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LET'S TALK ABOUT CAR T-CELL THERAPY AS A TREATMENT OPTION: BLOOD CANCERS

Monalisa Ghosh, MD
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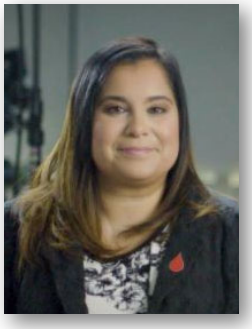
WELCOMING REMARKS

LET'S TALK ABOUT CAR T-CELL THERAPY AS A TREATMENT OPTION: BLOOD CANCERS



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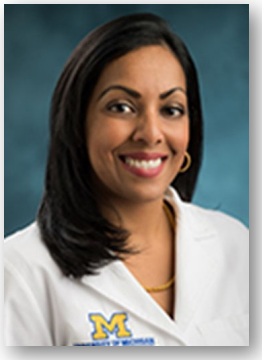

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DISCLOSURES

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Monalisa Ghosh, MD has financial relationship(s) with: BMS, Kite/Gilead, Miltenyi and Takeda *(Grant Support)* Cabaletta Bio*(Consultant)*

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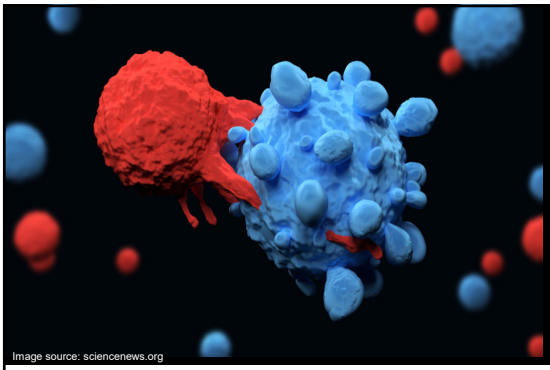

CAR T-cell Therapy

January 29, 2024
LLS Seminar

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Introduction to CAR T-cells

- History
- Structure and Function
- FDA-approved products

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Image source: Journal for Immunotherapy of Cancer

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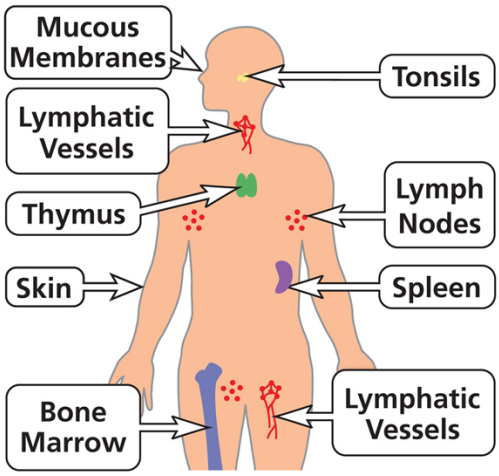
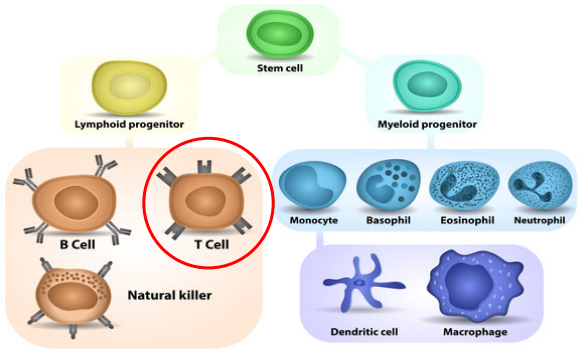
Immune System



What are T-cells and what do they have to do with cancer?



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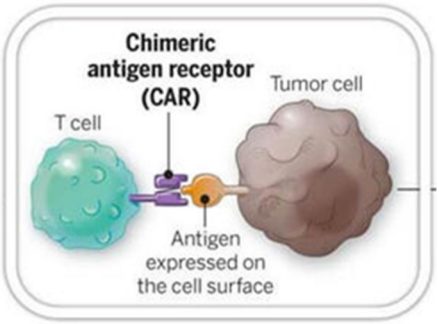
What Is A CAR T-cell?

- **CAR T-cell**
  - Genetically engineered T-cell
  - Designed to target a structure on the surface of cancer cells
  - **CAR** = **C**himeric **A**ntigen **R**eceptor
- **Function**
  - CAR T-cells divide in the bloodstream after being infused through a vein
  - They make many more of themselves
  - Each CAR T-cell can kill thousands of tumor cells
  - Can last for years in the body



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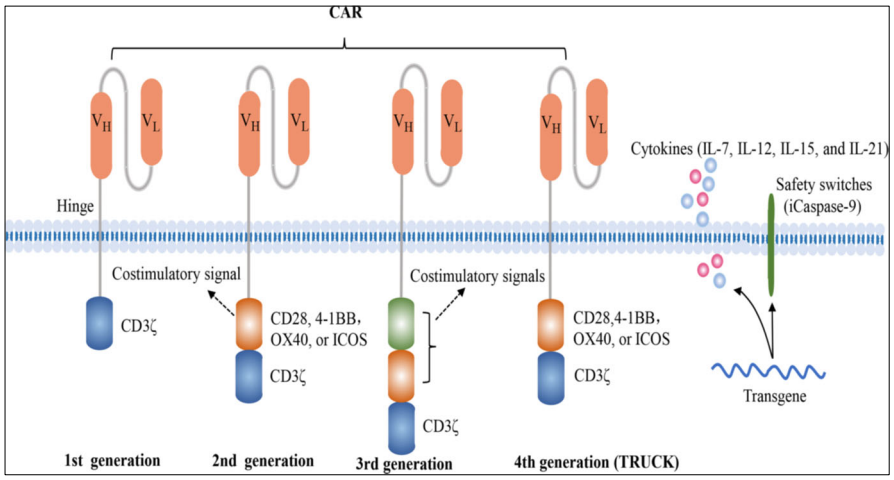
Structure of the Chimeric Antigen Receptor (CAR)



