13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Chimeric Antigen Receptor T-Cell Therapy

Thursday, April 29, 2021
5:00 PM – 6:30 PM ET

Medical Oncologists

Jeremy Abramson, MD
Caron Jacobson, MD
Noopur Raje, MD

Oncology Nurse Practitioners

Sonia Glennie, ARNP, MSN, OCN
Alli McClanahan, MSN, APRN, ANP-BC
Elizabeth Zerante, MS, AGACNP-BC

Moderator

Neil Love, MD

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Massachusetts General Hospital
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Caron Jacobson, MD
Assistant Professor of Medicine
Harvard Medical School
Dana-Farber Cancer Institute
Boston, Massachusetts

Noopur Raje, MD
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Massachusetts General Hospital Cancer Center
Professor of Medicine
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Oncology Nurse Practitioners

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Alli McClanahan, MSN, APRN, ANP-BC
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Mayo Clinic
Rochester, Minnesota

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Commercial Support

This activity is supported by an educational grant from Bristol-Myers Squibb Company.

Dr Love — Disclosures

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Dr Abramson — Disclosures

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Contracted Research	Bristol-Myers Squibb Company, Seagen Inc

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Dr Jacobson — Disclosures

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Contracted Research	Kite, A Gilead Company, Pfizer Inc, Precision BioSciences

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Dr Raje — Disclosures

Consulting Agreements	Amgen Inc, bluebird bio, Celgene Corporation

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Ms Glennie — Disclosures

Speakers Bureau	Janssen Biotech Inc, Pharmacyclics LLC, an AbbVie Company

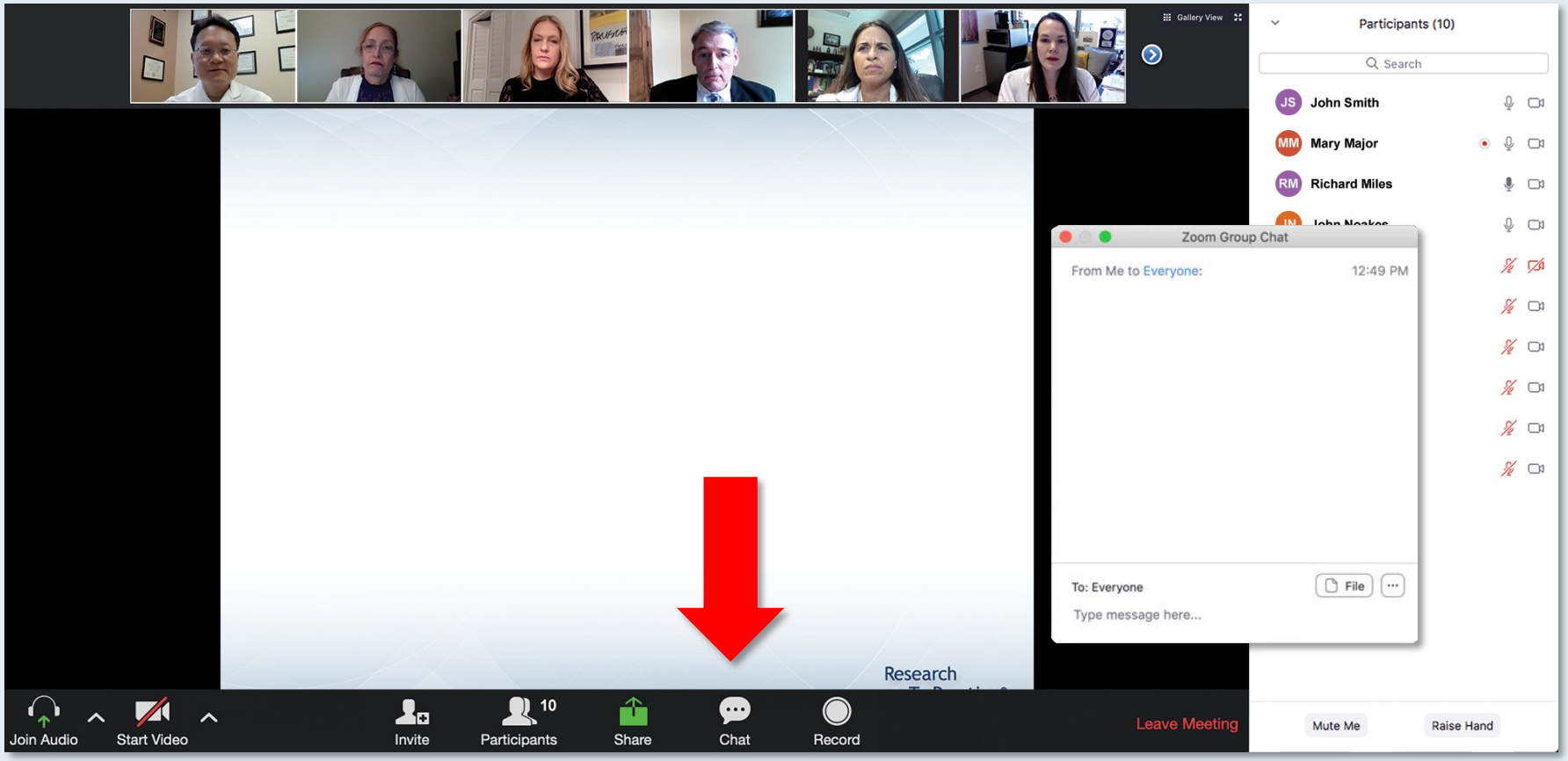
Ms McClanahan — Disclosures

No relevant conflicts of interest to disclose.

Ms Zerante — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

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Familiarizing Yourself with the Zoom Interface

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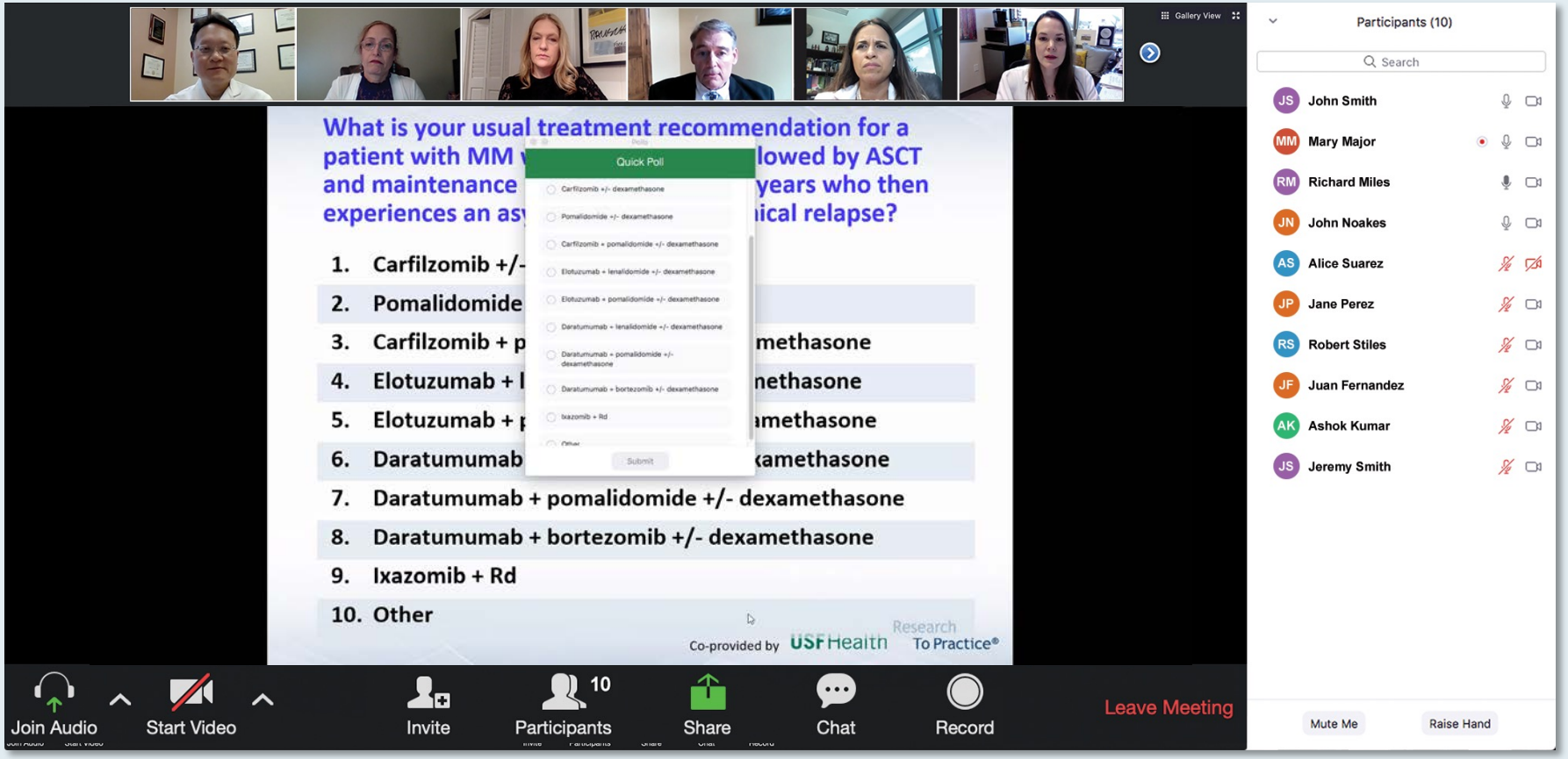

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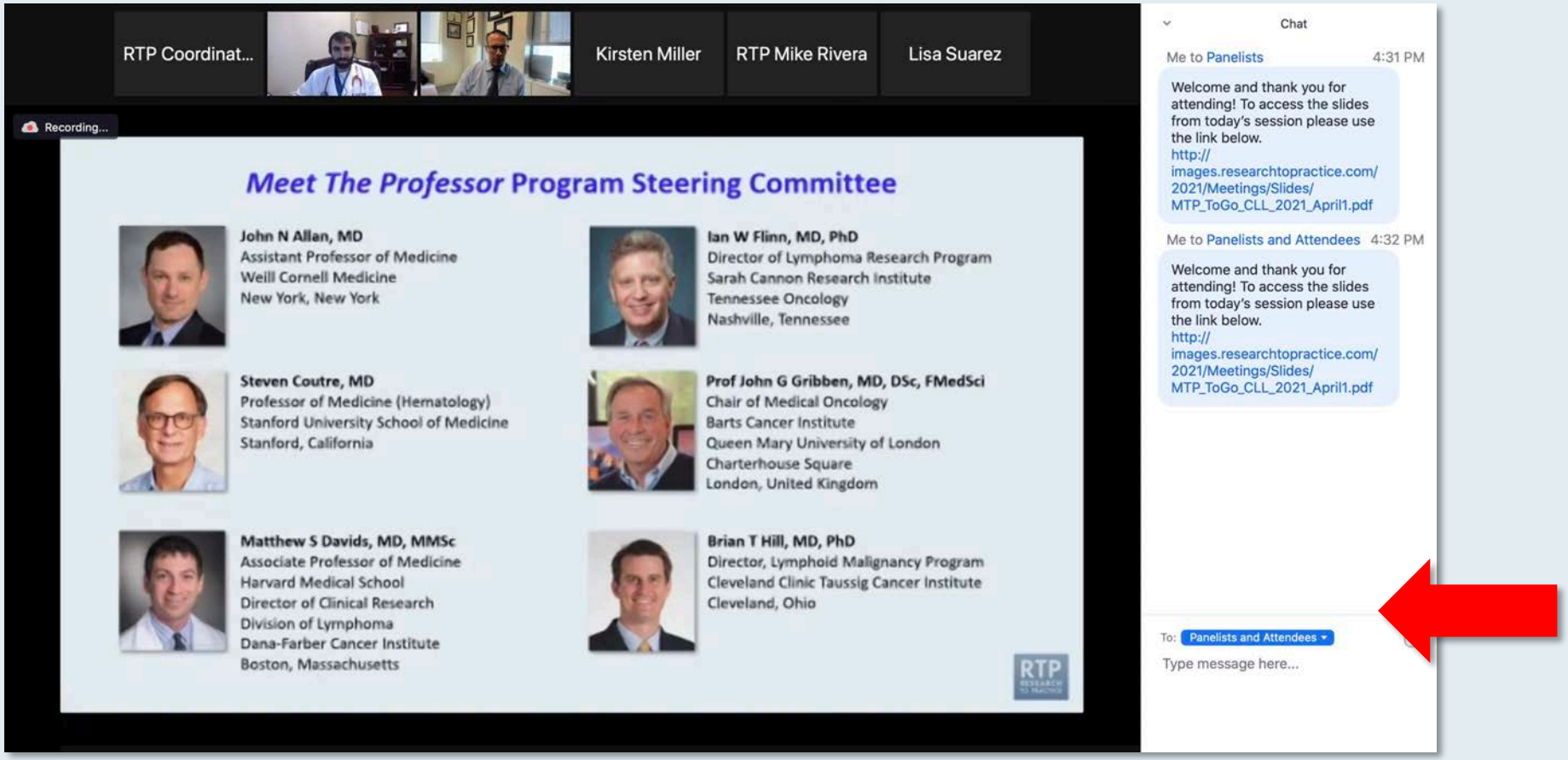
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



Drag the white line above the submission box up to create more space for your message.

