13th Annual Oncology Grand Rounds

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

Hodgkin and Non-Hodgkin Lymphomas

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

Medical Oncologists

Stephen M Ansell, MD, PhD
Carla Casulo, MD
John P Leonard, MD

Oncology Nurse Practitioners

Jacklyn Gideon, MSN, AGPCNP-BC
Robin Klebig, APRN, CNP, AOCNP
Mollie Moran, APRN-CNP, AOCNP

Moderator

Neil Love, MD

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Medical Oncologists

Stephen M Ansell, MD, PhD
Professor of Medicine
Chair, Lymphoma Group
Mayo Clinic
Rochester, Minnesota

Carla Casulo, MD
Associate Professor of Medicine
Division of Hematology/Oncology
Director, Hematology/Oncology
Fellowship Program
University of Rochester
Wilmot Cancer Institute
New York, New York

John P Leonard, MD
Richard T Silver Distinguished Professor of
Hematology and Medical Oncology
Senior Associate Dean for Innovation
and Initiatives
Executive Vice Chair, Joan and Sanford I Weill
Department of Medicine
Weill Cornell Medicine
New York, New York

Oncology Nurse Practitioners

Jacklyn Gideon, MSN, AGPCNP-BC
Advanced Practice Provider
Lead Apheresis APP
Hematopoietic Cellular Therapy Program
Section of Hematology/Oncology
The University of Chicago Medicine and
Biological Sciences
Chicago, Illinois

Robin Klebig, APRN, CNP, AOCNP
Nurse Practitioner
Assistant Professor of Medicine
Division of Hematology
Mayo Clinic
Rochester, Minnesota

Mollie Moran, APRN-CNP, AOCNP
The James Cancer Hospital and Solove
Research Institute
The Ohio State University

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Commercial Support

This activity is supported by educational grants from Bristol-Myers Squibb Company, Epizyme Inc, Incyte Corporation, Novartis and Seagen Inc.

Dr Love — Disclosures

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Dr Ansell — Disclosures

Contracted Research to Institution	ADC Therapeutics SA, Affimed, Bristol-Myers Squibb Company, Regeneron Pharmaceuticals Inc, Seagen Inc, Takeda Oncology, Trillium Therapeutics Inc

Dr Casulo — Disclosures

No relevant conflicts of interest to disclose.

Dr Leonard — Disclosures

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Contracted Research	Epizyme Inc, Genentech Foundation, Janssen Biotech Inc

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Ms Gideon — Disclosures

No relevant conflicts of interest to disclose.