Source: Zhang, Frontiers in Immunology, June 2022

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History of CAR T-cell Therapy

- First studied in B-cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkin's B-cell lymphoma
- First simple CAR T was developed in 1993
- First FDA approved drug:
  - Tisagenlecleucel (Kymriah) for pediatric and young adult ALL
  - **6 products** FDA approved for acute B-cell leukemia, non-Hodgkin's lymphoma, and multiple myeloma over 5 years

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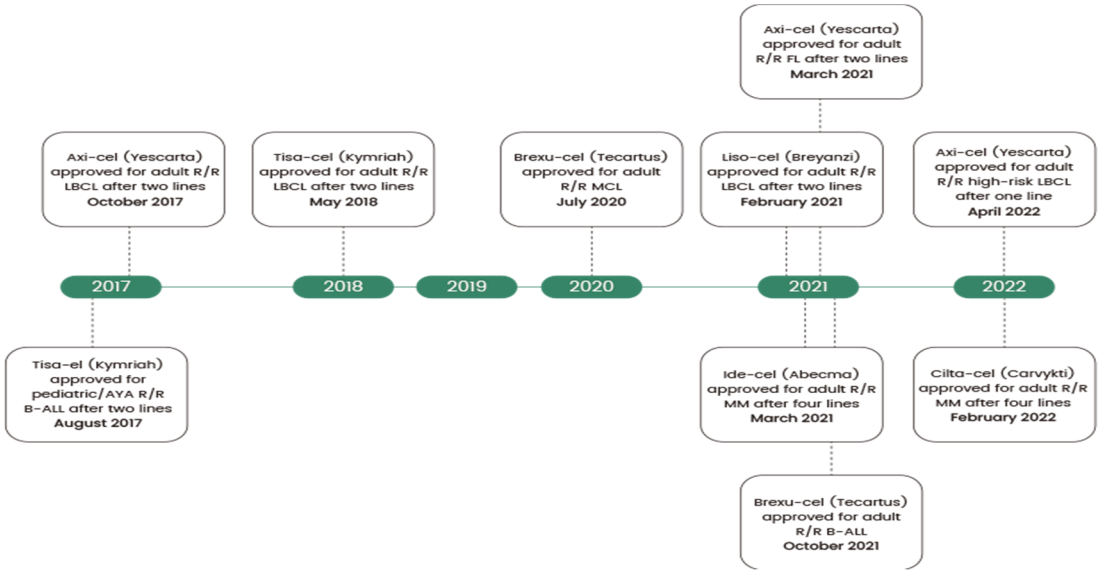
Timeline of FDA Approved CAR T-cell Therapies



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Tisagenlecleucel (Kymriah)

- Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (B-ALL) that is either refractory or in a second or later relapse
- Adult patients with relapsed or refractory large B-cell lymphoma– after two or more lines of systemic therapy—including: diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)
- Adult patients with relapsed or refractory FL after two or more lines of systemic therapy

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Axicabtagene ciloleucel (Yescarta)

- Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy
- Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)
- Adult patients with relapsed or refractory FL after two or more lines of systemic therapy

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Brexucabtagene autoleucel (Tecartus)

- Relapsed or refractory mantle cell lymphoma (MCL)
- Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

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Lisocabtagene maraleucel (Breyanzi)

- Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
- Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
- Relapsed or refractory disease after two or more lines of systemic therapy

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Idecabtagene vicleucel (Abecma)

- Relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

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Ciltacabtagene autoleucel (Carvykti)

- Relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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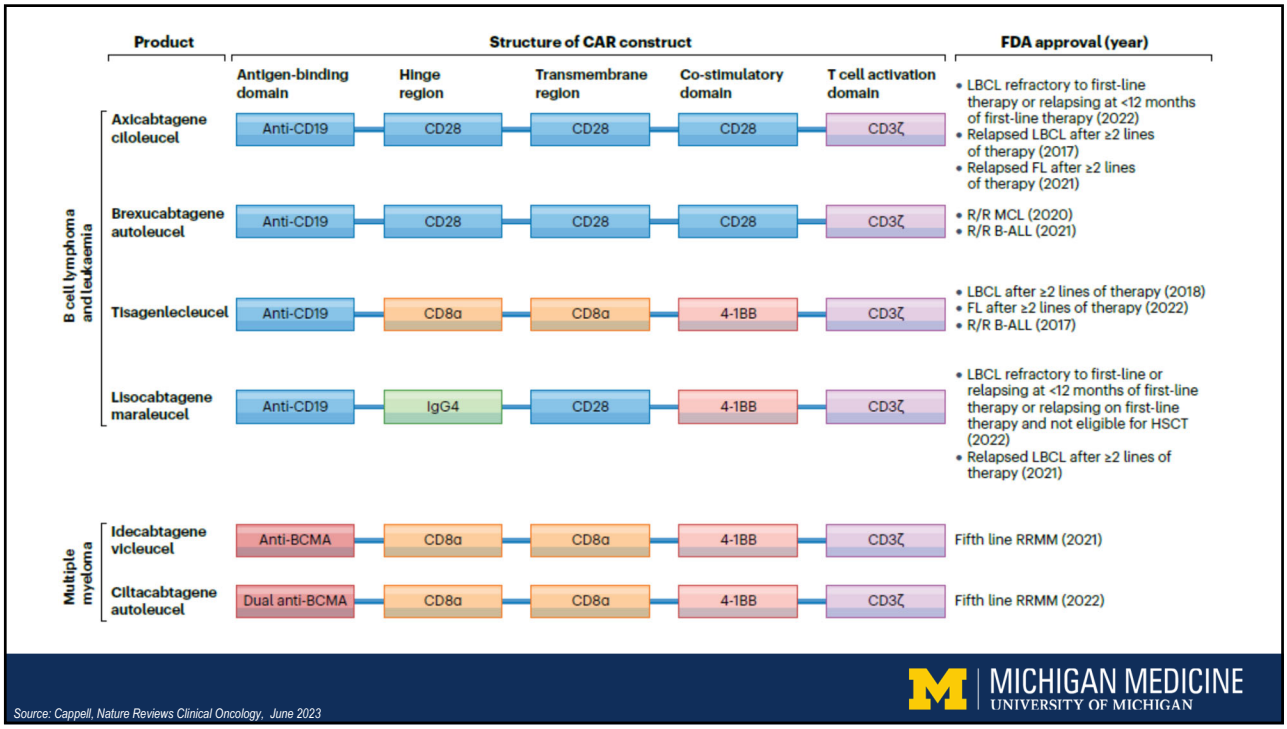

Source: Cappell, Nature Reviews Clinical Oncology, June 2023

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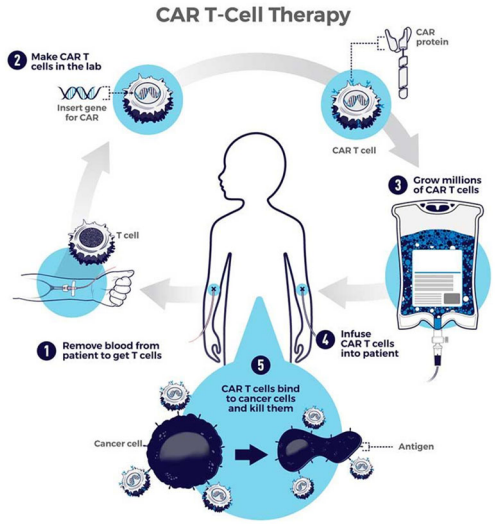
Manufacturing CAR T-cells

- Individualized products
- All FDA-approved products come from the person's own cells
- All require 4-6 hour apheresis (cell collection) procedure to collect one's T-cells
- Manufacture time ranges from 3-6 weeks
- Cells cannot usually be infused more than once
- For some products, cells must be collected and shipped fresh to the manufacturer.



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How well do CAR T-cell therapies work?

- Acute lymphoblastic leukemia (ALL)
- Diffuse large B-cell lymphoma (DLBCL)
- Follicular lymphoma (FL)
- Mantle cell lymphoma (MCL)
- Multiple Myeloma (MM)

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Image source: Journal for Immunotherapy of Cancer

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Pivotal CAR T-cell Therapy Trials in ALL

Product	Tisagenlecleucel	Brexucabtagene autoleucel
Approved indication	ALL (up to 25 years old)	ALL (≥18 years, median 40)
Trial	ELIANA	ZUMA-3
Costimulatory Domain	4-1BB	CD28
Number of patients	n=92	n=71
CRS	Total=77% Severe=46%	Total=89% Severe=24%
Neurotoxicity	Total=40% Severe=13%	Total=60% Severe=25%
Response Rate	**ORR at 3 months: 83%** OS 12 months: 76% RFS 12 months: 59%	**ORR at 3 mos: 71% CR or Cri (56% CR)** Median OS: 18.2 months Median RFS: 11.6 months

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Pivotal CAR T-cell Therapy Trials in DLBCL

Product	Tisagenlecleucel	Axicabtagene ciloleucel	Lisocabtagene maraleucel
Approved indication	DLBCL (≥18): >2 lines	DLBCL (≥18): >2 lines, >1 line in primary ref or early relapse	DLBCL (≥18): >2 lines
Trial	JULIET (phase II)	ZUMA-1 (phase II)	TRANSCEND001 (phase II)
Costimulatory Domain	4-1BB	CD28	4-1BB
Number of patients	n=81 (JULIET)	n=101	n=268
CRS	Total=58% Severe=23%	Total=94% Severe=13%	Total=46% Severe=4%
Neurotoxicity	Total=58% Severe=12%	Total=84% Severe=31%	Total=35% Severe=12%
Response Rate	**DLBCL ORR 3 mos: 52%** , CR 32% , CR 40% 12 months ALL median f/u>12mos: ORR 81%	**ORR at 3 mos: 82%,** CR 54% Median f/u 15.4mos: 40% CR	**ORR at 3 mos: 74%,** CR 54%, CR 65% at 6 mos, CR 62% at 9 months