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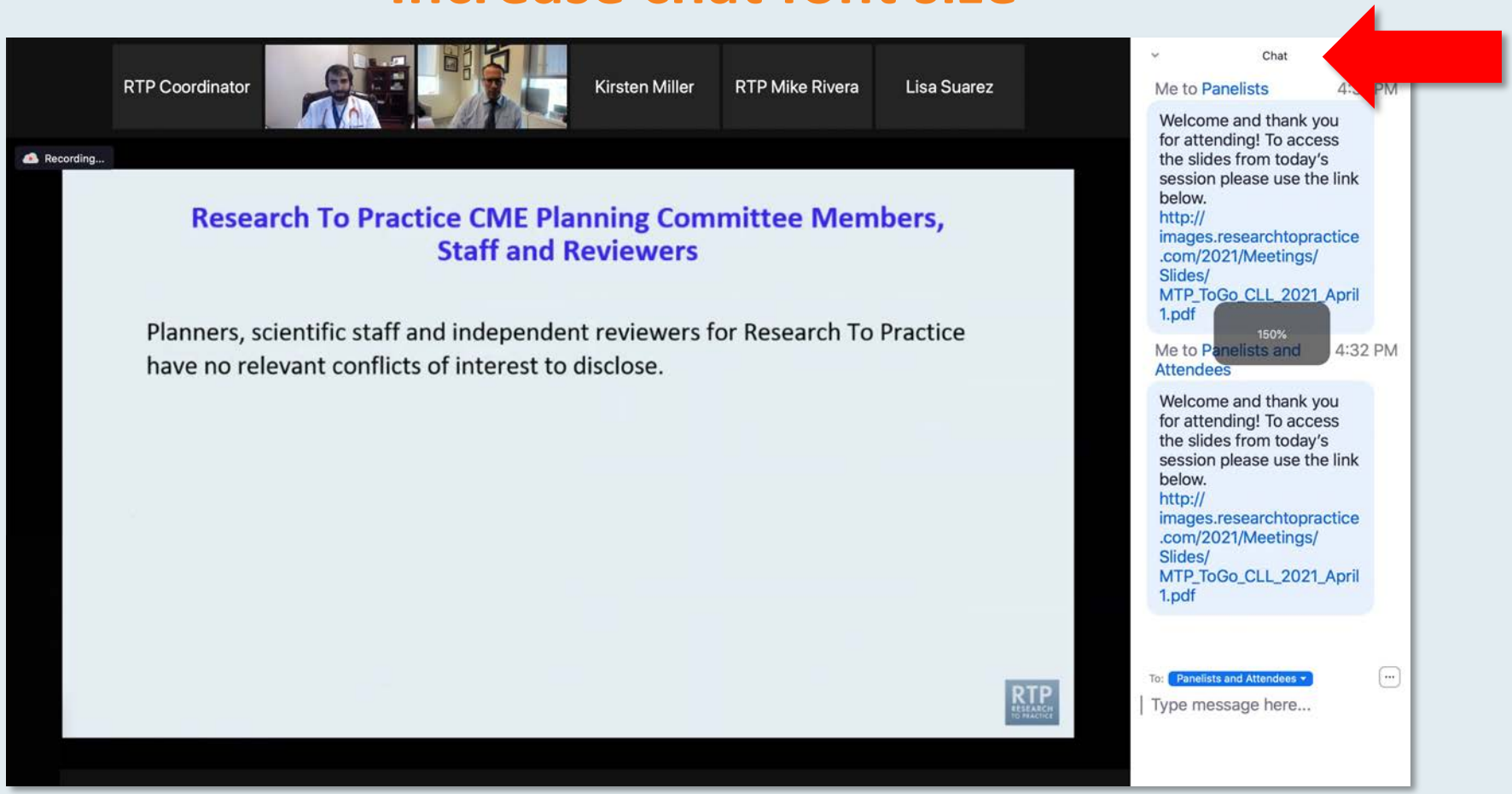
Increase chat font size



Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

ONCOLOGY TODAY

WITH DR NEIL LOVE

CHIMERIC ANTIGEN RECEPTOR T-CELL THERAPY IN NON-HODGKIN LYMPHOMA

DR TANYA SIDDIQI

CITY OF HOPE NATIONAL MEDICAL CENTER

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13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series Held During the 46th Annual ONS Congress

Breast Cancer
Tuesday, April 20, 2021
8:30 AM – 10:00 AM ET

Non-Small Cell Lung Cancer
Tuesday, April 20, 2021
5:00 PM – 6:30 PM ET

Acute Myeloid Leukemia
Wednesday, April 21, 2021
12:00 PM – 1:00 PM ET

Colorectal and Gastroesophageal Cancers
Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

Prostate Cancer
Thursday, April 22, 2021
8:30 AM – 10:00 AM ET

Hodgkin and Non-Hodgkin Lymphomas
Thursday, April 22, 2021
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Multiple Myeloma
Tuesday, April 27, 2021
8:30 AM – 10:00 AM ET

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Ask the Expert: Clinical Investigators Provide Perspectives on the Management of Renal Cell Carcinoma

In Partnership with Project Echo® and Florida Cancer Specialists

Tuesday, May 4, 2021
5:00 PM – 6:00 PM ET

Faculty

Chung-Han Lee, MD, PhD

Moderator

Neil Love, MD

Current Concepts and Recent Advances in Oncology

A Daylong Clinical Summit Hosted in Partnership with Medical Oncology Association of Southern California (MOASC)

Saturday, May 15, 2021
10:30 AM – 6:30 PM ET

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Saturday, May 15, 2021

10:30 AM — Breast Cancer
Ruth O'Regan, Tiffany A Traina

11:30 AM — Multiple Myeloma
Kenneth Anderson, Noopur Raje

12:50 PM — Chronic Lymphocytic Leukemia and Lymphomas
Craig Moskowitz, Jeff Sharman

1:50 PM — Genitourinary Cancers
Joaquim Bellmunt, Sumanta Kumar Pal

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Saturday, May 15, 2021

3:15 PM — Gastrointestinal Cancers
Wells A Messersmith, Eileen M O'Reilly

4:15 PM — Acute Myeloid Leukemia and Myelodysplastic Syndromes
Harry Paul Erba, Rami Komrokji

5:35 PM — Lung Cancer
D Ross Camidge, Benjamin Levy

Up for Debate: Oncology Investigators Provide Their Take on Current Controversies in Patient Care

A Daylong Multitumor Educational Webinar
in Partnership with Florida Cancer Specialists

Saturday, May 22, 2021
10:15 AM – 4:15 PM ET

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Saturday, May 22, 2021

10:15 AM — Lung Cancer
John V Heymach, Stephen V Liu

11:30 AM — Genitourinary Cancers
Maha Hussain, Elizabeth R Plimack

12:45 PM — Chronic Lymphocytic Leukemia and Lymphomas
Jonathan W Friedberg, Laurie H Sehn

2:00 PM — Multiple Myeloma
Irene M Ghobrial, Sagar Lonial

3:15 PM — Breast Cancer
Virginia Kaklamani, Nancy U Lin

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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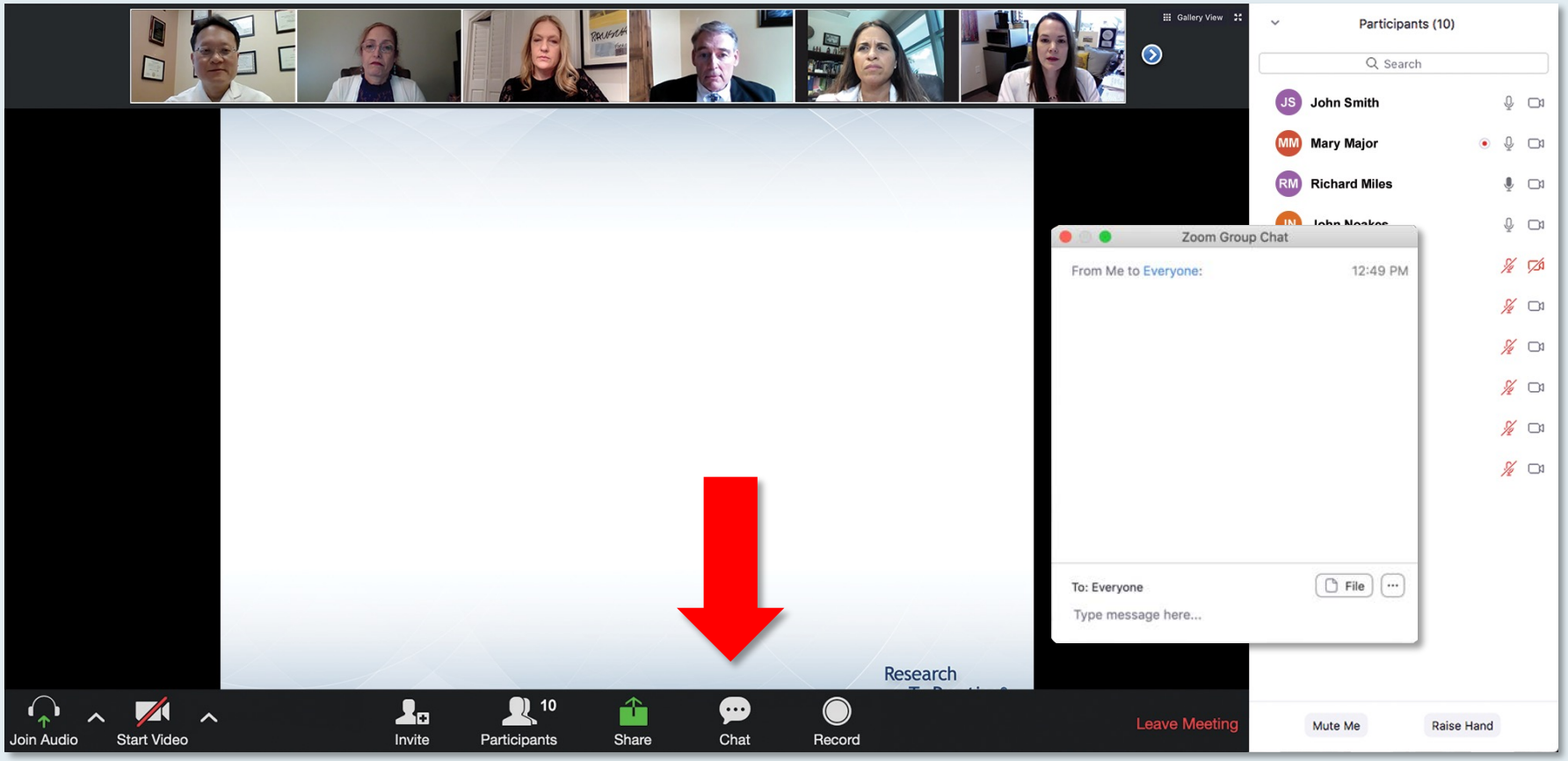

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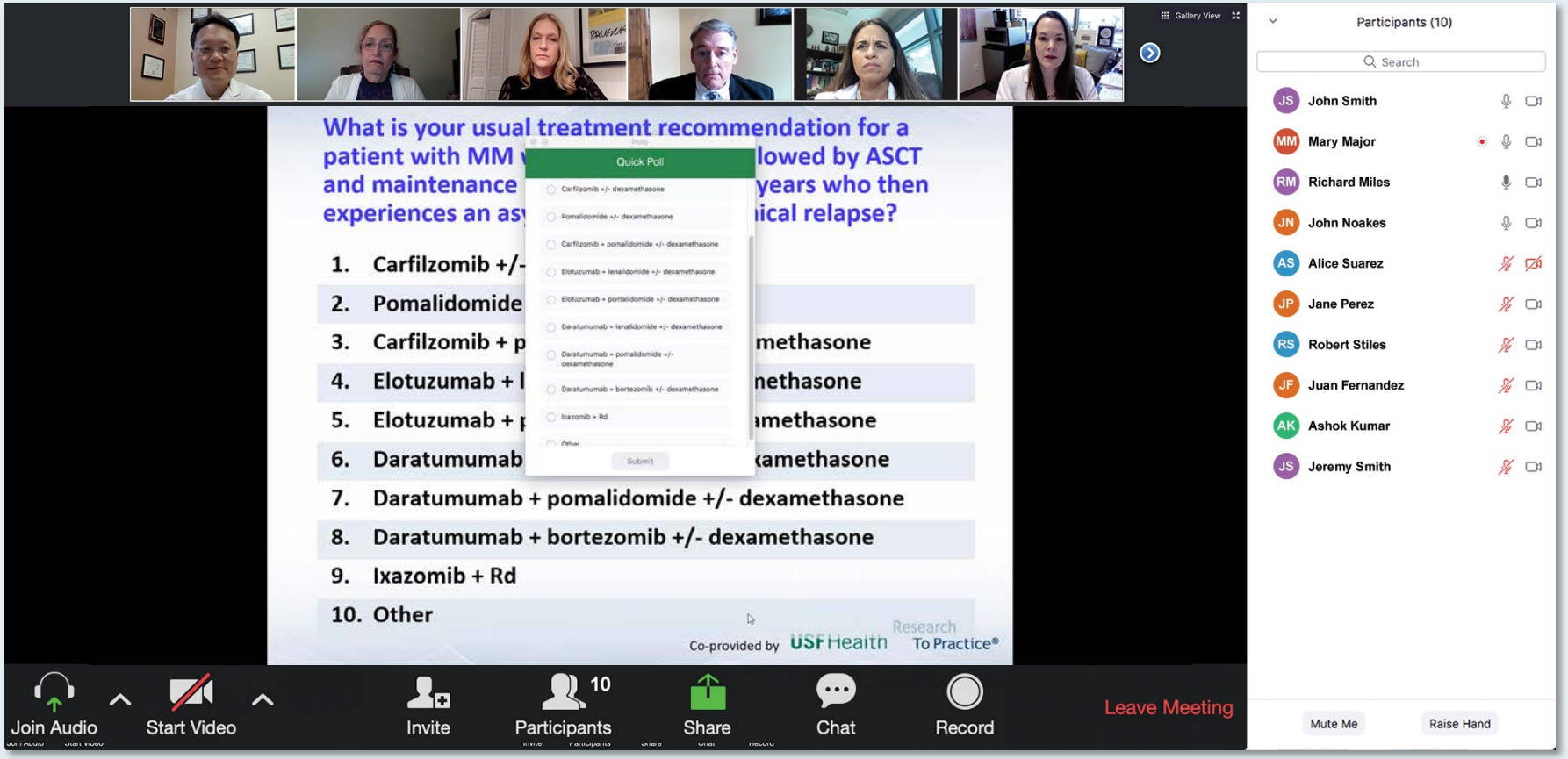

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Perelman Center for Advanced Medicine
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University of Chicago Medicine
Chicago, Illinois

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Oncology Grand Rounds Nursing Webinar Series

Monday	Tuesday	Wednesday	Thursday	Friday
19	20 Breast Ca 8:30 AM Lung Ca 5:00 PM	21 AML 12:00 PM CRC and GE Ca 4:45 PM	22 Prostate Ca 8:30 AM Lymphomas 5:00 PM	23
26	27 Multiple Myeloma 8:30 AM Gynecologic Ca 5:00 PM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM CAR-T 5:00 PM	30

