

# ImmunoACT NexCAR19<sup>™</sup>

(Actalycabtagene autoleucel) solution for intravenous infusion

<u>A</u>ccessible & Affordable <u>C</u>utting-Edge Research <u>T</u>ransforming Ideas to Reality

### NexCAR19<sup>™</sup>



(Actalycabtagene autoleucel) solution for intravenous infusion

### A fighting chance to achieve remission

- NexCAR19 is a prescription drug for treating specific relapsed or refractory B-cell cancers (lymphomas and acute lymphoblastic leukemia) 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 reinfusing the modified T-cells, which are empowered to identify & destroy certain B-cell cancers.





**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 physician. 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.



# When Should You Consider NexCAR19?



### If you were diagnosed with one of the following cancers:

- 1) B-cell Acute Lymphoblastic Leukaemia
- 2) High grade B-lymphomas
- 3) Low grade B-lymphomas





### One or more lines of treatment of these were already administered:

- 1. Chemotherapy
- 2. Immunotherapy by monoclonal antibodies
- 3. Bone Marrow Transplant (using yours or a donor's bone marrow)

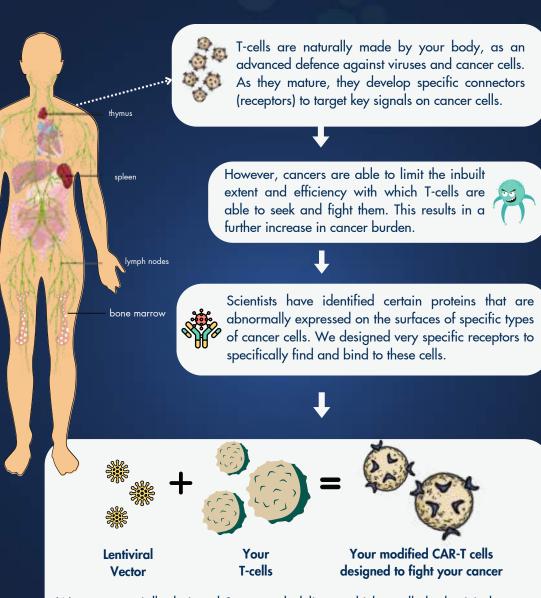
Despite these, your cancer returned or was not effectively treatable.

### This is where other advanced treatments become useful. NexCAR19 may be one of the options that works for you

- Certain cells in your body called T-cells, are naturally supposed to be fighting off cancers. Sometimes, they're just not well equipped to do that.
- NexCAR19 is an advanced treatment, called CAR-T cell therapy, which arms your T-cells with the exact weapons they need to target your cancer cells and destroy them.

### How does NexCAR19 work?





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). These CARs are connectors that will target a specific protein called CD19 on your B-cell cancer. Now that they are trained, your T-cells will seek and destroy these cancer cells, using their inbuilt processes.

## How do you receive NexCAR19?





### Prescription:

Based on your treatment record and disease burden, your doctor prescribes treatment with a CD19-directed CAR-T cell therapy.

### Leukapheresis:

Your White Blood Cells (WBCs) are extracted by a machine, through a process called Leukapheresis.





### Manufacturing:

ImmunoACT's scientists manufacture NexCAR19 specifically on the T-cells which have been selected from your white blood cells, at our state-of-the-art manufacturing facilities

### Infusion:

NexCAR19 is manufactured specifically to an optimal dose for you, and is typically administered as a Single Intravenous Infusion. Prior to this, you would receive a chemotherapy regimen to prime your body for the therapy





### Monitoring:

After your infusion with NexCAR19, you are monitored under hospitalization for ~10 -12 days to manage any potential side effects. After discharge, we encourage you to have regular follow ups with your doctor to evaluate your progress

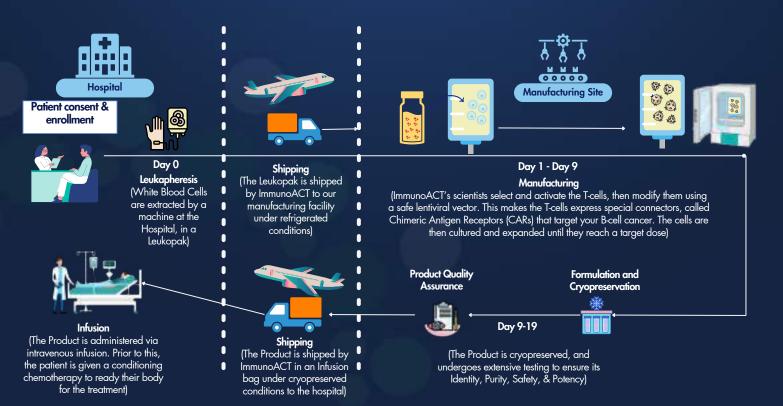


In clinical trials, NexCAR19 was found to be significantly safe with low toxicities. This is because it is uniquely Humanized, designed to be more familiar to your immune system. It is also one of the most cost-effective CAR-T cell therapies for r/r B-cell cancers in the world.





### From Vein-to-Vein



### Clinical Highlights



### 19 days



Average vein-tovein interval from extraction of patient's white blood cells to infusion of NexCAR19

### 10 days



Average inpatient duration in the Hospital after treatment with NexCAR19

### 90 days



Median outpatient follow up to ensure a durable and safe response with NexCAR19



In our clinical trials, around **70**% of B-cell Lymphomas and B-Acute Lymphoblastic Leukaemia in relapsed or refractory settings, positively responded to treatment. In real world settings however, outcomes may be vary.

Data shows that if a positive result occurs, it is typically within 1 month after infusion. Partial response indicates a significant decrease in tumour burden. Complete response indicates no detectable presence of the tumour, but it does not necessarily mean that your cancer is cured, as results may be different.

You are encouraged to follow up regularly with your treating physician to monitor the long-term impact of the treatment and improving your outcomes.



### 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 minimalize 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.

### 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 lymphocytosis

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 treated with supportive medicines to suppress inflammation by your treating 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.



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





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 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 - as single dose treatments.

Gene-modified cell therapies are very 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 are expensive. Our goal is to make them as affordable and accessible as possible.







www.immunoact.com

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