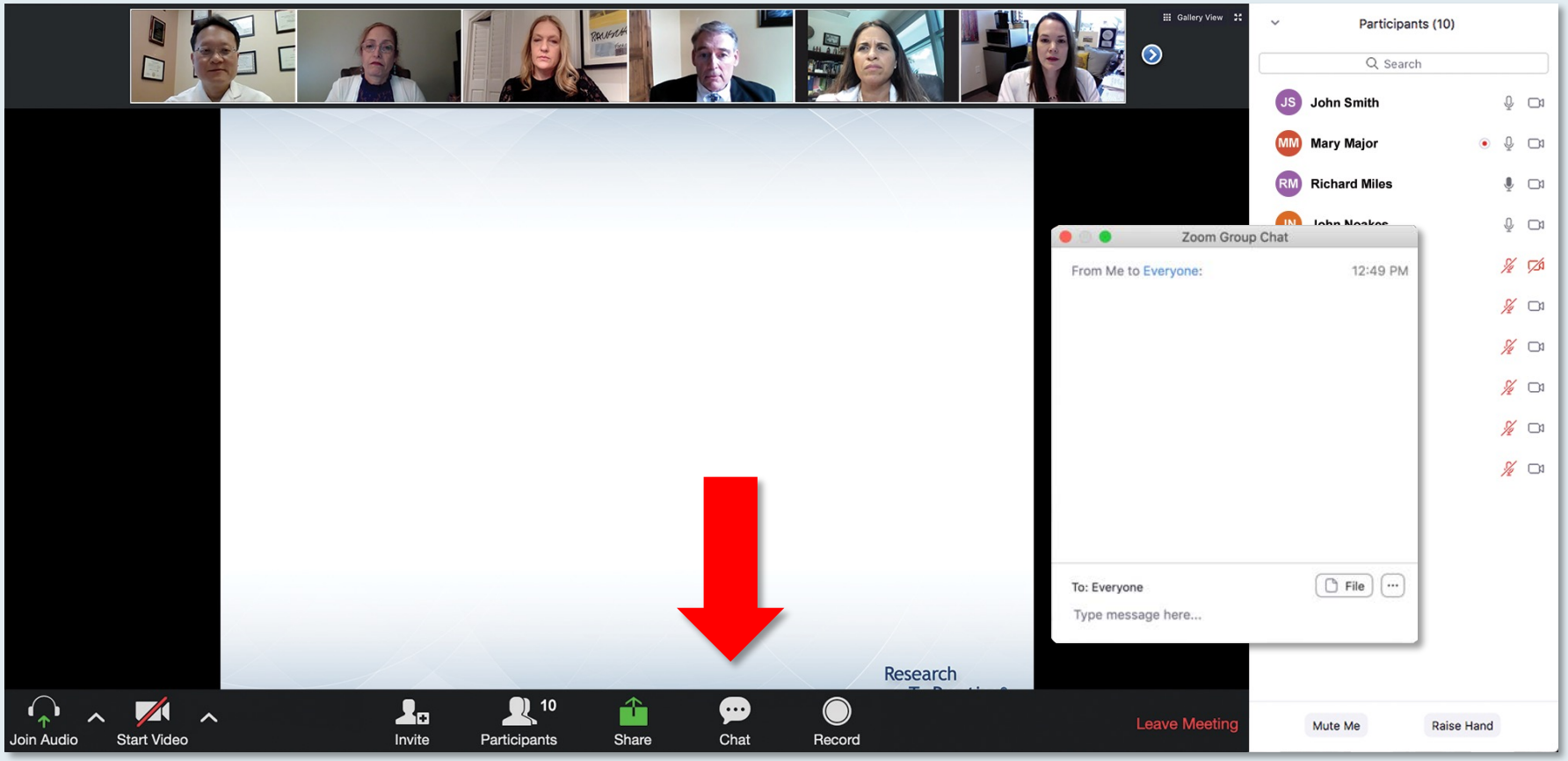
Ms Klebig — Disclosures

No relevant conflicts of interest to disclose.

Ms Moran — 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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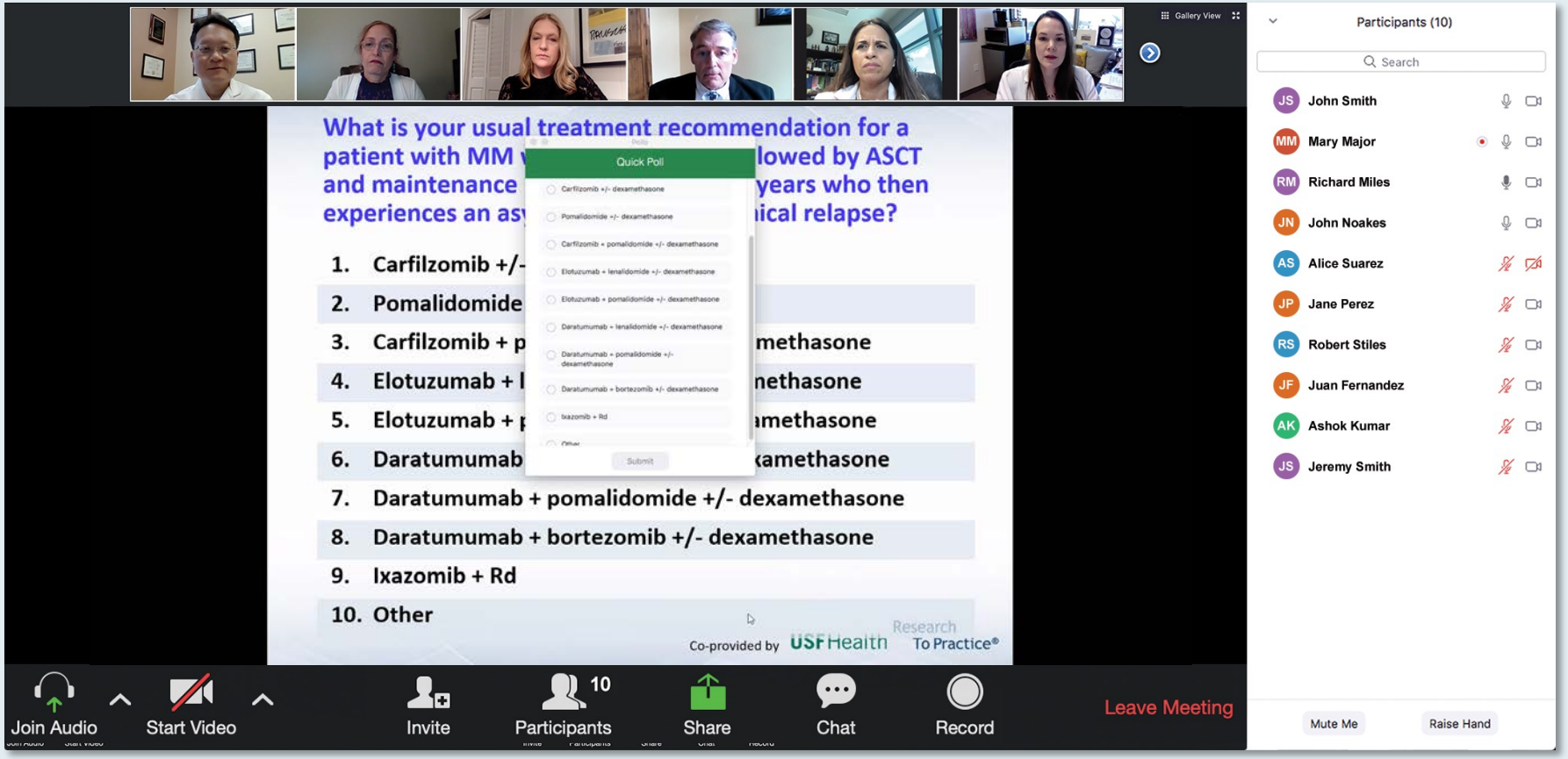
Familiarizing Yourself with the Zoom Interface