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Practice-Changing Phase III CAR T-cell Therapy Trials in DLBCL: CAR T-cell therapy versus standard (autologous stem cell transplant)

Product	Tisagenlecleucel	Axicabtagene ciloleucel	Lisocabtagene maraleucel
Patient Population	DLBCL (≥18): primary refractory or relapsed within 12 months	DLBCL (≥18): primary refractory or relapsed within 12 months	DLBCL (≥18): primary refractory or relapsed within 12 months
Trial	BELINDA	ZUMA-7	TRANSFORM
ORR – CAR T arm	75%	83%	86%
ORR – SOC arm	54%	50%	48%
EFS – CAR T arm PFS – CAR T arm	3 months --	**8.3 months** 14.7 months	**10.1 months** 14.8 months
EFS – SOC arm PFS – SOC arm	3 months --	2 months 3.7 months	2.3 months 5.7 months

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CAR T-Cell Therapy in Follicular Lymphoma and Mantle Cell Lymphoma

Product	Axicabtagene ciloleucel	Brexucabtagene autoleucel	Tisagenlecleucel
Approved indication	FL (≥18 years): >2 lines	MCL (≥18 years): >2 lines	FL (≥18 years): >2 lines
Trial	ZUMA-5 (phase II)	ZUMA-2 (phase II)	ELARA (phase II)
Costimulatory Domain	CD28	CD28	4-1BB
Number of patients	n=153 (84 with FL)	n=74	n=97
CRS	Total=78% Severe=6%	Total=91% Severe=18%	Total=49% Severe=0%
Neurotoxicity	Total=56% Severe=15%	Total=81% Severe=37%	Total=~37% Severe=1%
Response Rate	**ORR at 3 months (FL): 94%%** (79% CR) PFS 18 months: 65%% OS 18 months: 87%	**ORR at 12 months: 87%** CR at 12 months: 62% PFS at 12 months: 67% OS at 12 months: 83%	**ORR at 3 months: 86%** CR at 3 months: 69%

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CAR-T Cell Therapy in Multiple Myeloma (BCMA Targeted)

Product	Idecabtagene Vicleucel	Ciltacabtagene autoleucel
Approved indication	MM (≥18 years): >4 lines	MM (≥18 years): > 4 lines
Trial	KarMMa (phase III)	CARTITUDE (phase III)
Costimulatory Domain	4-1BB	4-1BB
Number of patients	n=124	n=97
CRS	Total=85% Severe=9%	Total=95% Severe=5%
Neurotoxicity	Total=28% Severe=4%	Total=26% Severe=11% *parkinsonian symptoms seen
Response Rate	**ORR at 13 months: 72%** VGPR at 13 months: 54% sCR at 13 months: 29% MRD negative: 93% Median PFS: 11.1 months Median OS: 24 months	**ORR at 18 months: 84%** VGPR at 18 months: 14% sCR at 18 months: 67% Median DOR: 21.8 months

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Cell Therapies for Non-cancerous Diseases

- Viral-directed cytotoxic T-lymphocytes (EBV, BK virus, CMV)
- Sickle cell disease
- Autoimmune diseases
- Surgical interventions: cardiac, ocular, spinal injury recovery
- Renal transplant: combined with stem cell transplant
- Solid organ transplants to mediate rejection

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What are the major side effects of CAR T-cell therapy?

- Cytokine release syndrome
- Neurologic symptoms
- Low antibody (Ig) levels
- Low blood counts
- Infections
- Secondary cancers?

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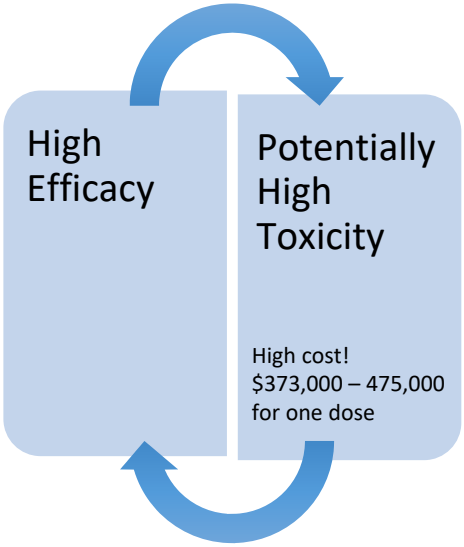

