicity.
- Refer to the Important Safety Information in this brochure for more details.



1m+



3m+



6m+



Regular follow-ups

Test for response to treatment

Proximity to the Hospital

Discussion Guide



Points to discuss with your physician about NexCAR19



- What is NexCAR19?
- What are the steps I need to follow during the treatment cycle with NexCAR19?
- Can I expect to achieve remission with NexCAR19? Is it the right treatment for me?
- What are the possible side effects of NexCAR19? Will I be receiving other treatments and/or supportive medications with or after NexCAR19?
- What are the steps involved in the process of administering NexCAR19 based on my condition?
- Will I be receiving any treatments before Leukapheresis?
- When will my Leukapheresis be scheduled? What do I do to prepare for it?
- When can I expect the NexCAR19 product to be infused? What should I do to prepare for Conditioning Chemotherapy?
- After infusion, how frequently do I follow up to ensure that my response assessment is comprehensive?
- What can I expect after I am discharged from the hospital?
- I need to financially plan for CAR-T cell therapy. What are the costs involved in the entire treatment cycle, and supportive care? What are the long-term costs?
- How do I get insurance provider support for NexCAR19? Are there any Patient Access Programs or Supporting Resource Providers for NexCAR19?
- What are the best practices for me after infusion? What would I need to modify in my day-to-day life?

Caregiver's Preparation Pointers

Your loved one's journey with their B-cell cancer is filled with challenges. Being prepared for each step of this treatment will smoothen the care process.

- Insurance paperwork & cards
- Medical records including laboratory tests, chemotherapy reports, CT scans or bone marrow biopsy reports

- List & duration of prior treatments, and responses to each of the treatments
- List of current medications





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Important Safety Information

Unlike other CAR-T cell therapies, NexCAR19 is Humanized - designed specifically to limit the severity of side effects triggered by your immune system, aimed to minimize hospitalization time after infusion. However, there are still side effects that are associated with the treatment and certain precautions we recommend:

Side Effects:

NexCAR19 may cause side effects that are severe and/or life-threatening. Call/visit your physician or get emergency help right away if you get any of the following:

- Fever (100.4°F/38°C or higher).
- Difficulty breathing.
- Chills or shaking chills.
- Confusion.
- Dizziness or lightheadedness.
- Severe nausea, vomiting, or diarrhea.
- Fast or irregular heartbeat.
- Severe fatigue or weakness.

It is important to inform your physician that you received NexCAR19. They might give you other medicines to treat your side effects.

Precautions:

Before receiving NexCAR19, inform your physician about any medical issues, including if you have or have had

- Neurologic problems (such as seizures, stroke, or memory loss).
- Lung or breathing problems.
- Heart problems.
- Liver problems.
- Kidney problems.
- A recent or active infection.

Inform your physician about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Inform your physician if you are pregnant, planning to be pregnant, or breastfeeding. A pregnancy test may be then performed prior to your starting treatment. No information is available of NexCAR19 use in pregnant or breastfeeding women, hence, its use is not recommended in cases of pregnancy.



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Important Safety Information

- Cytokine Release Syndrome

Cytokine release syndrome (CRS) may occur when your immune system becomes highly active. It is the most common and expected side effect of NexCAR19, as well as other CAR-T therapies. Symptoms range from fever or low blood pressure to irregular or rapid heartbeat. CRS may be associated with liver, kidney, and heart dysfunction and bleeding disorders. If CRS events occur, they are usually seen within 10 days of infusion. Your treatment team will check your progress after infusion. Members of your team are trained to recognize the symptoms of CRS and have specific medicines to treat it.

- Neurological Events

NexCAR19 may also have effects on the central nervous system, making you feel confused, agitated, dizzy, or disoriented. More severe symptoms might affect your speech or consciousness or cause seizures. Be sure to tell your treatment team right away if you experience any neurological symptoms.