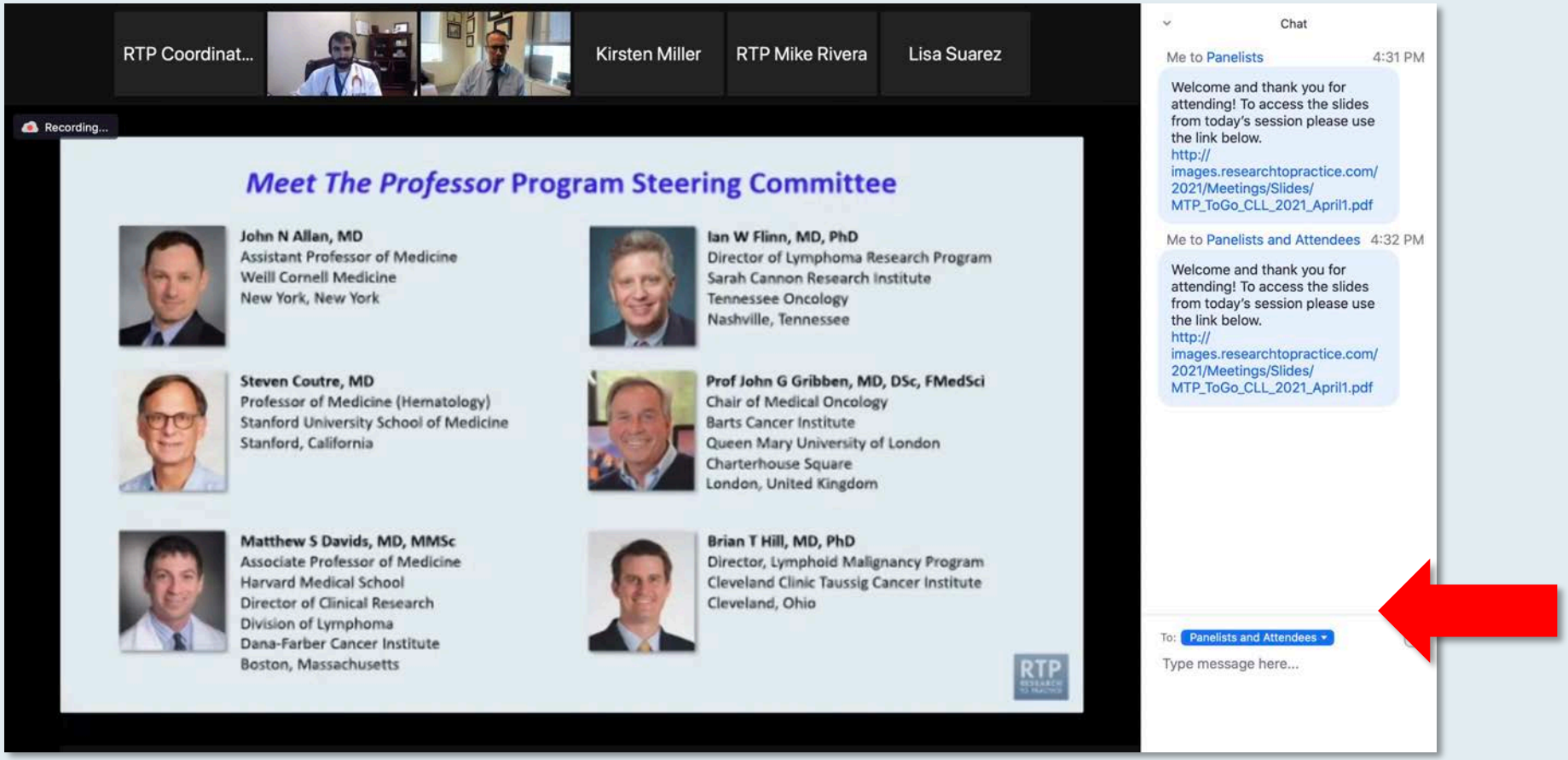
How to answer poll questions



When a poll question pops up, click your answer choice from the available options.