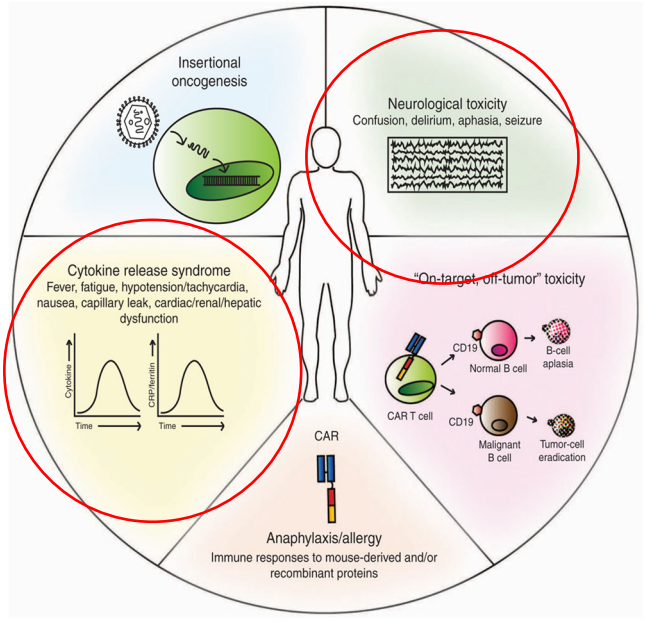

Bonifant et al. *Oncoimmunology*, 2016.

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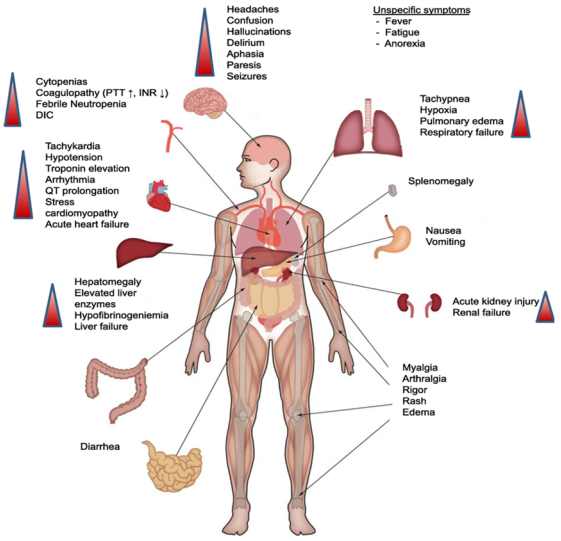
Symptoms of Cytokine Release Syndrome (CRS)



- **Fever** – most common
- **Hypotension** (low blood pressure) – somewhat common
- **Hypoxia** (low blood oxygen levels) – less common

Treated with:
- Supportive care (IV fluids, Tylenol, oxygen)
- Tocilizumab (anti IL-6 therapy)
- Steroids

Rare:
- Arrhythmias, cardiomyopathy
- Organ failure (renal, hepatic)
- HLH
- Coagulopathies

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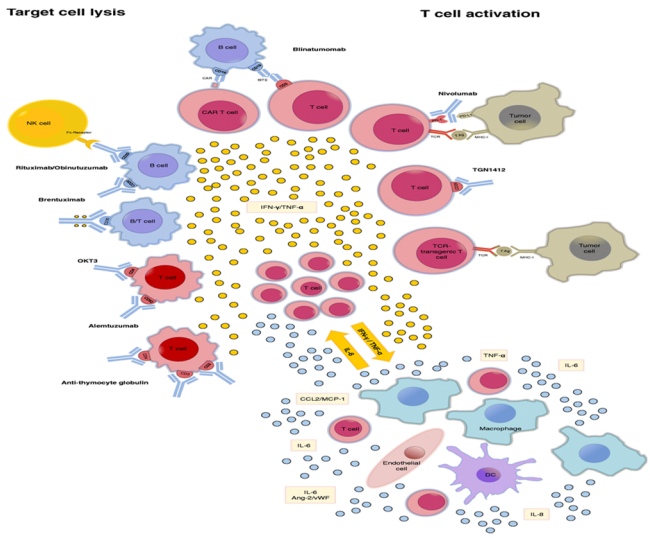
Mechanism of Cytokine Release Syndrome



- CAR T-cells are activated upon binding tumor cells
- Recruit other immune cells via "cytokines"
- Other immune cells (macrophages, monocytes) release cytokines which cause inflammation

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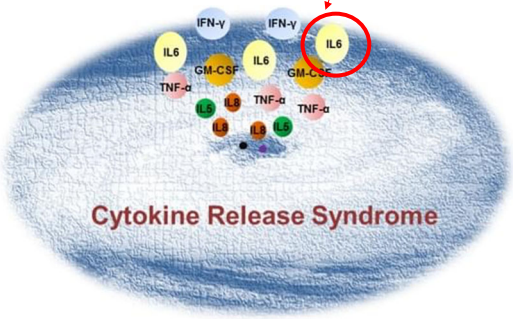
Treatment of CRS: General Principles

Tocilizumab: monoclonal antibody to IL6 receptor

- Treatment:
  - Supportive care
  - **Anti-IL-6 therapy (tocilizumab or siltuximab)**
  - Corticosteroids (like dexamethasone)



- Tociluzumab:
  - Use not correlated with tumor response

- Corticosteroids:
  - Try to avoid because it kills/impairs the CAR-T cells; correlated with less tumor responsiveness

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Consensus CRS Grading System

ASBMT CRS Consensus Grading

CRS Parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever*	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C
With Hypotension	None	Not requiring vasopressors	Requiring a vasopressor with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
And/or† Hypoxia	None	Requiring low-flow nasal cannula‡ or blow-by	Requiring high-flow nasal cannula‡, facemask, nonrebreather mask, or Venturi mask	Requiring positive pressure (eg, CPAP, BiPAP, intubation and mechanical ventilation)

Organ toxicities associated with CRS may be graded according to CTCAE v5.0 but they do not influence CRS grading.