- HLH/Hemophagocytic lymphohistiocytosis

Upon administration of NexCAR19, HLH may occur due to excessive activation of the immune system, this can present with fever and low blood counts. It is diagnosed based on certain specific blood tests. This is usually treated with special medications to suppress inflammation by your treating haematologist/medical oncologist.

- Prolonged Low Blood Cell Counts (Cytopenia)

NexCAR19 may cause a condition called cytopenia. This is when you have low levels of 1 or more types of blood cells. Your treatment team will do blood tests to check all your blood cell counts after treatment with NexCAR19. Cytopenia that lasts a long time (prolonged) may increase your risk of infection. Cytopenia will be monitored, and your treatment team is prepared to manage it. Tell your doctor right away if you get a fever, are feeling tired, or have bruising or bleeding.

Other cautionary measures post-treatment with NexCAR19:

- Do not drive, operate heavy machinery, or participate in any physically intensive activity for approximately 8 weeks after you get NexCAR19, as the treatment can affect short term motor coordination, inducing sleepiness, confusion, weakness, dizziness, and seizures.
- Do not donate blood, organs, tissues, sperm, oocytes, and other cells without consulting your physician.

R&D Partner



Clinical Partner



Other Partners



Reach out to your haematologist/medical oncologist regarding treatment with NexCAR19. To find the nearest Partner Hospital for administration of NexCAR19, please email us at helpdesk@immunoact.com or contact us on +91 2248259140

Frequently Asked Questions about NexCAR19



Q. Why does it take a few weeks for NexCAR19 to be administered? How is this different from other drugs which are available off-the-shelf at the Pharmacy?

A. NexCAR19 is made from a patient's own T-cells. The cells are sent to our controlled laboratory, cultured, modified and then multiplied to reach a desirable dose. This takes ~19 days from Leukapheresis.

Q. How many days after the therapy would CRS be expected? Is it long term?

A. Cytokine Release Syndrome (CRS) is the most frequent after-effect of the therapy, but it is expected within the first 4 weeks of the infusion, not long term.

Q. How common are the serious side effects?

A. In our clinical trials, severe symptoms were seen in ~5% of patients. These side effects may depend upon several factors, including the pre-existing disease burden and your clinical condition.

Q. How many days will I need to follow-up with my haematologist/medical oncologist?

A. After discharge, you may be asked to follow up weekly or twice a week for the first month. The frequency of follow-up will decrease with time based on your physician's discretion. If you achieve remission beyond 6 months, this frequency may shorten to twice a year but it is recommended to continue follow-ups for up to 15 years.

In the event of any adverse reactions or active infections, your haematologist/medical oncologist may indicate more frequent follow-ups.

Q. Are there any special precautions I need to take after infusion with NexCAR19 and discharge?

A. Following are some of the precautions we recommend:

- Consume meals cooked under hygienic conditions
- Keep away from crowded places, to decrease the risk of infection (isolation from family or caregivers is not necessary)
- Follow-up regularly with your haematologist/medical oncologist as per their recommendations
- Do not start or stop any medications without consulting your haematologist/medical oncologist
- In the event that you are seeking treatment for any other condition, inform your physician about these conditions when consulting for treatment with NexCAR19



About ImmunoACT



ImmunoACT was established in 2018, spun-out of the Bioscience & Bioengineering Lab at IIT-Bombay & incubated at SINE, with the mission to bring life-saving cell & gene therapies to patients at an affordable cost. It is the culmination of research efforts as early as 2013.

From the initial design to the final product, Research & Development to Clinical Trials and Commercialization, we are a Fully Integrated Cell and Gene Therapy Company, that adheres to the highest global standards of cell therapy manufacturing.



Our therapies against cancers are designed to train your immune system so that they do the job they were always meant to - destroying tumours. We encode the right instructions in your cells to fight specific cancers - preferably as single dose treatments.