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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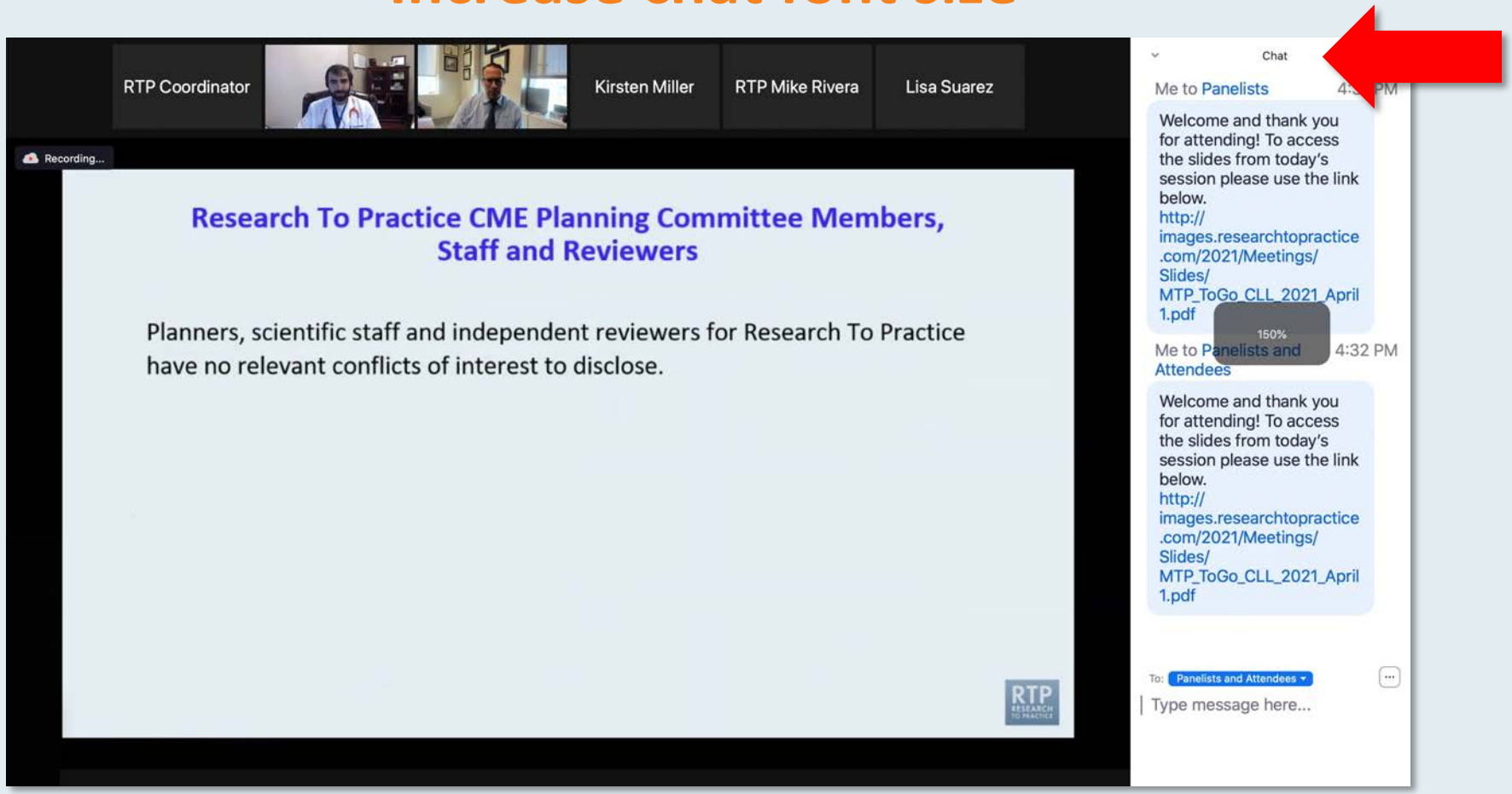
Familiarizing Yourself with the Zoom Interface

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

Key Presentations on Non-Hodgkin and Hodgkin Lymphomas from the 2020 ASH Annual Meeting

DR LAURIE SEHN

BC CANCER CENTRE FOR LYMPHOID CANCER

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Spotify

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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
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4:45 PM – 5:45 PM ET

Prostate Cancer
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8:30 AM – 10:00 AM ET

Chimeric Antigen Receptor T-Cell Therapy
Thursday, April 29, 2021
5:00 PM – 6:30 PM 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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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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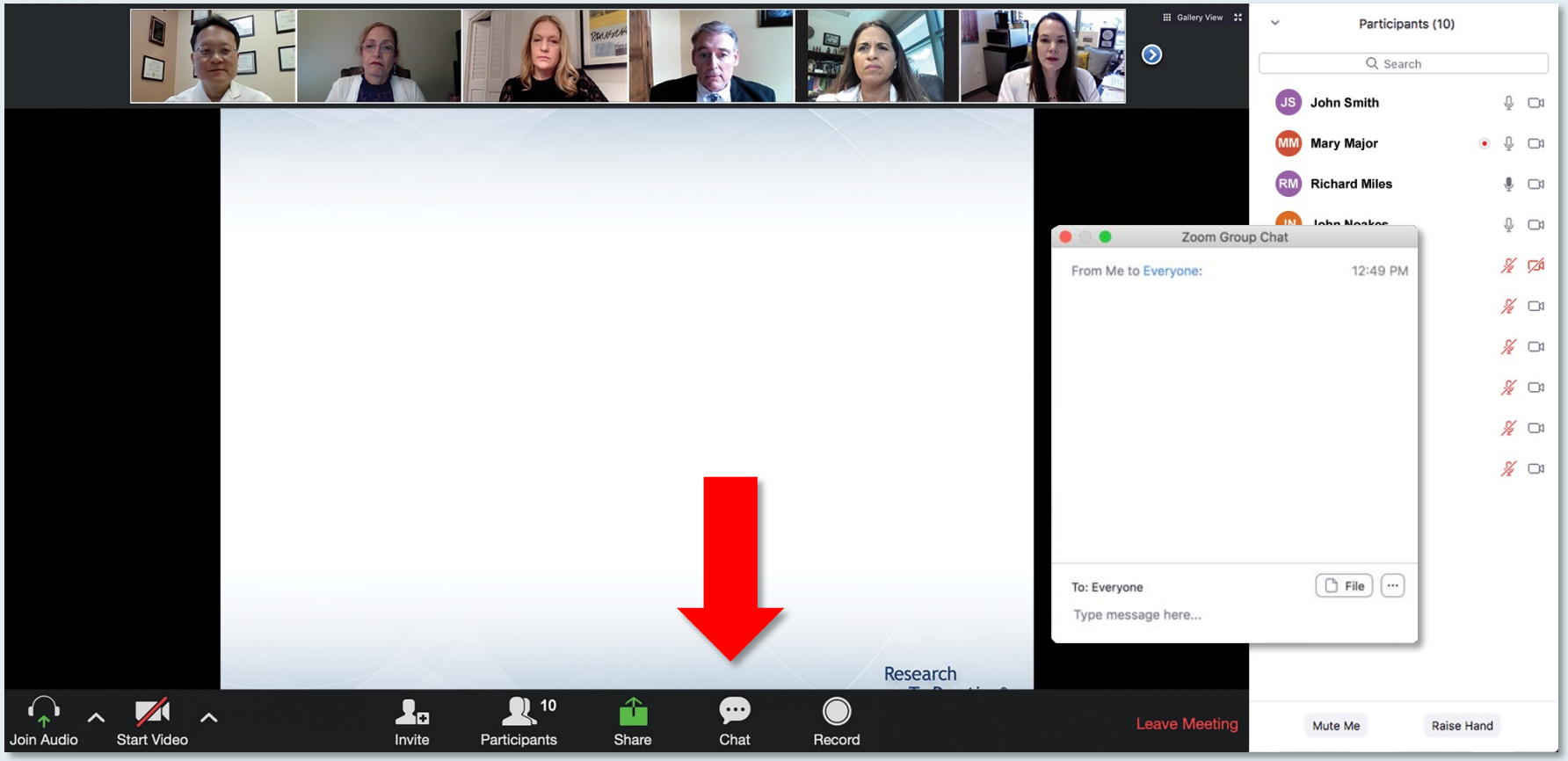