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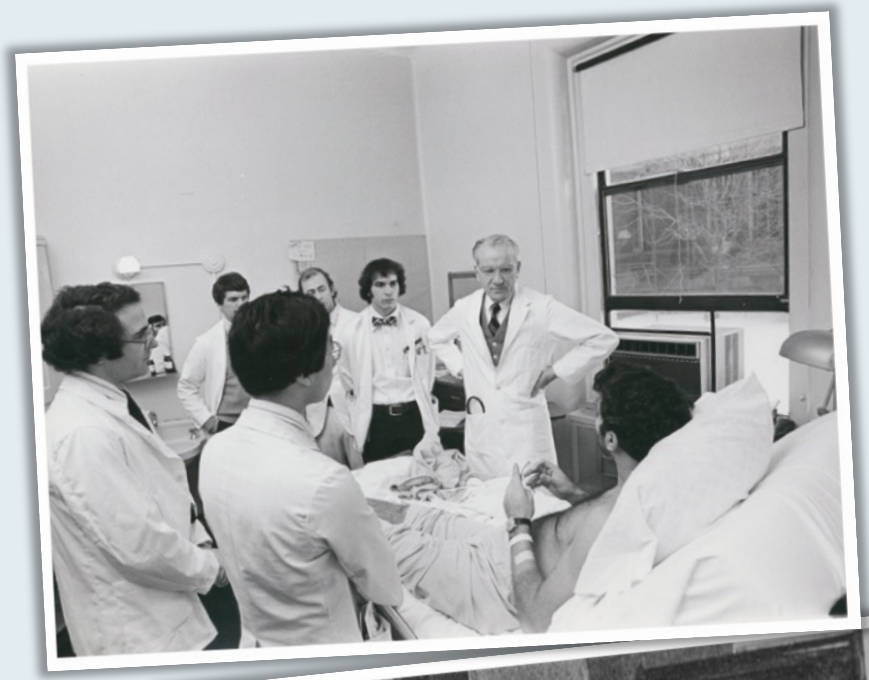

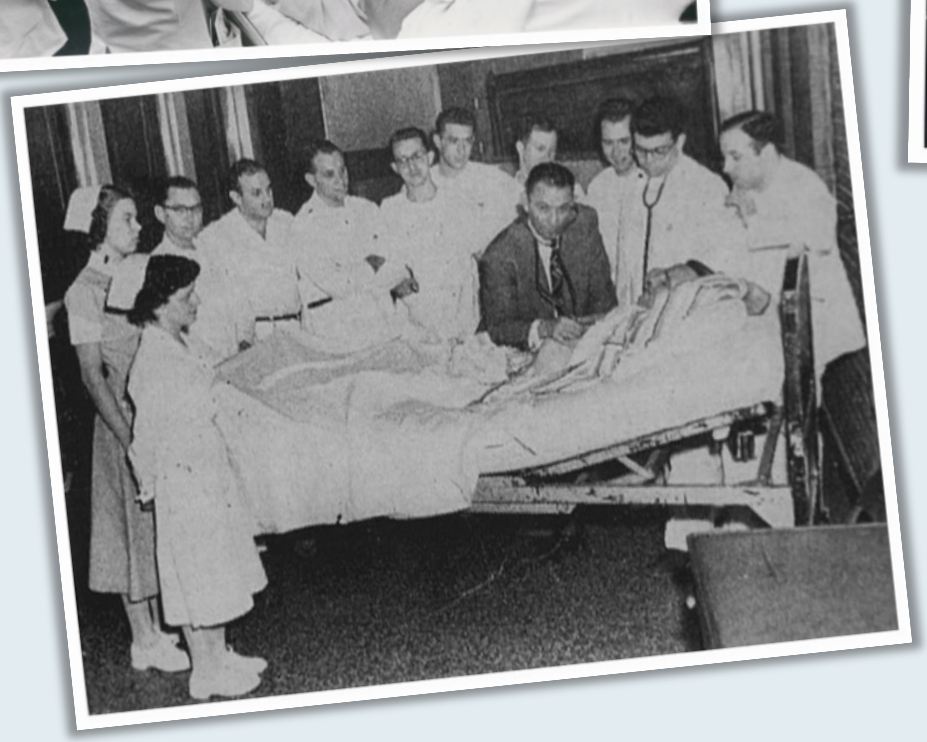


The Birmingham News

13th Annual Oncology Grand Rounds

Oncology Nurse Practitioners

Case Presentations

- Key patient-education issues
- Biopsychosocial considerations:
  - Family/loved ones
  - The bond that heals

Clinical Investigators

Oncology Strategy

- New agents and regimens
- Predictive biomarkers
- Ongoing research and implications

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Jeremy Abramson, MD
Caron Jacobson, MD
Noopur Raje, MD

Oncology Nurse Practitioners

Sonia Glennie, ARNP, MSN, OCN
Alli McClanahan, MSN, APRN, ANP-BC
Elizabeth Zerante, MS, AGACNP-BC

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE


Elizabeth Zerante MS, AGACNP-BC


Alli McClanahan, MSN, APRN, ANP-BC


Sonia Glennie, ARNP MSN OCN

Agenda

Module 1: CD19-Targeted CAR T-Cell Therapy in CLL/Lymphomas

- **Case 1 (Ms Glennie):** A 66-year-old man with relapsed DLBCL who received axicabtagene ciloleucel
- **Case 2 (Ms Zerante):** A 62-year-old woman with relapsed CLL who received lisocabtagene maraleucel
- **Case 3 (Ms McClanahan):** A 63-year-old man from the Netherlands with high-grade DLBCL who received axicabtagene ciloleucel

Module 2: COVID-19, CAR T-Cell Therapy and Clinical Oncology

Module 3: BCMA-Targeted CAR T-Cell Therapy in Multiple Myeloma

- **Case 4 (Ms McClanahan):** A 69-year-old man who received BCMA-targeted CAR T-cell therapy bb21217
- **Case 5 (Ms Zerante):** A 77-year-old man who received BCMA-targeted CAR T-cell therapy bb21217
- **Case 6 (Ms McClanahan):** A 64-year-old man who received BCMA-targeted CAR T-cell therapy bb21217 during the COVID-19 pandemic

Module 4: “What Is to Give Light Must Endure the Burning”

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How many patients, if any, in your practice have received some form of chimeric antigen receptor (CAR) T-cell therapy?

1. None
2. 1 patient
3. 2 patients
4. 3 patients
5. >3 patients

CAR T-cell therapy is commonly associated with…

1. Cytokine release syndrome (CRS)
2. Neurotoxicity
3. Rash
4. Peripheral neuropathy
5. Both CRS and neurotoxicity
6. I don’t know

Case Presentation – A 66-year-old man with relapsed/ refractory DLBCL who received axicabtagene ciloleucel (Part 1)

Ms Glennie

- Software engineer initially diagnosed with early germinal center DLBCL and received R-CHOP x 6 cycles and achieved a CR
- Experienced bulky disease relapse and enrolled on clinical trial of acalabrutinib plus RICE, but scans showed mixed response with some new areas of hypermetabolism
- Treated with axicabtagene ciloleucel
  - Experienced Grade 2 CRS and Grade 4 ICANS

Case Presentation – A 66-year-old man with relapsed/ refractory DLBCL who received axicabtagene ciloleucel (Part 2)

Ms Glennie

- Software engineer initially diagnosed with early germinal center DLBCL and received R-CHOP x 6 cycles and achieved a CR
- Experienced bulky disease relapse and enrolled on clinical trial of acalabrutinib plus RICE, but scans showed mixed response with some new areas of hypermetabolism
- Treated with axicabtagene ciloleucel on clinical trial and currently in CR
  - Experienced Grade 2 CRS and Grade 4 ICANS
- ***Patient has had a challenging recovery but is in CR***

RTP RESEARCH TO PRACTICE

Case Presentation – A 66-year-old man with relapsed/ refractory DLBCL who received axicabtagene ciloleucel (Part 3)

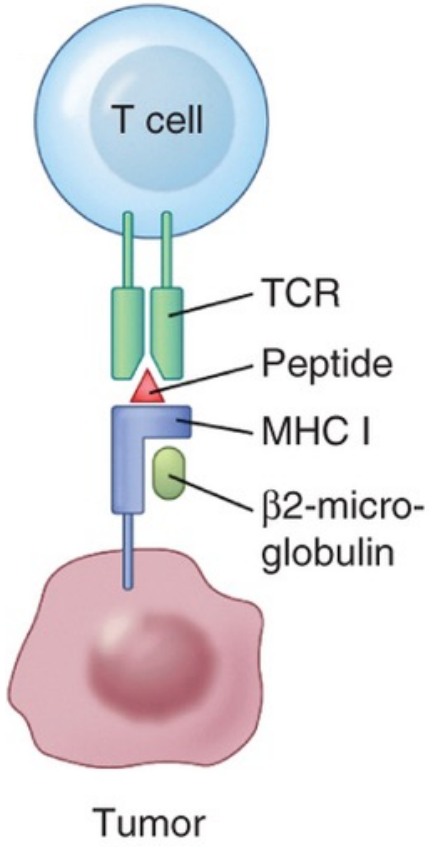
Ms Glennie

- Software engineer initially diagnosed with early germinal center DLBCL and received R-CHOP x 6 cycles and achieved a CR
- Experienced bulky disease relapse and enrolled on clinical trial of acalabrutinib plus RICE, but scans showed mixed response with some new areas of hypermetabolism
- Treated with axicabtagene ciloleucel and currently in CR
  - Experienced Grade 2 CRS and Grade 4 ICANS
- Patient has had a challenging recovery but is in CR
- ***Management of ICANS***

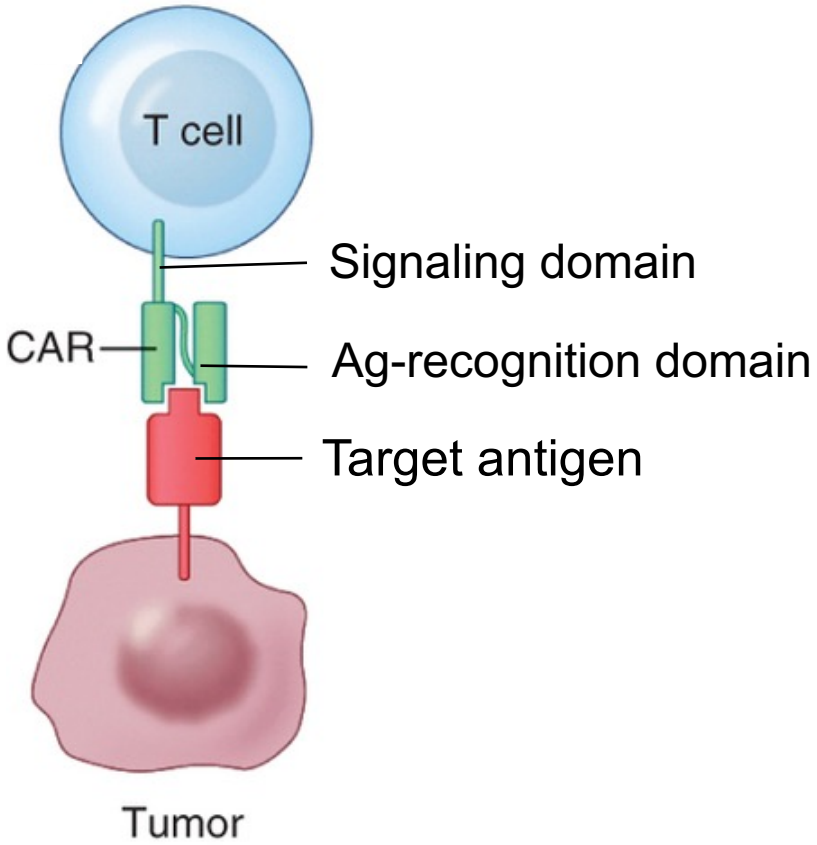
RTP RESEARCH TO PRACTICE

Chimeric Antigen Receptor (CAR) Modified T cells

Normal T cell



CAR T cell

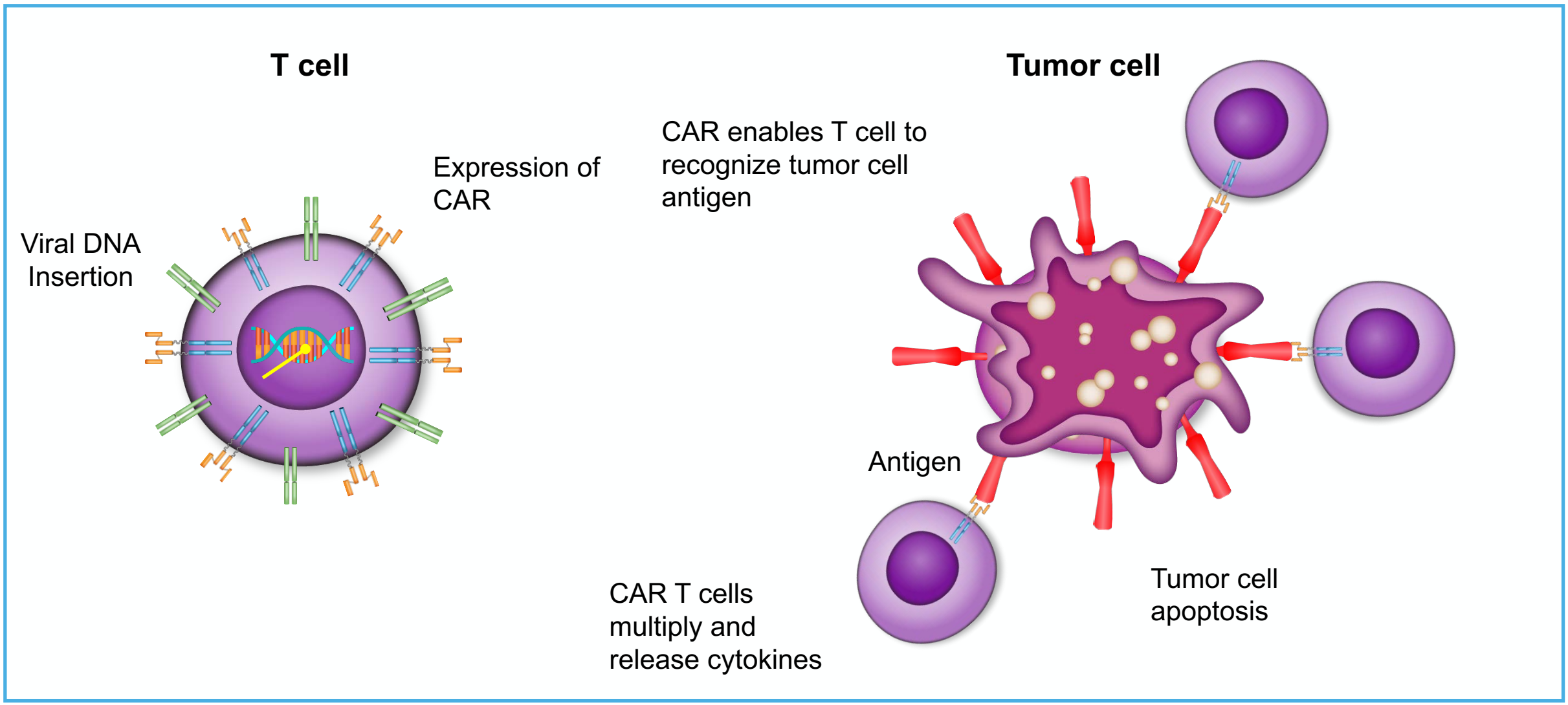


- **Genetically engineered T cells altered to express an artificial receptor, CAR**