* Fever is defined as temperature ≥38°C not attributable to any other cause. In patients who have CRS then receive antipyretics or anticytokine therapy such as tocilizumab or steroids, fever is no longer required to grade subsequent CRS severity. In this case, CRS grading is driven by hypotension and/or hypoxia.

† CRS grade is determined by the more severe event: hypotension or hypoxia not attributable to any other cause. For example, a patient with temperature of 39.5°C, hypotension requiring 1 vasopressor, and hypoxia requiring low-flow nasal cannula is classified as grade 3 CRS.

‡ Low-flow nasal cannula is defined as oxygen delivered at ≤6 L/minute. Low flow also includes blow-by oxygen delivery, sometimes used in pediatrics. High-flow nasal cannula is defined as oxygen delivered at >6 L/minute.

Lee et al, BBMT, Dec 2018.

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Lee et al, BBMT, Dec 2018.

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Neurologic Toxicity/Immune Effector Cell Associated Neurologic Syndrome (ICANS)

- Types
  - Early: concurrent with CRS and high fevers
  - Delayed: as CRS is resolving or following resolution of CRS
  - In absence of CRS
- Onset and duration
  - Majority occurs within 2 weeks (few cases up to 8 weeks post cell infusion)
  - Most events are transient (median duration: 5 days)
  - Median onset 5-7 days
- Clinical Presentation
  - Headache, encephalopathy, delirium, anxiety, tremor
  - Other manifestations: disturbance in consciousness, seizures, disorientation, confusion, agitation, aphasia

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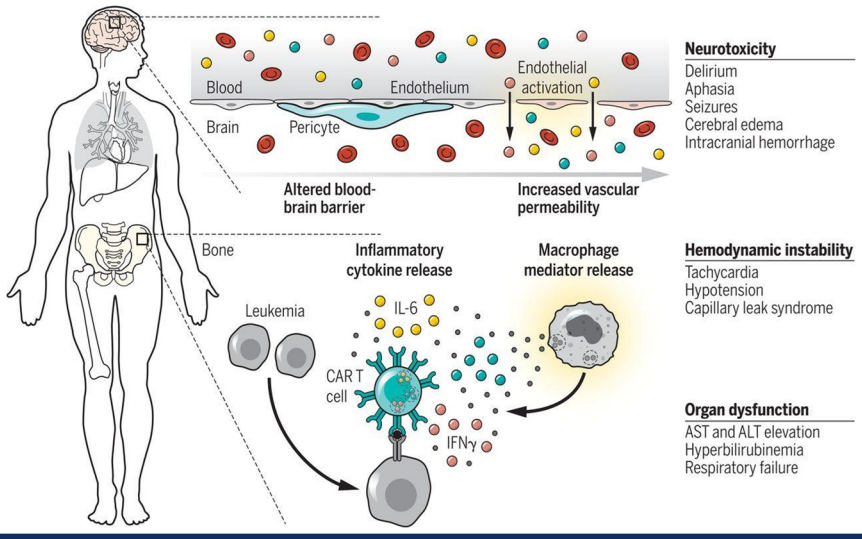
Mechanism of ICANs



- Caused by cytokines entering the brain and causing inflammation
- Symptoms may include:
  - Confusion
  - Difficulty speaking
  - Headaches
  - Bleeding in the brain
  - Seizures
  - Loss of consciousness
- Treatment: Steroids

Image source: *Science*

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Consensus ICANS Grading System

Table 6
ASBMT ICANS Consensus Grading for Adults

Neurotoxicity Domain	Grade 1	Grade 2	Grade 3	Grade 4
ICE score*	7-9	3-6	0-2	0 (patient is unarousable and unable to perform ICE)
Depressed level of consciousness†	Awakens spontaneously	Awakens to voice	Awakens only to tactile stimulus	Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse. Stupor or coma
Seizure	N/A	N/A	Any clinical seizure focal or generalized that resolves rapidly or nonconvulsive seizures on EEG that resolve with intervention	Life-threatening prolonged seizure (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between
Motor findings‡	N/A	N/A	N/A	Deep focal motor weakness such as hemiparesis or paraparesis
Elevated ICP/cerebral edema	N/A	N/A	Focal/local edema on neuroimaging§	Diffuse cerebral edema on neuroimaging; Decerebrate or decorticate posturing; or Cranial nerve VI palsy; or Papilledema; or Cushing's triad

Table 5
Encephalopathy Assessment Tools for Grading of ICANS

CARTOX-10 [12]	ICE
Orientation: orientation to year, month, city, hospital, president/prime minister of country of residence: 5 points Naming: ability to name 3 objects (eg, point to clock, pen, button): 3 points Writing: ability to write a standard sentence (eg, "Our national bird is the bald eagle"): 1 point Attention: ability to count backwards from 100 by 10: 1 point	Orientation: orientation to year, month, city, hospital: 4 points Naming: ability to name 3 objects (eg, point to clock, pen, button): 3 points Following commands: ability to follow simple commands (eg, "Show me 2 fingers" or "Close your eyes and stick out your tongue"): 1 point Writing: ability to write a standard sentence (eg, "Our national bird is the bald eagle"): 1 point Attention: ability to count backwards from 100 by 10: 1 point

Lee et al, BBMT, Dec 2018.