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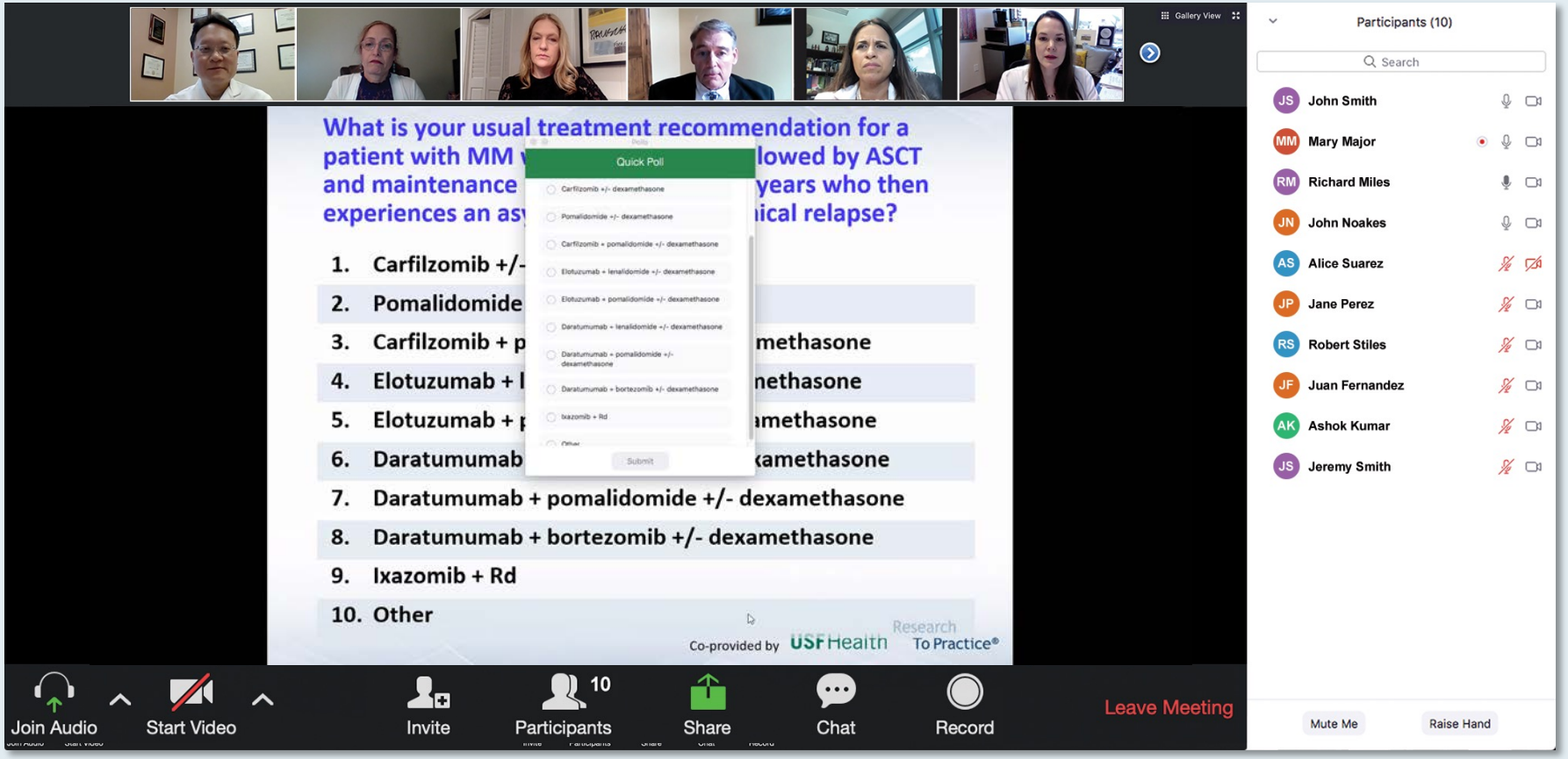