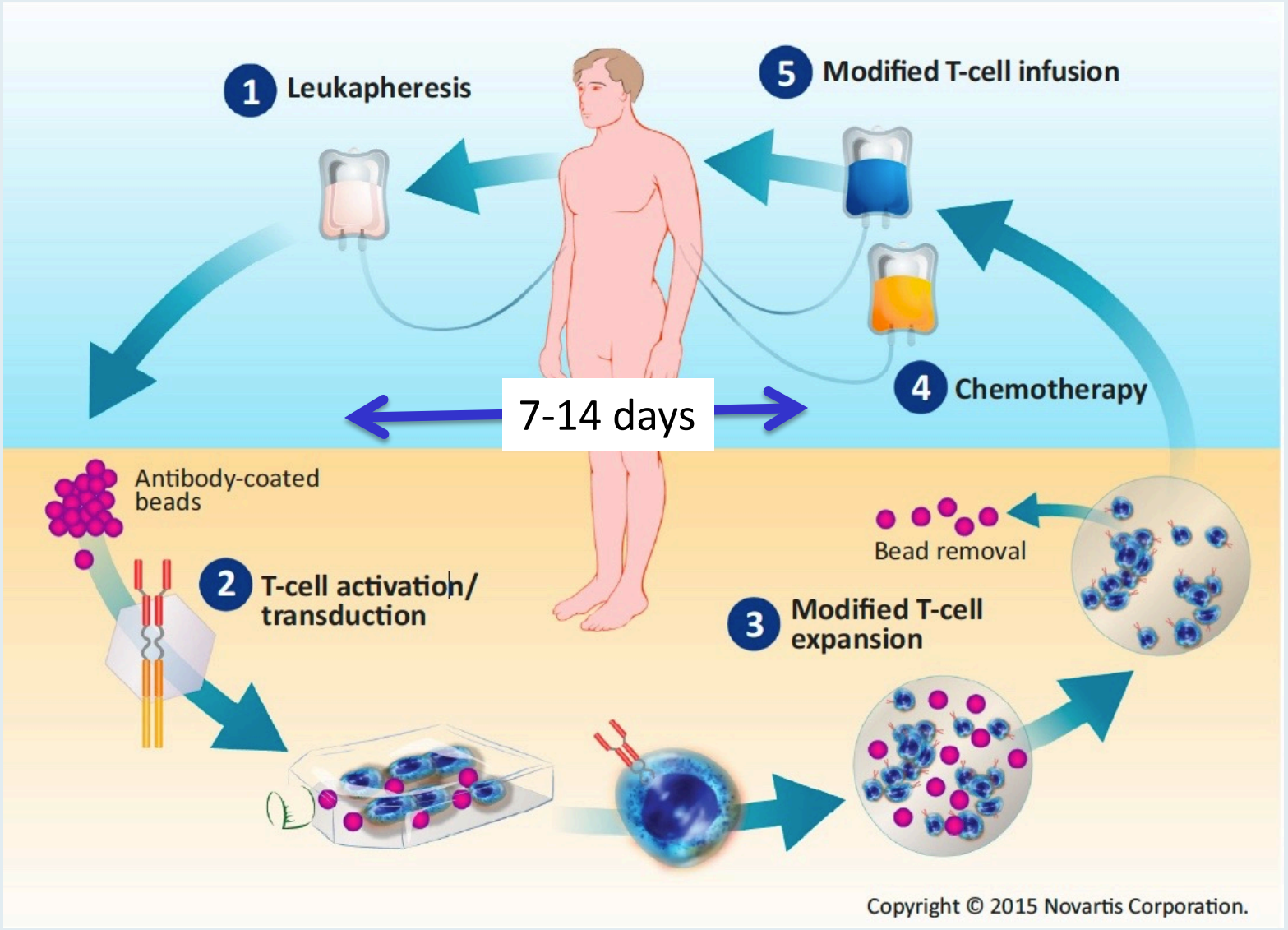
Courtesy of Sattva S Neelapu, MD

Adapted from Hinrichs & Restifo. Nat Biotech 2013

CAR T Cells: Mechanism of Action



Overview of CAR T-Cell Therapy



Modification, Courtesy, David Porter, MD

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CAR T-Cell Therapy-Associated Cytokine Release Syndrome (CRS)

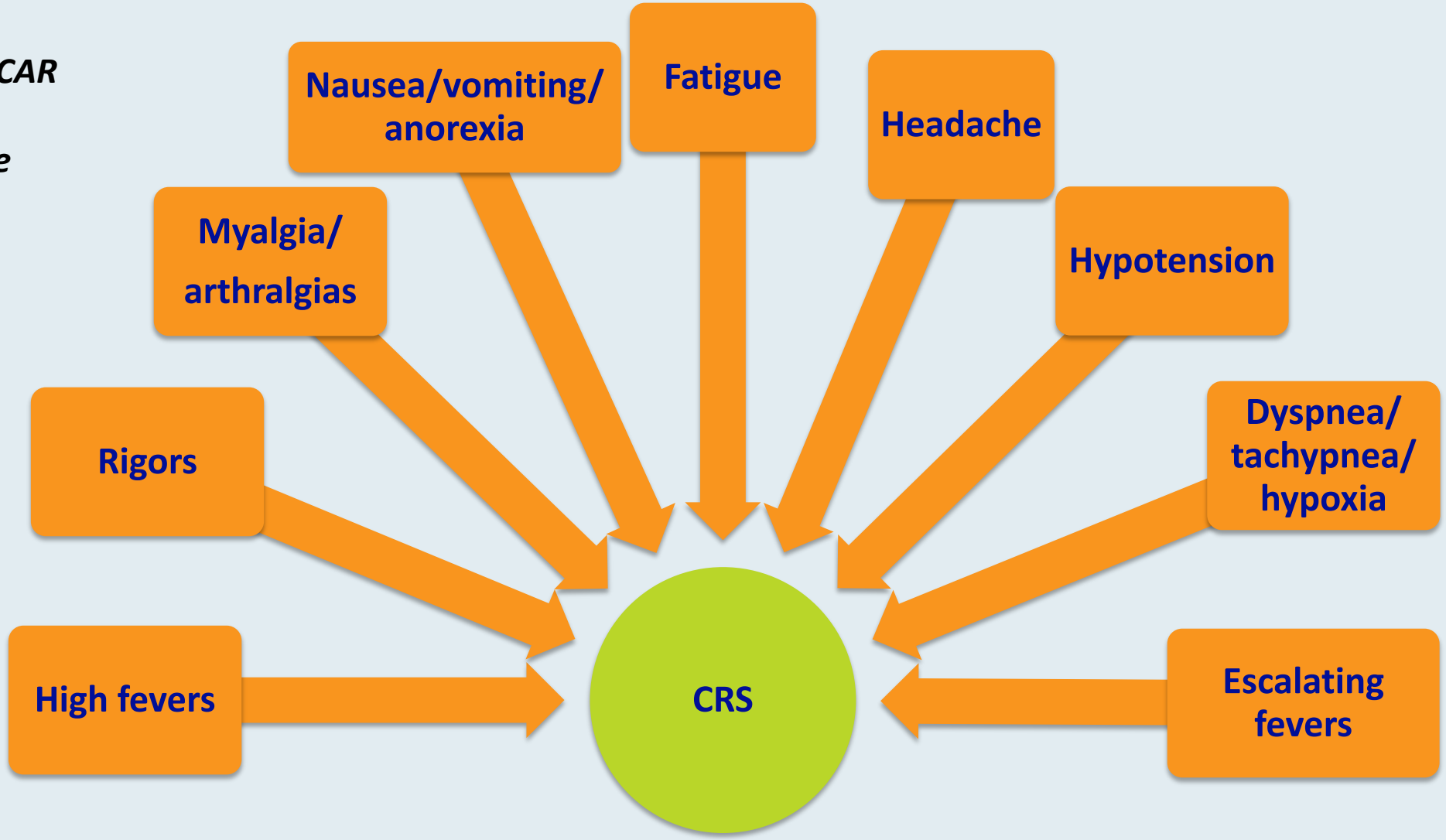
CRS — May be mild or life-threatening

- Occurs with CART19 activation and expansion
- Dramatic cytokine elevations (IL-6, IL10, IFNɣ, CRP, ferritin)
- Fevers initially (can be quite high: 105˚F)
- Myalgias, fatigue, nausea/anorexia
- Capillary leak, headache, hypoxia and hypotension
- CRS-related mortality 3% to 10%

Varadarajan I, Lee DW. *Cancer J* 2019;25(3):223-30.
Abramson JS et al. ASCO 2019 Education Book.

Cytokine Release Syndrome (CRS): Common Symptoms

Based on CAR T-cell experience



Diagnosis based on <u>clinical</u> symptoms and events

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CAR T-Cell Therapy-Associated Neurologic Toxicity

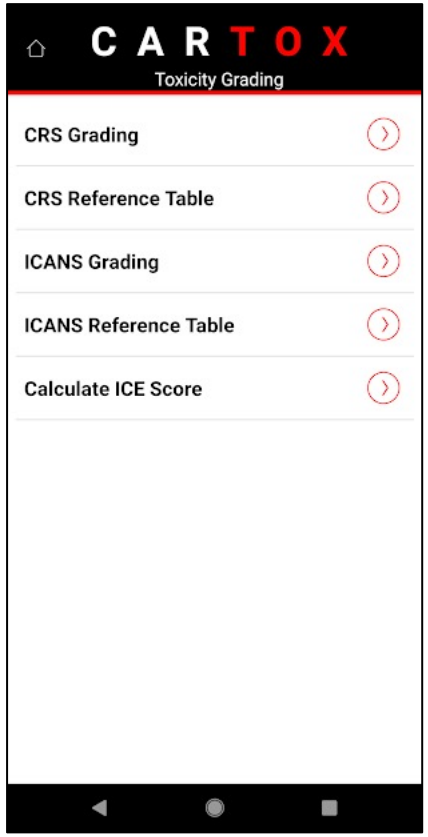
Neurologic toxicity — May be mild or life-threatening

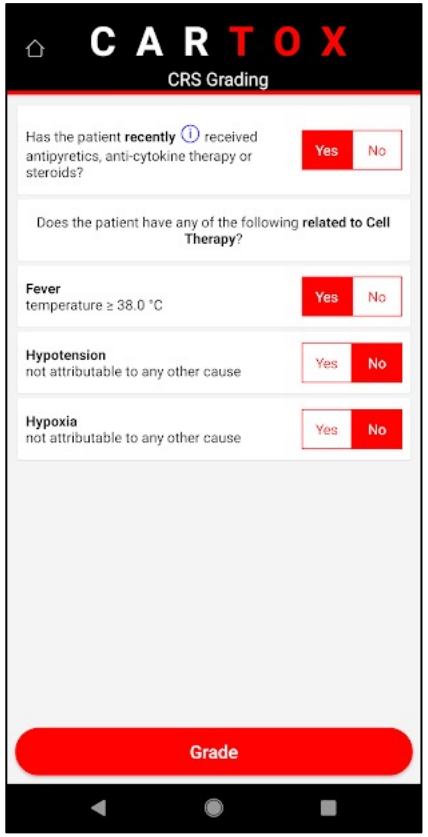
- Mechanism unclear, referred to as immune effector cell-associated neurotoxicity syndrome (ICANS)
- Encephalopathy
- Seizures
- Delirium, confusion, aphasia, agitation, sedation, coma

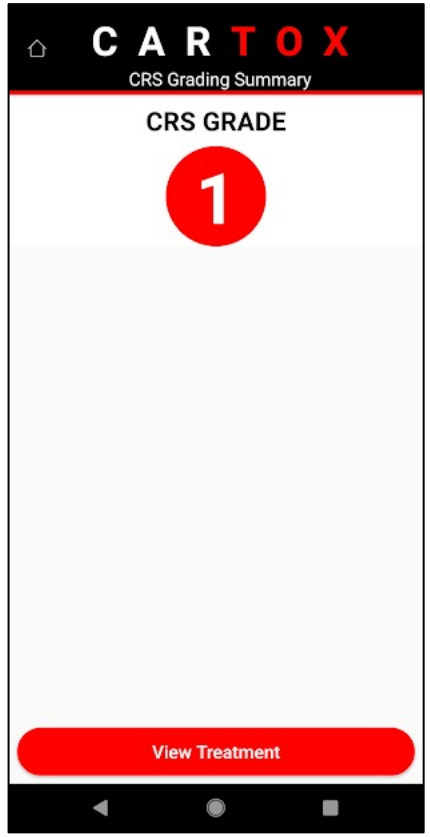
Varadarajan I, Lee DW. *Cancer J* 2019;25(3):223-30.
Abramson JS et al. ASCO 2019 Education Book.