Gene-modified cell therapies are complex, and require several years of research and development, as well as extensive clinical trials, with international infrastructure requirements and personalisation of the therapies - which comes at a significant cost. Our goal is to make them as affordable and accessible as possible.



For any queries about NexCAR19:

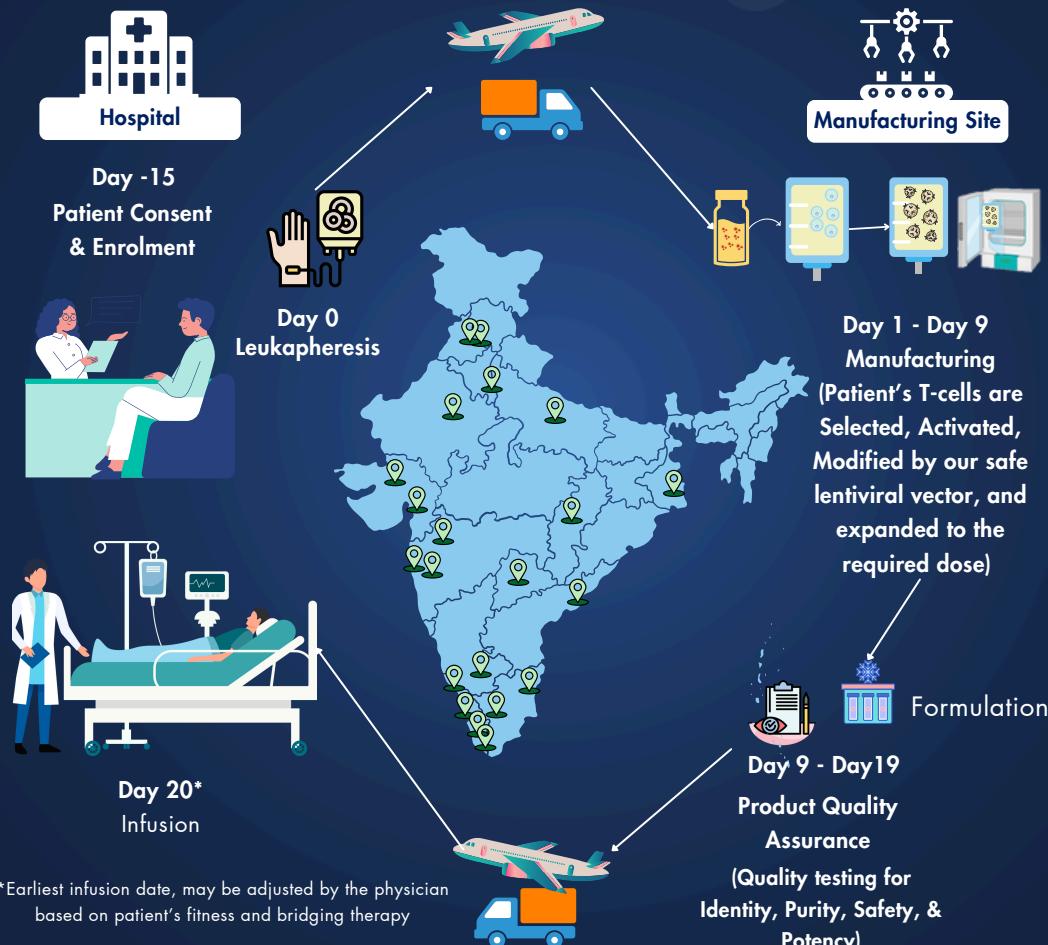
Email us at helpdesk@immunoact.com Or call us on +91- 2248259140

Visit our website: www.immunoact.com

ImmunoAdoptive Cell Therapy Private Limited, 1st Floor, Plot R, 977,
T.T.C. Industrial Area, MIDC Rabale, Navi Mumbai, Maharashtra 400701



Delivering high quality, personalized, humanized CAR-T cells within 20 days
(vein-to-vein)



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