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Medical Oncologists

Jeremy Abramson, MD
Director, Center for Lymphoma
Massachusetts General Hospital
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Carey K Anders, MD
Professor of Medicine
Medical Director of the Duke Center of Brain and Spine Metastases
Duke Cancer Institute
Durham, North Carolina

Stephen M Ansell, MD, PhD
Professor of Medicine
Chair, Lymphoma Group
Mayo Clinic
Rochester, Minnesota

Johanna Bendell, MD
Chief Development Officer
Director, Drug Development Unit Nashville
Sarah Cannon Research Institute
Tennessee Oncology
Nashville, Tennessee

Carla Casulo, MD
Associate Professor of Medicine
Division of Hematology/Oncology
Director, Hematology/Oncology Fellowship Program
University of Rochester
Wilmot Cancer Institute
New York, New York

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Medical Oncologists

Daniel Catenacci, MD
Associate Professor, Department of Medicine
Section of Hematology and Oncology
Director, Interdisciplinary Gastrointestinal Oncology Program
Assistant Director, Translational Research
Comprehensive Cancer Center
The University of Chicago Medical Center and Biological Sciences
Chicago, Illinois

Robert L Coleman, MD
Chief Scientific Officer
US Oncology Research
Gynecologic Oncology
The Woodlands, Texas

Courtney D DiNardo, MD, MSCE
Associate Professor, Department of Leukemia
Division of Cancer Medicine
The University of Texas MD Anderson Cancer Center
Houston, Texas

Elisabeth I Heath, MD
Associate Center Director, Translational Sciences
Chair, Genitourinary Oncology Multidisciplinary Team
Professor of Oncology and Medicine
Hartmann Endowed Chair for Prostate Cancer Research
Director, Prostate Cancer Research
Karmanos Cancer Institute
Wayne State University School of Medicine
Detroit, Michigan

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Medical Oncologists

Thomas J Herzog, MD
Paul and Carolyn Flory Professor
Deputy Director, University of Cincinnati Cancer Center
Vice-Chair, Quality and Safety
Department of Obstetrics and Gynecology
University of Cincinnati Medical Center
Associate Director, GOG Partners
Cincinnati, Ohio

John V Heymach, MD, PhD
Professor and Chair
Thoracic/Head and Neck Medical Oncology
The University of Texas MD Anderson Cancer Center
Houston, Texas

Brian T Hill, MD, PhD
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

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

Shaji K Kumar, MD
Mark and Judy Mullins Professor of Hematological Malignancies
Consultant, Division of Hematology
Professor of Medicine
Mayo Clinic
Rochester, Minnesota

John P Leonard, MD
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Senior Associate Dean for Innovation and Initiatives
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Weill Cornell Medicine
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Medical Oncologists

Sagar Lonial, MD
Chair and Professor
Department of Hematology and Medical Oncology
Anne and Bernard Gray Family Chair in Cancer
Chief Medical Officer
Winship Cancer Institute
Emory University School of Medicine
Atlanta, Georgia

Kathy D Miller, MD
Ballvé-Lantero Professor
Division of Hematology/Oncology
Associate Director for Clinical Research
The Indiana University Melvin and Bren Simon Cancer Center
Indianapolis, Indiana

John M Pagel, MD, PhD
Chief of Hematologic Malignancies Program
Center for Blood Disorders and Stem Cell Transplantation
Swedish Cancer Institute
Seattle, Washington

Paul K Paik, MD
Associate Attending Physician
Clinical Director, Thoracic Oncology Service
Memorial Sloan Kettering Cancer Center
New York, New York

Daniel P Petrylak, MD
Professor of Internal Medicine
(Medical Oncology) and Urology
Yale School of Medicine
New Haven, Connecticut

Zofia Piotrowska, MD, MHS
Assistant Professor of Medicine
Harvard Medical School
Massachusetts General Hospital
Boston, Massachusetts

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Medical Oncologists

Noopur Raje, MD
Director, Center for Multiple Myeloma
Massachusetts General Hospital Cancer Center
Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Paul G Richardson, MD
Clinical Program Leader and Director of Clinical Research
Jerome Lipper Multiple Myeloma Center
Dana-Farber Cancer Institute
RJ Corman Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Charles J Ryan, MD
Professor of Medicine
BJ Kennedy Chair in Clinical Medical Oncology
Director, Division of Hematology, Oncology and Transplantation
University of Minnesota
Minneapolis, Minnesota

A Oliver Sartor, MD
CE and Bernadine Laborde Professor for Cancer Research
Medical Director, Tulane Cancer Center
Assistant Dean for Oncology
Tulane Medical School
New Orleans, Louisiana

Eytan M Stein, MD
Assistant Attending Physician
Director, Program for Drug Development in Leukemia
Leukemia Service, Department of Medicine
Memorial Sloan Kettering Cancer Center
New York, New York

Mary-Ellen Taplin, MD
Professor of Medicine
Harvard School of Medicine
Dana-Farber Cancer Institute
Boston, Massachusetts

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Medical Oncologists

Krishnansu S Tewari, MD
Professor and Division Director
Division of Gynecologic Oncology
University of California, Irvine
Irvine, California

Jennifer Woyach, MD
Professor
Division of Hematology
Department of Internal Medicine
The Ohio State University Comprehensive Cancer Center
Columbus, Ohio