Lee et al, BBMT, Dec 2018.

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Risk of Secondary Cancers

F.D.A. Issues Warning of Cancer Risk Linked to CAR-T Therapies

The agency has reviewed reports of cancer patients whose treatments resulted in the development of secondary blood cancers. Several companies will be required to carry the new warning.

- Very small number of T-cell lymphomas and myelodysplastic syndrome reported several months to years after CAR T-cell therapy
- No evidence at this point to directly link CAR T to secondary cancers
- Benefits still far outweigh the risks

Source: New York Times

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Emerging Immune Effector Cell Therapies

Allogeneic CAR T-cells

NK Cells

Umbilical cord derived cells

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Autologous CAR T-cells – Current Available Products

- Benefits
  - No risk of graft versus host disease
  - Potentially longer persistence
  - Low risk of rejection
- Challenges
  - Exhausted T-cells
  - Long manufacturing time (3-6 weeks)
  - High manufacturing costs due to individualized production
  - People may develop apheresis-related side effects
  - Potential for collecting circulating tumor cells in the apheresis product

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Allogeneic CAR T-cells (from a Donor)

- Benefits
  - Derived from healthy donors with healthy immune systems
  - Less exhausted T-cells
  - "Off-the-shelf" product available immediately
  - Reduced manufacturing costs
- Challenges
  - Decreased persistence due to rejection by the host immune system
  - Risk of graft versus host disease

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Natural Killer CAR Cells

- Benefits
  - Can be obtained from 3rd party donors
  - Excellent natural killing function
  - Multiple potential sources
  - No risk of graft versus host disease
- Challenges
  - Limitations in tumor infiltration
  - May be subject to checkpoint blockade

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Other IEC Therapies

Cell Type	Advantages	Disadvantages
NK cells	Innate killing capacity, no GvHD, lower risk of off-target toxicity (MHC-1 mediated)	Decreased ability to penetrate tumor, persistence
iNKT cells	Killing via CAR or TCR, no GvHD, CNS activity	More challenging to isolate, persistence, more susceptible to LD chemotherapy
δT-cells	MHC-independent killing, no GvHD	Transduction, persistence, subsets might be immunosuppressive
iPSC	Unlimited replication, easier to scale up production	Risk of GvHD unless TCR is removed, persistence
SCM/early T-cell memory cells	Improved engraftment and expansion, less exhaustion (less differentiated phenotype)	Persistence and decreased cytotoxicity compared to other T-cell subsets

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Future Improvements in Immune Effector Cell Therapy

Improving IEC efficacy

Decreasing toxicities

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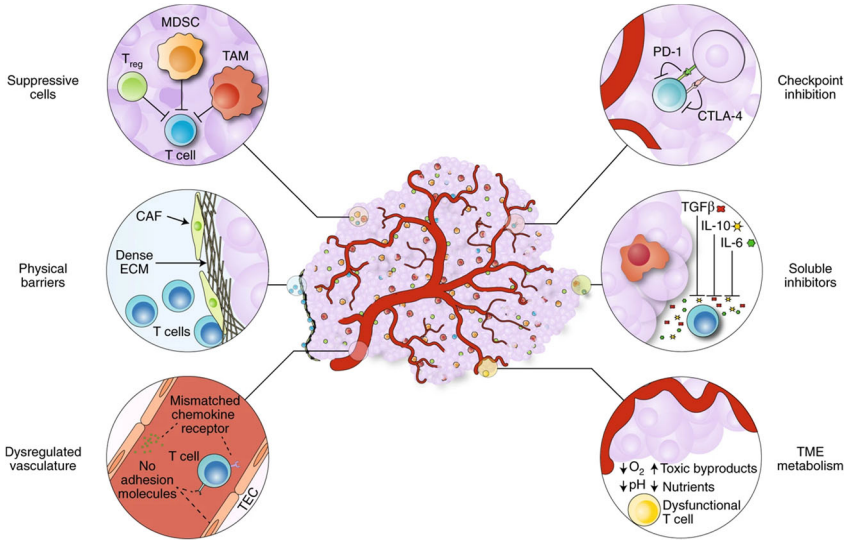
Mechanisms of Resistance to IEC Therapy

Major Barriers:

- Antigen Escape
- Tumor microenvironment preventing T-cell trafficking/infiltration
- T-cell exhaustion
- IEC persistence



Labanieh et al, Nature Engineering, 2018

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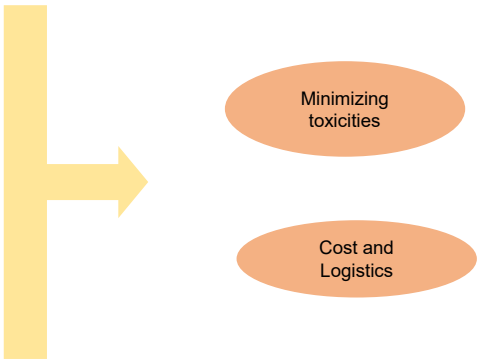
Challenges of IEC Therapy