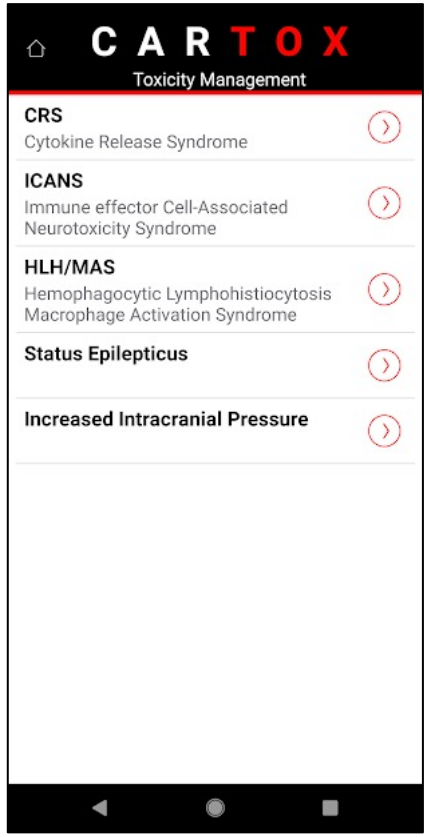
CARTOX App for Grading and Management of CRS and ICANS

Smart phone app available free on both App Store (iPhone) and Google Play (Android)









Sherry Adkins

Courtesy of Sattva S Neelapu, MD

Neelapu et al. *Nat Rev Clin Oncol,* Jan 2018

Lee et al. *Biol Blood Marrow Transplant,* 2019 Apr;25 (4):625-638

Patient Education Regarding CAR T-Cell Therapy

CRS	Neurotoxicity	Management of Toxicities
• Fever • Hypotension • Tachycardia • Hypoxia • Chills	• Tremors • Dizziness • Delirium • Confusion • Agitation • Cerebral Edema	• Tocilizumab • Steroids

Adkins, S. (2019). Car T cell therapy: adverse events and management. J. Adv Pract Onco Supple3. 21-28..

Patient Education Regarding CAR T-Cell Therapy

Logistics	Pancytopenia	Other
• Stay locally for 30 days • Inpatient vs outpatient • Frequent visits to hospital • Local Oncologist to coordinate care • Caregiver 24 hours a day	• Decreased blood counts • Blood and Platelet Transfusions • Growth Factor Support • Infections • Prophylactic Antibiotics	• When to come to ER • When to call the clinic • Ensure caregivers are present • Contact local oncologist

Adkins, S. (2019). Car T cell therapy: adverse events and management. J. Adv Pract Onco Supple3. 21-28..

Case Presentation – A 62-year-old woman with relapsed/refractory CLL who received lisocabtagene maraleucel (Part 1)

Ms Zerante

- Initially diagnosed with CLL in 2017 and her disease had progressed through multiple lines of therapy
- Experienced significant toxicities during her treatment for CLL
- She had a past medical history of stroke and diabetes; some issues with short-term memory
- Treated with lisocabtagene maraleucel on clinical trial

Case Presentation – A 62-year-old woman with relapsed/refractory CLL who received lisocabtagene maraleucel (Part 2)

Ms Zerante

- Initially diagnosed with CLL in 2017 and her disease had progressed through multiple lines of therapy
- She had a past medical history of stroke and diabetes; some issues with short-term memory
- Treated with lisocabtagene maraleucel on clinical trial
- ***Onset of CRS on day 3, and reoccurrence of CRS on day 15***
- ***Low-grade neurotoxicity treated with steroids → diabetic ketoacidosis***
- ***Reflections on the patient as a person and caring for her***

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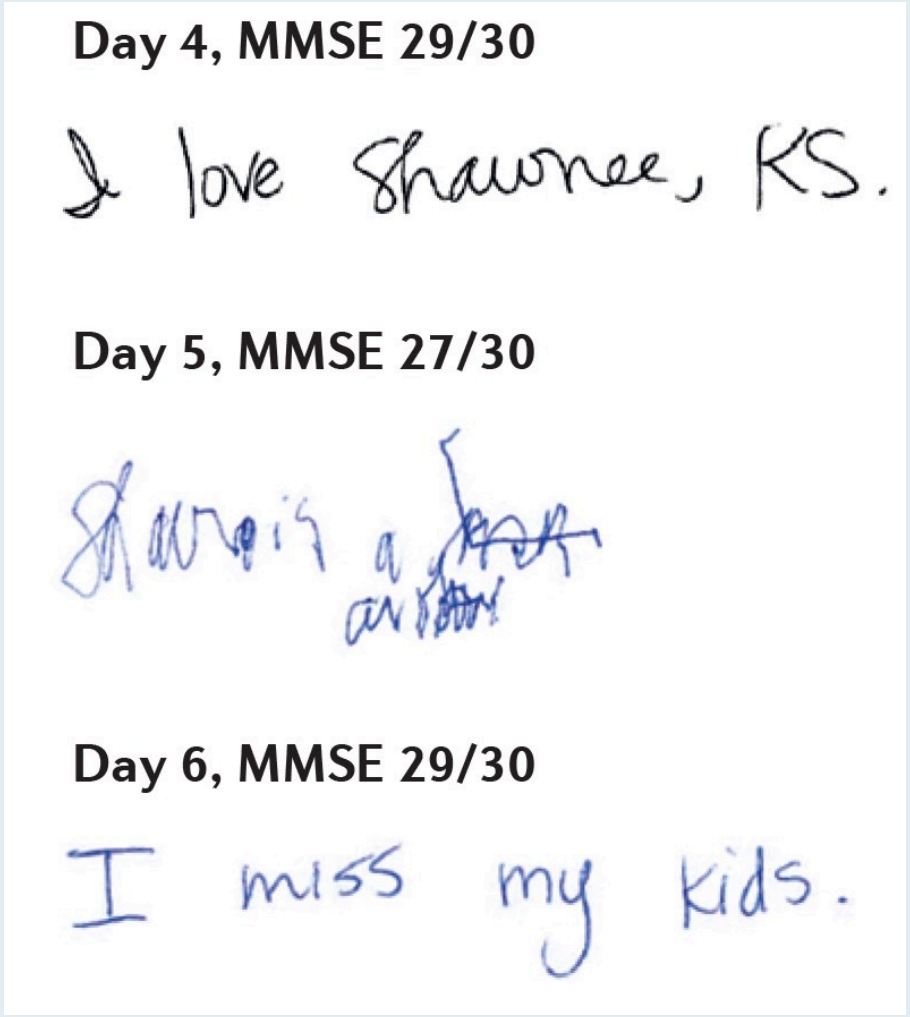
Case Presentation – A 63-year-old man from the Netherlands with high-grade DLBCL who received axicabtagene ciloleucel

Ms McClanahan

- Speaks English fluently as a second language
- Initial collection of cells not successful due to manufacturing issues
- Second collection successful and he received axicabtagene ciloleucel
- Experienced neurotoxicity – manifested as difficulty speaking English
- Grade 2 CRS

Handwriting Samples and MMSE After CAR T-Cell Therapy



- Handwriting samples and mini mental status exam (MMSE) scores obtained on days 4, 5, and 6 after CAR T-cell therapy
- Note how the patient's handwriting was markedly impaired on day 5, despite only a small decrease in their MMSE score.

Neelapu SS et al. *Nat Rev Clin Oncol* 2018;15(1):47-62.

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CD19 CAR T products in pivotal trials in NHL

	NCI	U Penn	FHCRC / SCH
CD19 Ab	FMC63	FMC63	FMC63
Hinge Transmembrane	CD28	CD8a	CD28
Signal 2	CD28	4-1BB	4-1BB
Signal 1	CD3ζ	CD3ζ	CD3ζ
Gene transfer	Retrovirus	Lentivirus	Lentivirus
	KTE-C19 **Axicabtagene ciloleucel** **Axi-cel**	**CTL-019** **Tisagenlecleucel**	**JCAR017 (CD4:CD8 = 1:1)** **Lisocabtagene maraleucel** **Liso-cel**

Courtesy of Sattva S Neelapu, MD

Adapted from van der Steegen et al. Nat Rev Drug Discov, 2015

FDA Approves Lisocabtagene Maraleucel for Relapsed or Refractory Large B-Cell Lymphoma

Press Release – February 5, 2021

"The Food and Drug Administration approved lisocabtagene maraleucel for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Efficacy was evaluated in TRANSCEND (NCT02631044), a single-arm, open label, multicenter trial that evaluated lisocabtagene maraleucel, preceded by lymphodepleting chemotherapy, in adults with R/R large B-cell lymphoma after at least two lines of therapy.

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-lisocabtagene-maraleucel-relapsed-or-refractory-large-b-cell-lymphoma

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Pivotal CAR-T Studies in DLBCL: Summary of Efficacy

	ZUMA-1 Axicabtagene ciloleucel	JULIET Tisagenlecleucel	TRANSCEND NHL 001 Lisocabtagene maraleucel
Evaluable patients	101	93	102 (core: 73)
Median follow-up	15.4 mo	19.3 mo	12 mo
Best ORR	83%	52%	75%
CR	58%	40%	55%
6-mo ORR	41%	33%	47%
12-mo OS	59%	49%	63%

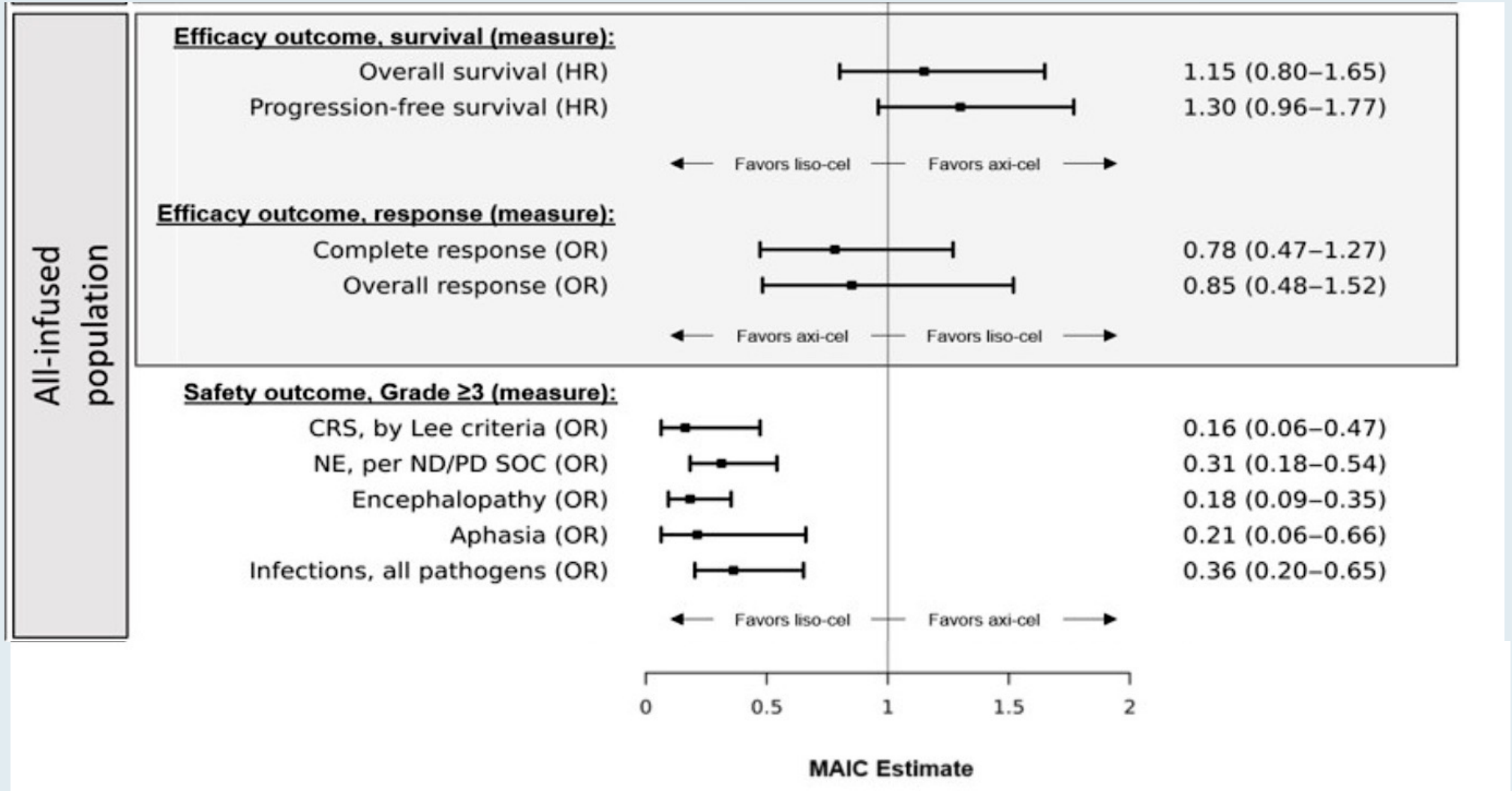
Locke F et al; ZUMA-1 Investigators. *Lancet Oncol* 2019;20(1):31-42.
Schuster SJ et al; JULIET Investigators. *N Engl J Med* 2019;380(1):45-56.
Abramson JS et al; TRANSCEND NHL 001 Investigators. *Proc ASCO* 2018;Abstract 7505.

Matching-Adjusted Indirect Comparison (MAIC) of Lisocabtagene Maraleucel (Liso-cel) vs Axicabtagene Ciloleucel (Axi-cel) and Tisagenlecleucel in Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL)

Maloney DG et al.