Sara M Tolaney, MD, MPH
Associate Director
Susan F Smith Center for Women's Cancers
Director of Clinical Trials, Breast Oncology
Director of Breast Immunotherapy Clinical Research
Senior Physician
Breast Oncology Program
Dana-Farber Cancer Institute
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

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Oncology Nurse Practitioners

Paula J Anastasia, MN, RN, AOCN
GYN Oncology Advanced Practice Nurse
University of California, Los Angeles
Los Angeles, California

Courtney Arn, CNP
The James Cancer Hospital and
Solove Research Institute
The Ohio State University
Columbus, Ohio

Monica Averia, MSN, AOCNP, NP-C
Oncology Nurse Practitioner
USC Norris Cancer Center
Los Angeles, California

Lesley Camille Ballance, MSN, FNP-BC
Sarah Cannon Center for Blood Cancer
Tennessee Oncology
Nashville, Tennessee

Kristen E Battiato, AGNP-C
Advanced Practice Providers
Memorial Sloan Kettering Cancer Center
New York, New York

Kathy D Burns, RN, MSN, AGACNP-BC, OCN
GU Medical Oncology
City of Hope Comprehensive Cancer Center
Duarte, California

Gretchen Santos Fulgencio, MSN, FNP-BC
University of California, San Francisco
Berkeley, California

Ilene Galinsky, NP
Senior Adult Leukemia Program Research
Nurse Practitioner
Dana-Farber Cancer Institute
Boston, Massachusetts

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Jacklyn Gideon, MSN, AGPCNP-BC
Advanced Practice Provider
Lead Apheresis APP
Hematopoietic Cellular Therapy Program
Section of Hematology/Oncology
The University of Chicago Medicine and
Biological Sciences
Chicago, Illinois

Charise Gleason, MSN, NP-C, AOCNP
Advanced Practice Provider Chief
Winship Cancer Institute of Emory University
Adjunct Faculty, Nell Hodgson Woodruff
School of Nursing
Atlanta, Georgia

Sonia Glennie, ARNP, MSN, OCN
Swedish Cancer Institute Center for
Blood Disorders
Seattle, Washington

Kelly EH Goodwin, MSN, RN, ANP-BC
Thoracic Cancer Center
Massachusetts General Hospital
Boston, Massachusetts

Allie Hershey, MSN, RN, ANP-BC, AOCNP
Oncology Nurse Practitioner, Breast Oncology
Susan F Smith Center for Women's Cancers
Dana-Farber Cancer Institute
Boston, Massachusetts

Corinne Hoffman, MS, APRN-CNP, AOCNP
Nurse Practitioner, Hematology
The James Comprehensive Cancer Center
The Ohio State University Wexner Medical Center
Columbus, Ohio

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Oncology Nurse Practitioners

Robin Klebig, APRN, CNP, AOCNP
Nurse Practitioner
Assistant Professor of Medicine
Division of Hematology
Mayo Clinic
Rochester, Minnesota

Kelly Leonard, MSN, FNP-BC
Family Nurse Practitioner
Dana-Farber Cancer Institute
Boston, Massachusetts

Patricia Mangan, RN, MSN, CRNP, APN, BC
Nurse Lead, Hematologic Malignancies and
Stem Cell Transplant Programs
Abramson Cancer Center
University of Pennsylvania
Philadelphia, Pennsylvania

Brenda Martone, MSN, NP-BC, AOCNP
Northwestern Medicine
Northwestern Memorial Hospital
Chicago, Illinois

Alli McClanahan, MSN, APRN, ANP-BC
Nurse Practitioner
Division of Hematology
Mayo Clinic
Rochester, Minnesota

Jessica Mitchell, APRN, CNP, MPH
Assistant Professor of Oncology
Mayo Clinic College of Medicine and Science
Rochester, Minnesota

Mollie Moran, APRN-CNP, AOCNP
The James Cancer Hospital and Solove
Research Institute
The Ohio State University
Columbus, Ohio

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Oncology Nurse Practitioners

Tara Plues, APRN, MSN
Hematology and Medical Oncology
Cleveland Clinic
Cleveland, Ohio

Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC
Nurse Practitioner
UAMS Division of Gynecologic Oncology
University of Arkansas for Medical Sciences
Little Rock, Arkansas

Tiffany A Richards, PhD, ANP-BC, AOCNP
Nurse Practitioner
Department of Lymphoma/Myeloma
The University of Texas
MD Anderson Cancer Center
Houston, Texas

Ronald Stein, JD, MSN, NP-C, AOCNP
Clinical Instructor of Medicine
USC Norris Comprehensive Cancer Center
Los Angeles, California

Victoria Sherry, DNP, CRNP, AOCNP
Oncology Nurse Practitioner for Thoracic Malignancies
Abramson Cancer Center
Perelman Center for Advanced Medicine
University of Pennsylvania Medical Center
Faculty, University of Pennsylvania School of Nursing
Philadelphia, Pennsylvania

Elizabeth Zerante, MS, AGACNP-BC
APN Inpatient Hematopoietic Cellular Therapy Service
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 GYN 5:00 PM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM CAR-T 5:00 PM	30