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Overcoming Toxicities

- Treatment
  - Siltuximab (anti-IL6 monoclonal antibody)
  - Anakinra (anti-IL1R monoclonal antibody)
  - Ruxolitinib (JAK inhibitor)
- Prophylaxis
  - IL6: tocilizumab, siltuximab – ongoing trials
  - Lenzilizumab (anti-GMCSF monoclonal antibody) – promising pre-clinical data, phase 2/3 trial ongoing
- CAR Construct/Cells used
  - Altering co-stimulatory domain
  - Engineering cells to release anti-cytokine antibodies
  - Suicide genes/safety switches
  - Use of NK cells

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Summary

- CAR T-cell therapy has been shown to be highly efficacious in hematologic malignancies
- Barriers remain, including:
  - Resistance to therapy due to tumor microenvironment and issues with T-cell effector function
  - Toxicities
  - Cost and logistics
- New IEC therapies are being developed to improve function and delivery to patients
  - Different cell sources
  - Strategies to improve efficacy including combination therapy
  - Strategies to mitigate toxicities
  - On-site manufacturing

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THANK YOU

To the patients, families, staff.

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ASK A QUESTION
LET'S TALK ABOUT CAR T-CELL THERAPY AS A TREATMENT OPTION: BLOOD CANCERS

Ask a question by phone:

Press star (*) then the number 1 on your keypad.

Ask a question by web:

Click "Ask a question"
Type your question
Click "Submit"

Due to time constraints, we can only take one question per person. Once you've asked your question, the operator will transfer you back into the audience line.

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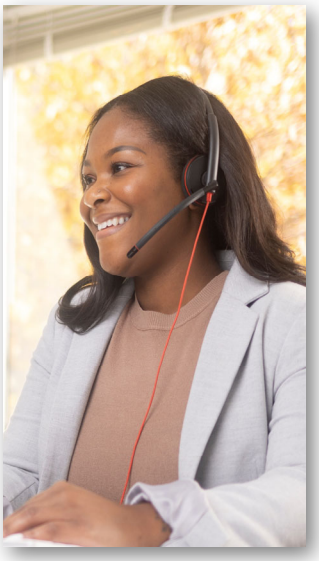
LLS EDUCATION & SUPPORT RESOURCES

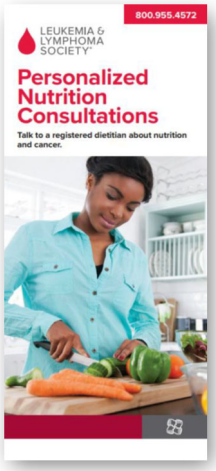


HOW TO CONTACT US:

To contact an **Information Specialist** about disease, treatment and support information, resources and clinical trials:
www.LLS.org/InformationSpecialists

Call: (800) 955-4572
Monday to Friday, 9 a.m. to 9 p.m. ET
Chat live online: www.LLS.org/InformationSpecialists
Monday to Friday, 10 a.m. to 7 p.m. ET
Email: www.LLS.org/ContactUs
All email messages are answered within one business day.

CLINICAL TRIAL SUPPORT CENTER
Work one-on-one with an LLS Clinical Trial Nurse Navigator who will help you find clinical trials and personally assist you throughout the entire clinical-trial process.
www.LLS.org/Navigation



NUTRITION CONSULTATIONS
Our registered dietitian has expertise in oncology nutrition and provides free one-on-one consultations by phone or email.
www.LLSNutrition.org

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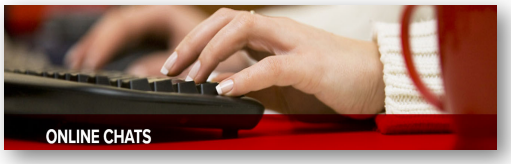

Online Chats

Online Chats are free, live sessions, moderated by oncology social workers. To register for one of the chats below, or for more information, please visit www.LLS.org/Chat

Education Videos

View our free education videos on disease, treatment, and survivorship. To view all patient videos, please visit www.LLS.org/EducationVideos

Patient Podcast

The Bloodline with LLS is here to remind you that after a diagnosis comes hope. To listen to an episode, please visit www.TheBloodline.org

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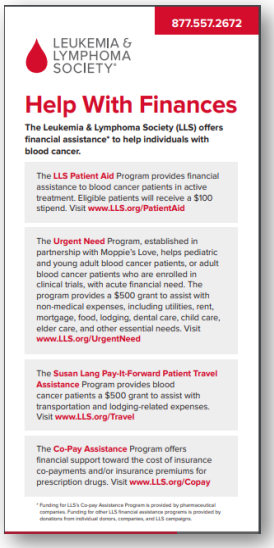
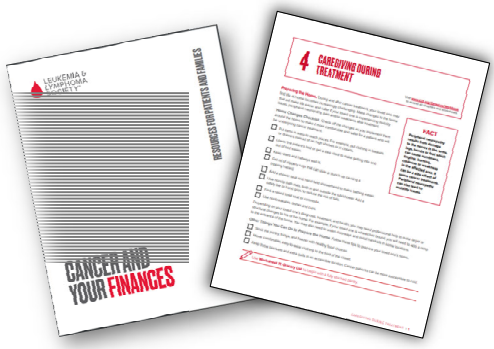


The Leukemia & Lymphoma Society (LLS) offers the following financial assistance programs to help individuals with blood cancers: **www.LLS.org/Finances**



To order free materials: **www.LLS.org/Booklets**

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