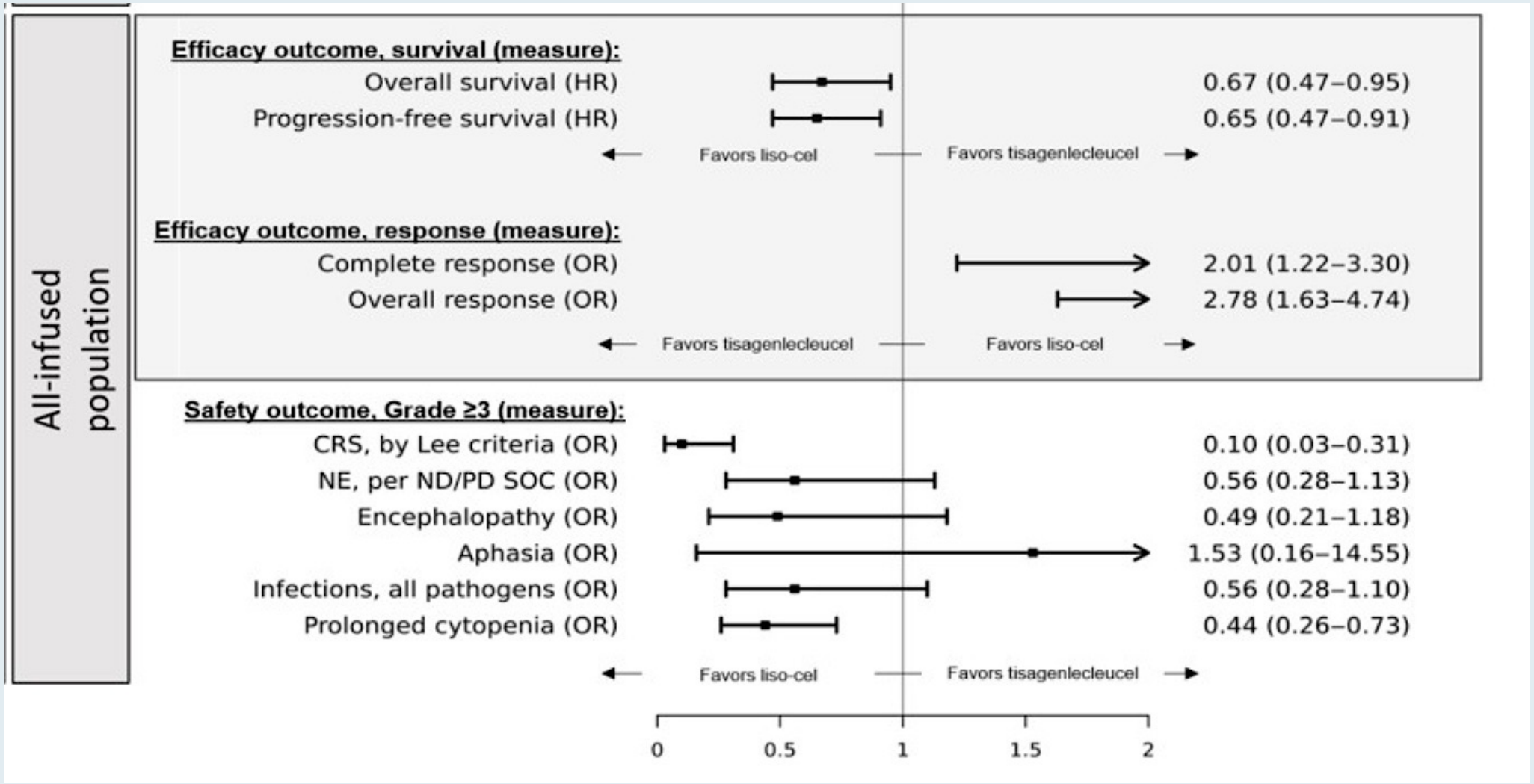
ASH 2020;Abstract 2116.

Matching-Adjusted Indirect Comparison of Liso-cel versus Axi-cel



Maloney DG et al. ASH 2020;Abstract 2116.

Matching-Adjusted Indirect Comparison of Liso-cel versus Tisagenlecleucel



Maloney DG et al. ASH 2020;Abstract 2116.

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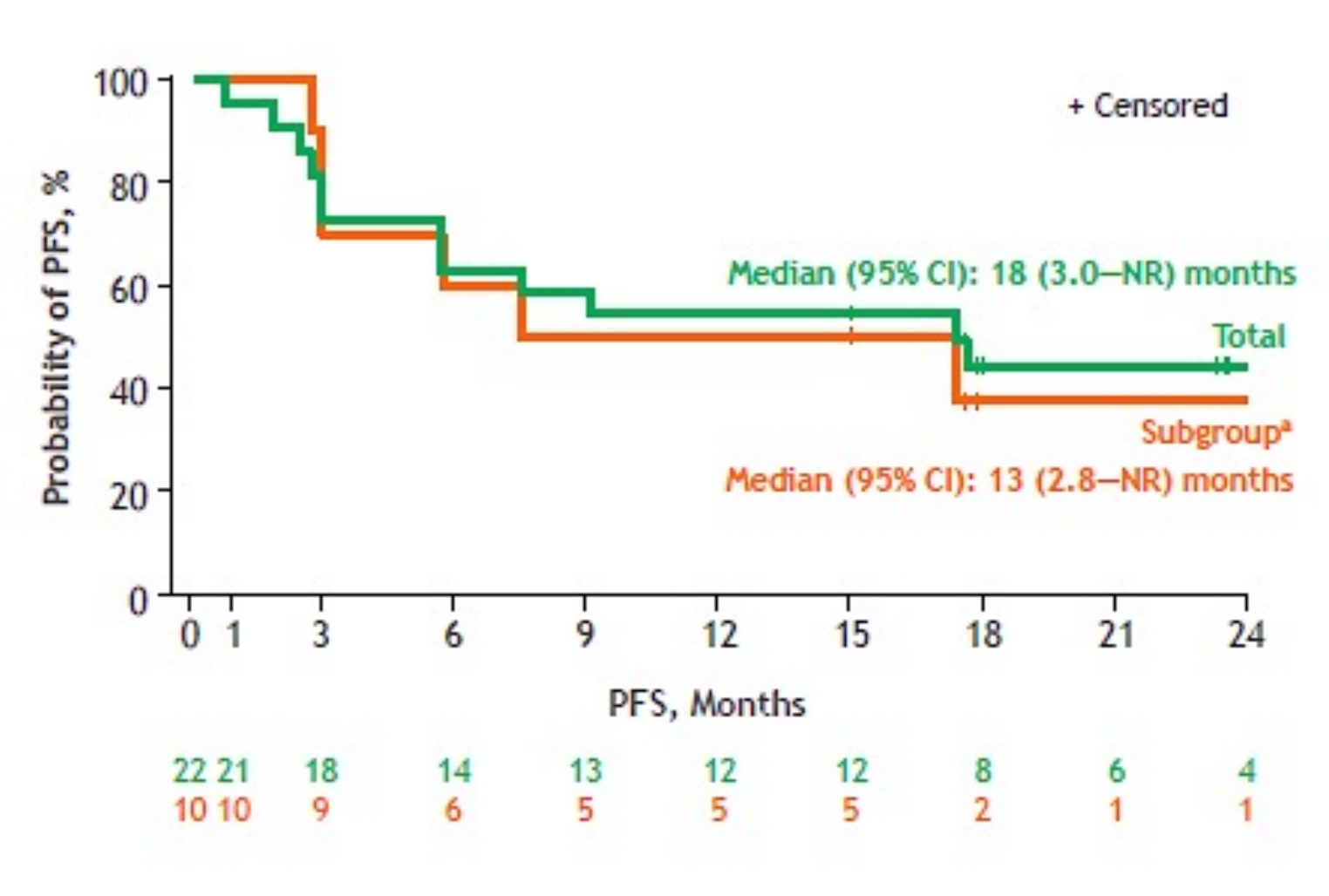
Updated Follow-Up of Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Treated with Lisocabtagene Maraleucel in the Phase 1 Monotherapy Cohort of Transcend CLL 004, Including High-Risk and Ibrutinib-Treated Patients

Siddiqi T et al.

ASH 2020;Abstract 546.

TRANSCEND CLL 04: Liso-cel Monotherapy Cohort



- ORR/CR = 82%/68%
- Median PFS 13 mo and DOR 50% at 12 mo
- Gr 3 CRS= 9% and NE 22% (No Grade 4/5)
- 4 of 6 progressions due to RT

Siddiqi T et al. ASH 2020;Abstract 546.

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Efficacy and Safety of Tisagenlecleucel in Adult Patients with Relapsed/Refractory Follicular Lymphoma: Interim Analysis of the Phase 2 Elara Trial

Fowler NH et al.

ASH 2020;Abstract 1149.

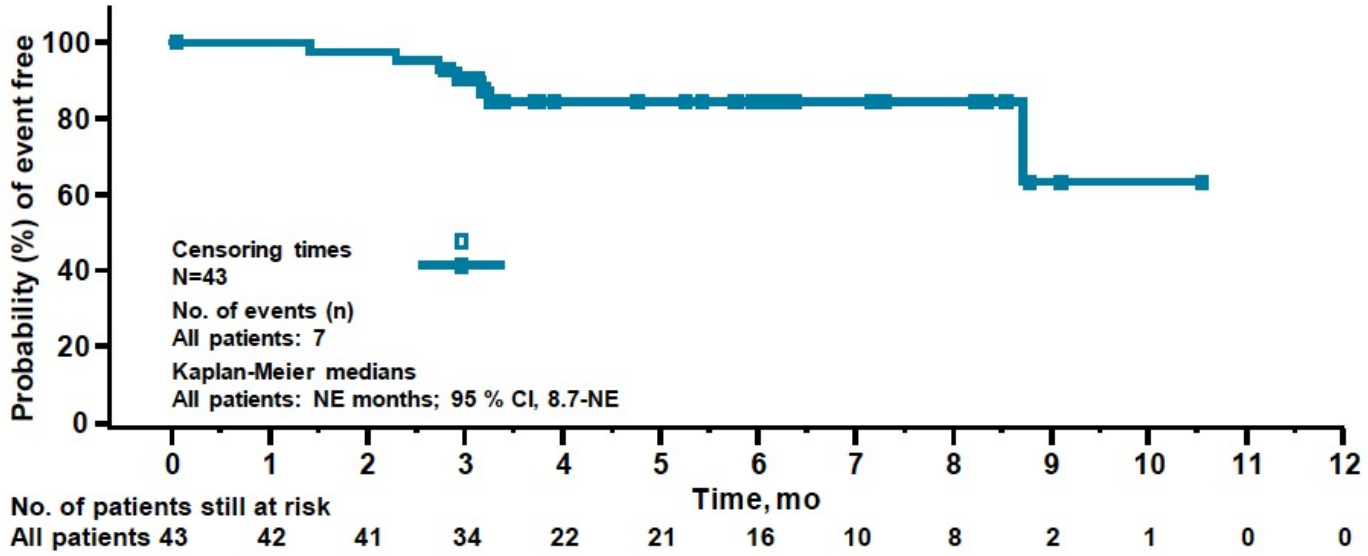
ELARA Interim Analysis: Primary CR Endpoint

Best Overall Response Rate

Response Rate, %	Patients Evaluable for Efficacy[a] (n=52)
CR	65.4[a]
PR	17.3
ORR (CR + PR)	82.7

- Investigator-assessed CR rate was 67.3%[b] (ORR 88.5%)
- ORR was consistent across subgroups, including prior SCT, disease status, and high-risk features

At 10 Months Median Follow-up for Efficacy, Median DOR Not Reached



- Median follow-up for efficacy (n=52): 9.9 months (6.0-15.6)
- Probability for a responding patient to remain in response ≥6 months was 84.4%
- 8 of 18 PRs (44%) converted to CRs; all but 1 occurred between Month 3 and Month 6
- Median time to next antilymphoma treatment was not reached
- 69% (36/52) had ongoing responses at the time of data cutoff

Fowler NH et al. ASH 2020;Abstract 1149.

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ELARA: Overall Safety Profile

Adverse Events, n (%)	Treated Patients N=97
Any AE (all grade)	92 (94.8)
AEs suspected to be drug-related	71 (73.2)
Any SAE	37 (38.1)
Suspected to be drug-related	26 (26.8)
Any grade 3/4 AE	68 (70.1)
Suspected to be drug-related	37 (38.1)
Death	3 (3.1)
Deaths due to study indication	3 (3.1)
Deaths within 30 days post infusion	0

	Treated Patients N=97	
AESI (within 8 weeks of infusion)	**All grades, %**	**Grade ≥3, %**
Cytokine release syndrome[a]	48.5	0
Serious neurological adverse reactions	9.3	1.0
Infections	18.6	4.1
Tumor lysis syndrome	1.0	0
Prolonged depletion of B cells/ agammaglobulinemia	9.3	0
Hematologic disorders including cytopenias		
Neutropenia[b,c]	28.9	24.7
Anemia[b]	22.7	12.4
Thrombocytopenia[b]	15.5	8.2

- Median onset of neurological events was 8.5 (4-190[d]) days
- Only 1 case of serious ICANS within the first 8 weeks
- CRS median onset was 4.0 (1-14) days

- **All neurological and CRS events resolved with appropriate management**

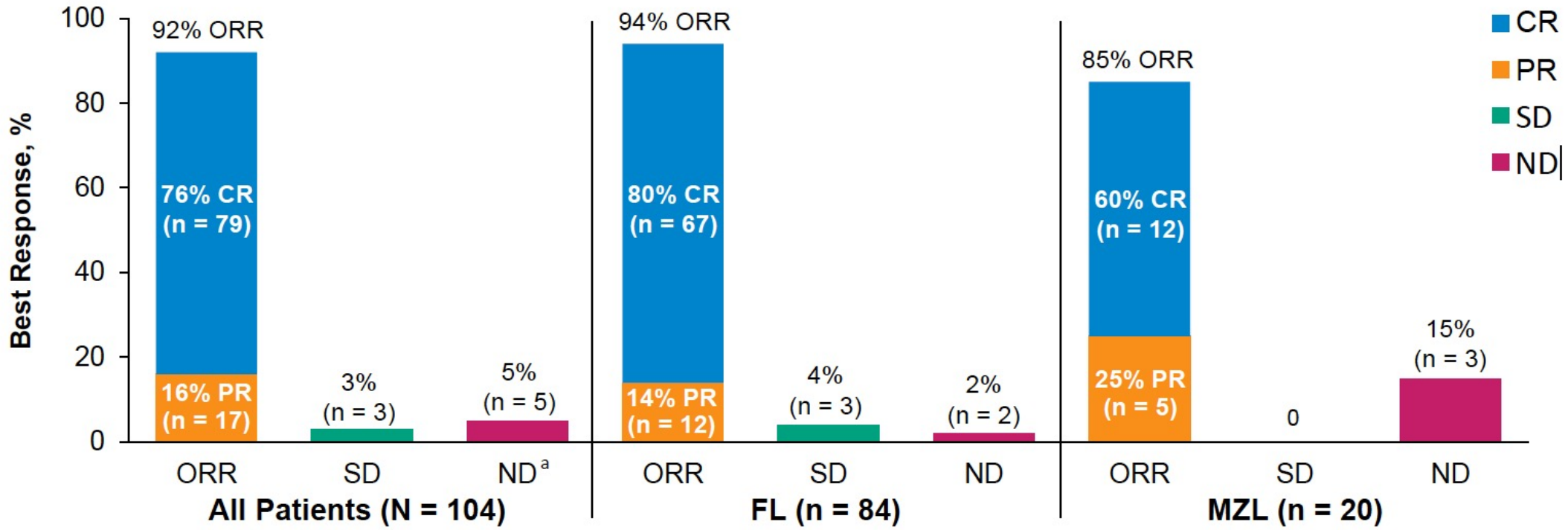
Fowler NH et al. ASH 2020;Abstract 1149.

Primary Analysis of Zuma-5: A Phase 2 Study of Axicabtagene Ciloleucel (Axi-Cel) in Patients with Relapsed/Refractory (R/R) Indolent Non-Hodgkin Lymphoma (iNHL)

Jacobson CA et al.

ASH 2020;Abstract 700.

ZUMA-5 Primary Endpoint: ORR by IRRC Assessment



- The median time to first response was 1 month (range, 0.8 – 3.1)
- Among the 25 patients with FL who initially had a PR, 13 (52%) subsequently converted to a CR after a median of 2.2 months (range, 1.9 – 11.2)

Jacobson CA et al. ASH 2020;Abstract 700.

FDA Approves Brexucabtagene Autoleucel for Relapsed or Refractory Mantle Cell Lymphoma

Press Release – July 24, 2020

The Food and Drug Administration granted accelerated approval to brexucabtagene autoleucel, a CD19-directed genetically modified autologous T cell immunotherapy, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

Approval was based on ZUMA-2 (NCT02601313), an open-label, multicenter, single-arm trial of 74 patients with relapsed or refractory MCL who had previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody, and a Bruton tyrosine kinase inhibitor. Patients received a single infusion of brexucabtagene autoleucel following completion of lymphodepleting chemotherapy. The primary efficacy outcome measure was objective response rate (ORR) per Lugano [2014] criteria as assessed by an independent review committee.

https://www.fda.gov/drugs/fda-approves-brexucabtagene-autoleucel-relapsed-or-refractory-mantle-cell-lymphoma

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

KTE-X19 CAR T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma

M. Wang, J. Munoz, A. Goy, F.L. Locke, C.A. Jacobson, B.T. Hill, J.M. Timmerman, H. Holmes, S. Jaglowski, I.W. Flinn, P.A. McSweeney, D.B. Miklos, J.M. Pagel, M.-J. Kersten, N. Milpied, H. Fung, M.S. Topp, R. Houot, A. Beitinjaneh, W. Peng, L. Zheng, J.M. Rossi, R.K. Jain, A.V. Rao, and P.M. Reagan

N Engl J Med 2020;382:1331-42

Agenda

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Module 4: “What Is to Give Light Must Endure the Burning”

13th Annual Oncology Grand Rounds
Acute Myeloid Leukemia
Wednesday, April 21, 2021
12:00 PM – 1:00 PM ET

Ilene Galinsky, NP
Dana-Farber Cancer Institute
Boston, Massachusetts

RTP RESEARCH TO PRACTICE

13th Annual Oncology Grand Rounds
Breast Cancer
Tuesday, April 20, 2021
8:30 AM – 10:00 AM ET

Allie Hershey, MSN, RN, ANP-BC, AOCNP
Dana-Farber Cancer Institute
Boston, Massachusetts

RTP RESEARCH TO PRACTICE

13th Annual Oncology Grand Rounds

Prostate Cancer

Thursday, April 22, 2021

8:30 AM – 10:00 AM ET

Ronald Stein, JD, MSN, NP-C, AOCNP

USC Norris Comprehensive Cancer Center

Los Angeles, California

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Module 4: “What Is to Give Light Must Endure the Burning”

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Ms Zerante: Educating patients about the toxicities associated with CAR T-cell therapy and autologous stem cell transplantation

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Case Presentation – A 69-year-old man and healthcare worker with multiple myeloma who received BCMA-targeted CAR T-cell therapy bb21217

Ms McClanahan

- 2011: Diagnosed with multiple myeloma s/p multiple lines of chemotherapy and SCT
- Bridging therapy with high-dose steroids
  - Bone marrow biopsy: 90% involvement
  - IgA level: 5,000
- Prophylactic anakinra and daily after CAR T infusion due to high risk of CRS
- Clinical trial of BCMA-targeted CAR T-cell therapy bb21217
- Rapid development of Grade 3 CRS, requiring norepinephrine, vasopressin, tocilizumab and dexamethasone with quick improvement
- Currently, one year s/p CAR T-cell therapy and is not receiving myeloma-targeted therapy

Case Presentation – A 77-year-old man with multiple myeloma who received BCMA-targeted CAR T-cell therapy bb21217

Ms Zerante

- PMH: Traumatic injury from an accident 20+ years ago damaging spinal cord and pelvic region
- 2018: Diagnosed with IgG lambda multiple myeloma
- Referred by multiple myeloma specialist after bridging chemotherapy and performance status optimization
- Imaging-guided bone marrow biopsies necessary due to placement of metal rods
- BCMA-targeted CAR T-cell therapy (bb21217)
    - Grade 1 CRS

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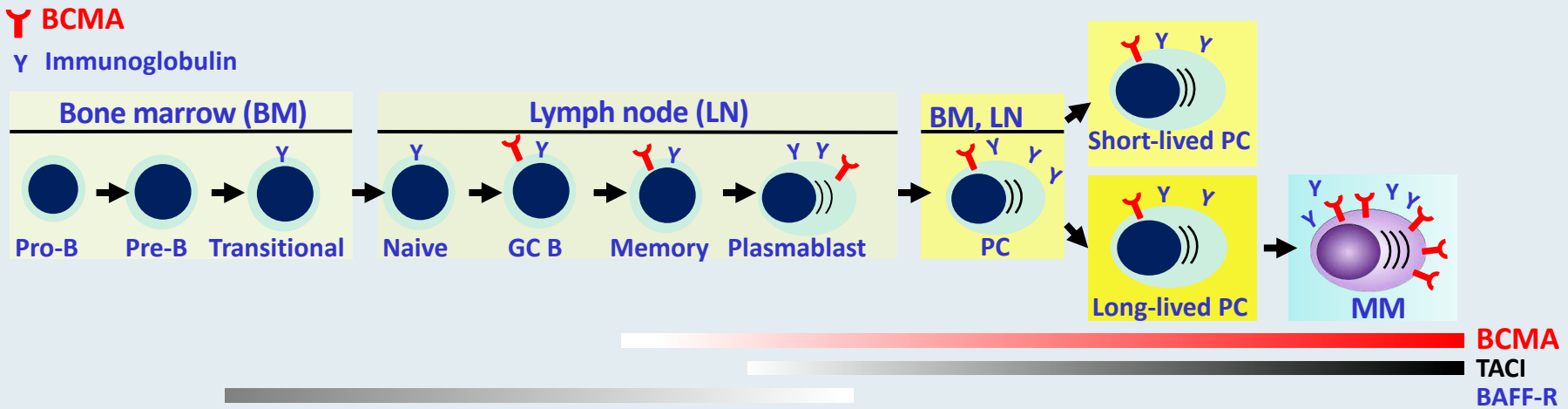
Case Presentation – A 64-year-old man with multiple myeloma who received BCMA-targeted CAR T-cell therapy bb21217 during the COVID-19 pandemic

Ms McClanahan

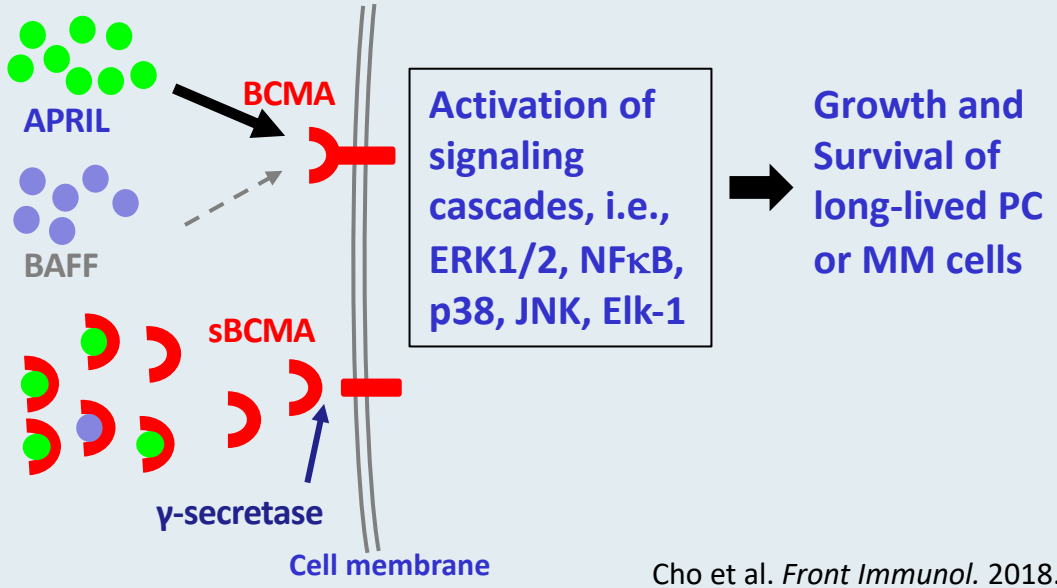
- 2019: Diagnosed with IgG lambda multiple myeloma
- Ixazomib/daratumumab/lenalidomide/dexamethasone → Auto SCT
  - Day 60 PET: PD
- Bridging daratumumab/pomalidomide/dexamethasone
- Clinical trial with BCMA-targeted CAR T-cell therapy bb21217
  - Mild CRS, not requiring tocilizumab or interventions
  - Day 30 restaging: Very good partial response

B-Cell Maturation Antigen (BCMA)
A Promising Target in Multiple Myeloma

A



B



- **BCMA is member of the TNF receptor superfamily**
  Expressed nearly universally on MM cells
  Expression largely restricted to plasma cells and some mature B cells
- **BCMA support survival of long-lived PCs, Ig Class switch and Ab Production**
- **Promotes proliferation, survival and associated with immunosuppressive BM microenvironment**

Cho et al. *Front Immunol.* 2018.

Courtesy of Nikhil C Munshi, MD

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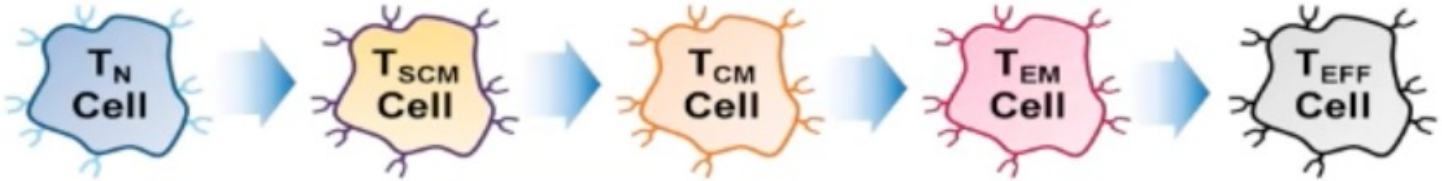
bb21217: Mechanism of Action

- bb21217 uses the same CAR molecule as bb2121,[1] but is cultured with the PI3K inhibitor, bb007, to enrich for T cells displaying a memory-like phenotype
- CAR T cells enriched for this phenotype may persist and function for longer than non-enriched CAR T cells[2]
- Persistence of functional CAR T cells after infusion may be one determinant of duration of response[3]



Memory-like phenotype
T-cell plasticity
Long-lived
Self-renewal

Effector-like phenotype
Terminally differentiated
Short-lived
No self-renewal

- When cultured in the presence of the PI3K inhibitor bb007, donor cells become enriched for memory-like CAR T cells and the percentage of senescent CAR T cells decreases.

Alsina M et al. ASH 2020;Abstract 130.

FDA Approves Idecabtagene Vicleucel for Multiple Myeloma

Press Release – March 26, 2021

"On March 26, 2021, the FDA approved idecabtagene vicleucel for the treatment of adult patients with 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. This is the first FDA-approved cell-based gene therapy for multiple myeloma.

Idecabtagene vicleucel is a BCMA-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell therapy. Each dose is customized using a patient's own T-cells, which are collected and genetically modified, and infused back into the patient.

Efficacy was evaluated in 100 patients who received idecabtagene vicleucel in the dose range of 300 to 460 x 106 CAR-positive T cells. Efficacy was established based on overall response rate (ORR), complete response (CR) rate, and duration of response (DOR), as evaluated by an Independent Response committee using the International Myeloma Working Group Uniform Response Criteria for Multiple Myeloma."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-idecabtagene-vicleucel-multiple-myeloma

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N Engl J Med 2021;384(8):705-16

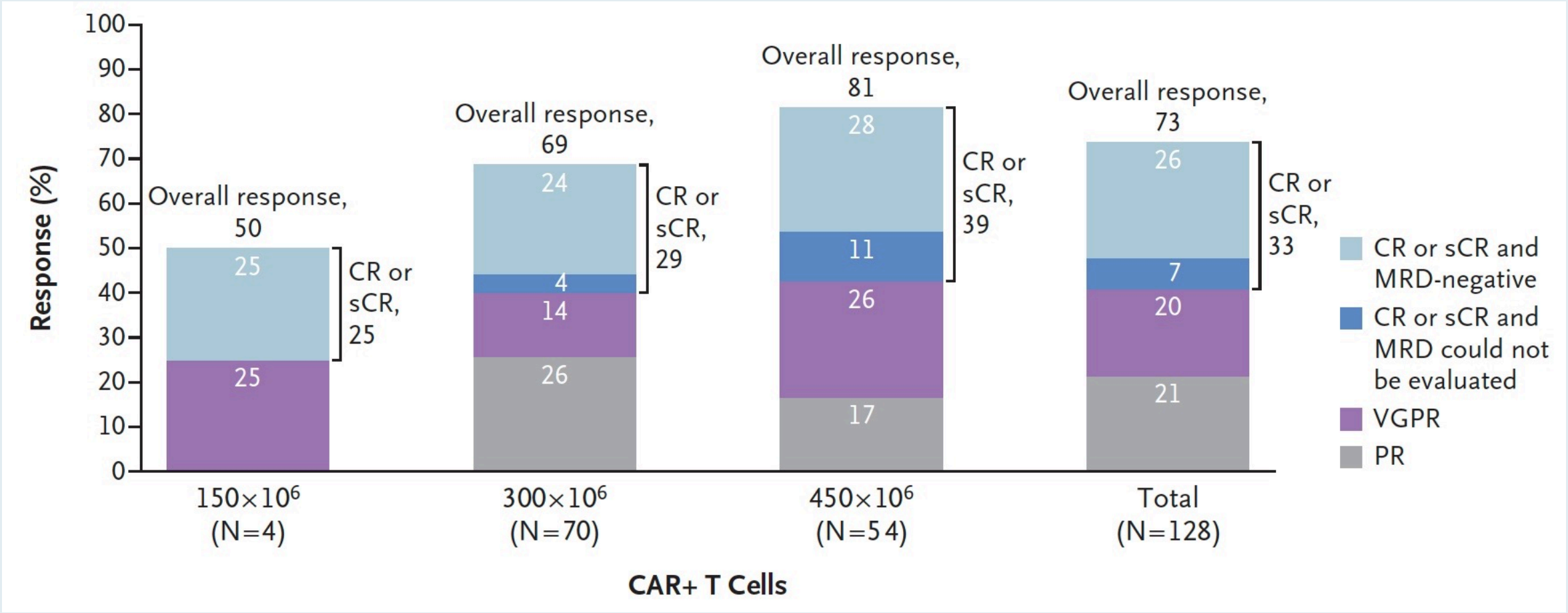
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma

Nikhil C. Munshi, M.D., Larry D. Anderson, Jr., M.D., Ph.D., Nina Shah, M.D., Deepu Madduri, M.D., Jesús Berdeja, M.D., Sagar Lonial, M.D., Noopur Raje, M.D., Yi Lin, M.D., Ph.D., David Siegel, M.D., Ph.D., Albert Oriol, M.D., Philippe Moreau, M.D., Ibrahim Yakoub-Agha, M.D., Ph.D., Michel Delforge, M.D., Michele Cavo, M.D., Hermann Einsele, M.D., Hartmut Goldschmidt, M.D., Katja Weisel, M.D., Alessandro Rambaldi, M.D., Donna Reece, M.D., Fabio Petrocca, M.D., Monica Massaro, M.P.H., Jamie N. Connarn, Ph.D., Shari Kaiser, Ph.D., Payal Patel, Ph.D., Liping Huang, Ph.D., Timothy B. Campbell, M.D., Ph.D., Kristen Hege, M.D., and Jesús San-Miguel, M.D., Ph.D.

KarMMa: Tumor Response, Overall and According to Target Dose



Munshi NC et al. *N Engl J Med* 2021;384(8):705-16.

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KarMMa: Select Adverse Events

Variable	Any Grade	Grade 3 or 4
	no. of patients (%)	
Adverse event*		
Any	128 (100)	127 (99)
Hematologic		
Neutropenia	117 (91)	114 (89)
Anemia	89 (70)	77 (60)
Thrombocytopenia	81 (63)	67 (52)
Leukopenia	54 (42)	50 (39)
Lymphopenia	35 (27)	34 (27)
Febrile neutropenia	21 (16)	20 (16)
Cytokine release syndrome†	107 (84)	7 (5)
Neurotoxic effect‡	23 (18)	4 (3)

Munshi NC et al. *N Engl J Med* 2021;384(8):705-16.

Investigational BCMA-Directed CAR-T Study Designs

Similar approach in the studies:

- R/R MM
- Steady state T cell collection
- CY/FLU lymphodepletion
- Single infusion

CARTITUDE-1: Phase 1b/2 Study Design

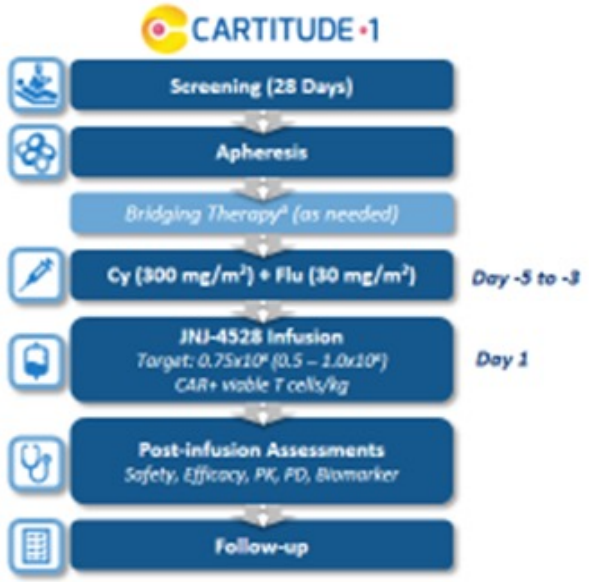
Primary Objectives

- **Phase 1b**: Characterize safety and confirm phase 2 dose as informed by the LEGEND-2 study
- **Phase 2**: Evaluate efficacy of JNJ-4528

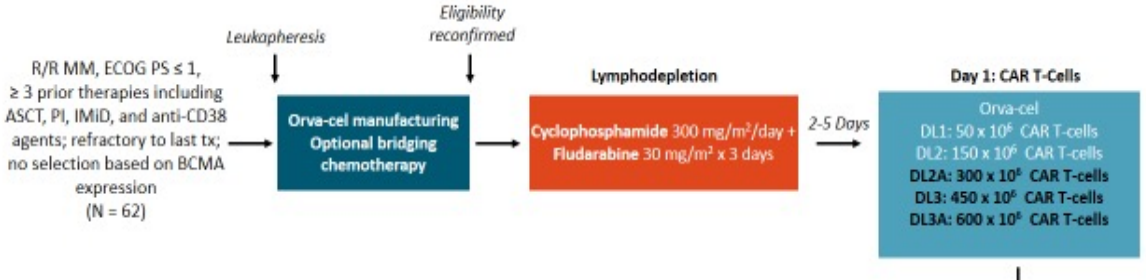
Key Eligibility Criteria

- Progressive MM per IMWG criteria
- ECOG PS ≤1
- Measurable disease
- Received ≥3 prior therapies or double refractory
- Prior PI, IMiD, anti-CD38 therapy

- Median administered dose = 0.73×10^6 ($0.52 - 0.89 \times 10^6$) CAR+ viable T cells/kg
- Median follow-up at data cut-off = 6 mo (3 – 14)



EVOLVE: Study Design



- Primary objectives (phase I): safety and tolerability (DLTs, AEs) and RP2D
- Secondary objectives (phase I): orva-cel pharmacokinetics, preliminary antitumor activity

Mailankody. ASCO 2020. Abstr 8504.

Courtesy of Edward A Stadtmauer, MD

ASCO 2020: 3 BCMA CAR-T Studies

Characteristics Summary

	KarMMa: idecabtagene vicleucel (n = 128)	EVOLVE: orvacabtagene autoleucel (n = 62)	CARTITUDE-1: JNJ-4528 (n = 29)
Age	61 (33-78)	61 (33-77)	60 (50-75)
High risk cytogenetics, %	35	41*	27
Tumor burden in BM, %	>50% PC = 51	—	≥60% PC = 24
Extramedullary PCs, %	39	23	10
Median prior line of therapy	6 (3-16)	6 (3-18)	5 (3-18)
Triple refractory, %	84	94	86
Bridging therapy, %	88	63	79
Unique properties	Human BCMA, 4-1BB, CD3z	Modified spacer, CD4: CD8 enriched for CM	Median cell dose 0.72x106 cells/kg 2 BCMA single chain antibodies

* Included +1q21

Approved 3/26/2021

Patel K. ASCO 2020 Discussant

ASCO 2020: 3 BCMA CAR-T Studies

Safety

	KarMMa	EVOLVE	CARTITUDE-1
ANC ≥G3, % ⬇	89	90	100
plts ≥G3, % ⬇	52	47	69
CRS: all, ≥G3, %	84, 6	89, 3	93, 7
Med. time to CRS, duration, days	1 (1-12) 5 (1-63)	2 (1-4) 4 (1-10)	7 (2-12) 4 (2-64)
ICANS: all, ≥G3, %	17, 3	13, 3	10, 3
HLH/MAS, %	—	5	? 7 (lfts)
Infections: all, ≥G3 %	69, —	40, 13	—, 19
Toci/steroid/ anakinra use, %	52/15/0	76/52/23	79/21/21

? This was not listed at MAS/HLH, I am just speculating → could this have been early MAS

Efficacy

	KarMMa (n = 128)	EVOLVE (n = 62)	CARTITUDE-1 (n = 29)
ORR, %	73 (66-81)	92	100
sCR/CR, %	33	36	86
MRD neg ≥10^{-5}, % (of evaluable)	94	84	81
PFS, DoR, months	8.8/10.7	NR*	NR**
Screened Apheresed Treated	150 140 128	—	35 35 29

* 300 x 10^6 cell dose cohort (lowest) = PFS 9.3 months, other med F/U = 8.8 and 2.3 month
** 9 mo PFS = 86%

Patel K. ASCO 2020 Discussant

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Perspectives on oncology life

Ms McClanahan

Ms Glennie

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Agenda

Module 1: CD19-Targeted CAR T-Cell Therapy in CLL/Lymphomas

- **Case 1 (Ms Glennie):** A 66-year-old man with relapsed DLBCL who received axicabtagene ciloleucel
- **Case 2 (Ms Zerante):** A 62-year-old woman with relapsed CLL who received lisocabtagene maraleucel
- **Case 3 (Ms McClanahan):** A 63-year-old man from the Netherlands with high-grade DLBCL who received axicabtagene ciloleucel

Module 2: COVID-19, CAR T-Cell Therapy and Clinical Oncology

Module 3: BCMA-Targeted CAR T-Cell Therapy in Multiple Myeloma

- **Case 4 (Ms McClanahan):** A 69-year-old man who received BCMA-targeted CAR T-cell therapy bb21217
- **Case 5 (Ms Zerante):** A 77-year-old man who received BCMA-targeted CAR T-cell therapy bb21217
- **Case 6 (Ms McClanahan):** A 64-year-old man who received BCMA-targeted CAR T-cell therapy bb21217 during the COVID-19 pandemic

Module 4: “What Is to Give Light Must Endure the Burning”

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13th Annual Oncology Grand Rounds

Hodgkin and Non-Hodgkin Lymphomas

Thursday, April 22, 2021
5:00 PM – 6:30 PM ET

Mollie Moran, APRN-CNP, AOCNP

Gynecologic Cancers

Tuesday, April 27, 2021
5:00 PM – 6:30 PM ET

Thomas J Herzog, MD

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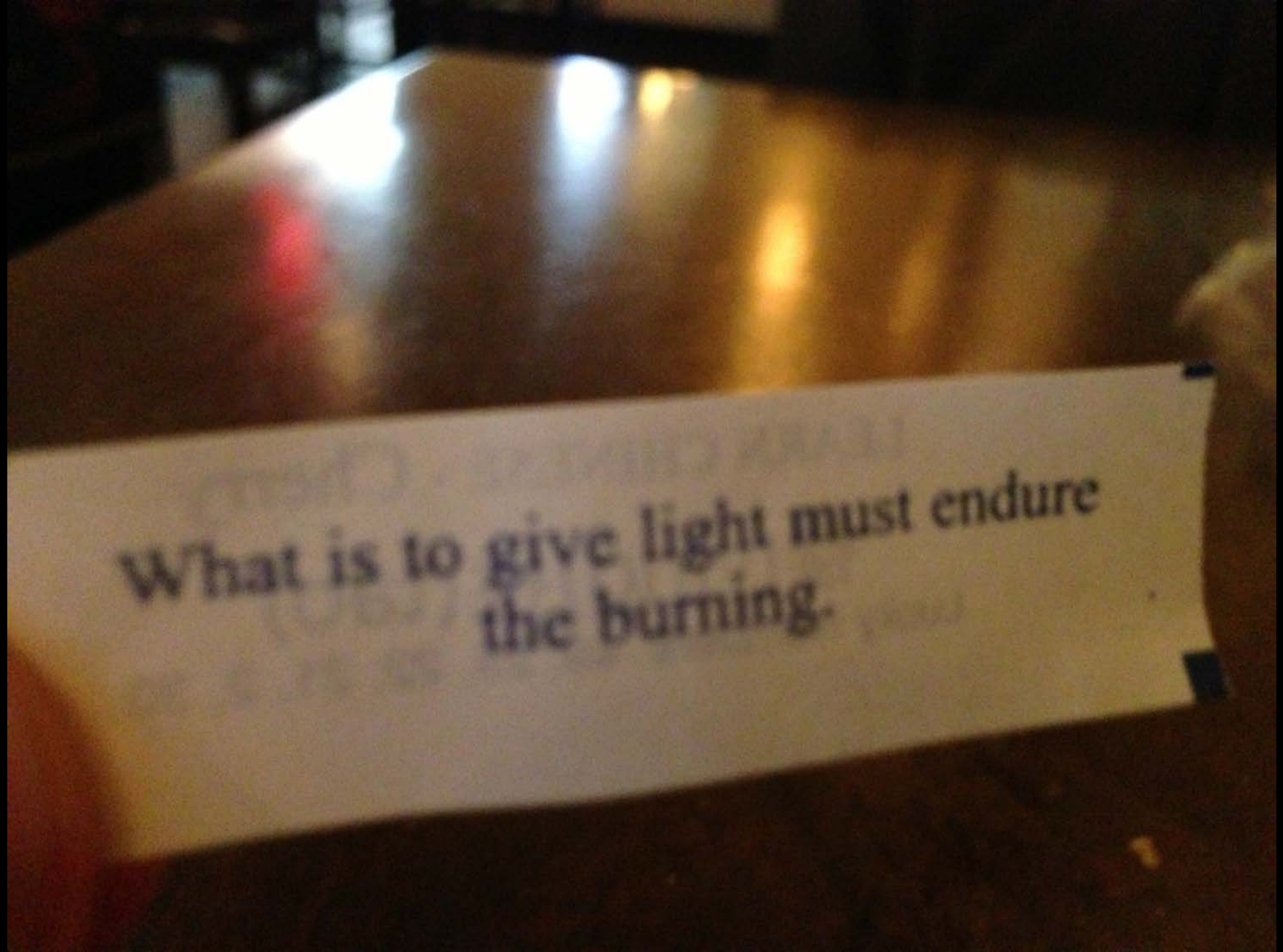
What is to give light must endure
the burning.


Elizabeth Zerante MS, AGACNP-BC


Alli McClanahan, MSN, APRN, ANP-BC


Sonia Glennie, ARNP MSN OCN

Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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