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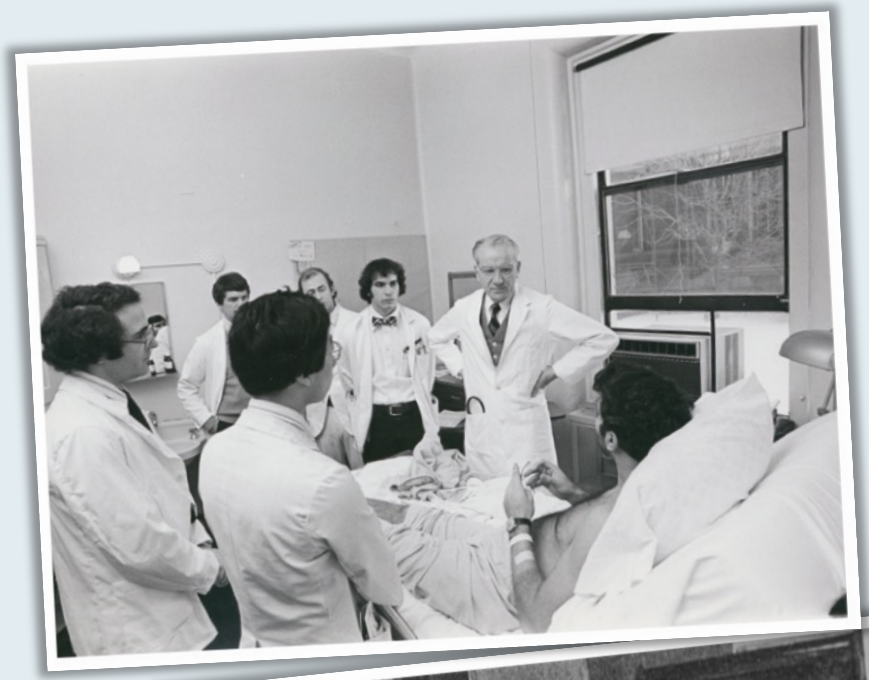

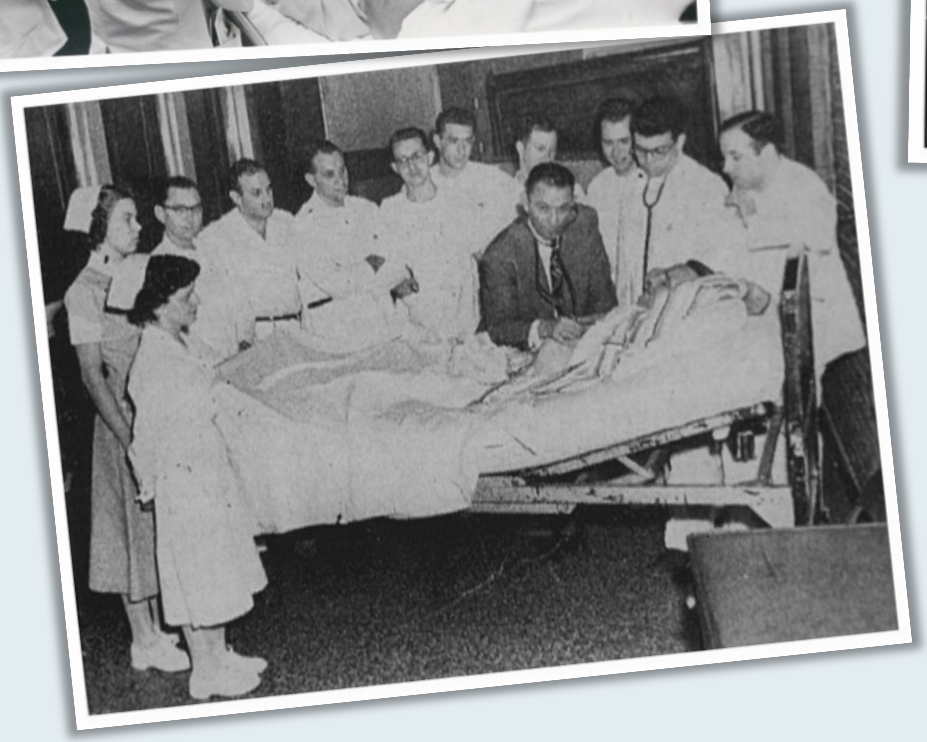


The Birmingham News

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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13th Annual Oncology Grand Rounds

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

Hodgkin and Non-Hodgkin Lymphomas

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

Medical Oncologists

Stephen M Ansell, MD, PhD
Carla Casulo, MD
John P Leonard, MD

Oncology Nurse Practitioners

Jacklyn Gideon, MSN, AGPCNP-BC
Robin Klebig, APRN, CNP, AOCNP
Mollie Moran, APRN-CNP, AOCNP

Moderator

Neil Love, MD

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Jacklyn Gideon, MSN, AGPCNP-BC


Robin Klebig, APRN, CNP, AOCNP


Mollie Moran, APRN-CNP, AOCNP

Agenda

Case 1 (Ms Moran): A 27-year-old woman with Hodgkin lymphoma

Case 2 (Ms Klebig): A 76-year-old man with newly diagnosed follicular lymphoma

Case 3 (Ms Klebig): An 83-year-old woman with relapsed DLBCL

Case 4 (Ms Gideon): A 66-year-old woman with relapsed DLBCL

Case 5 (Ms Gideon): A 70-year-old man with relapsed mantle cell lymphoma

Communicating bad news

Robin Klebig, APRN, CNP, AOCNP

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Case Presentation – A 27-year-old woman with Hodgkin lymphoma (Part 1)

Ms Moran

- Patient notices lumps in her neck, feels “run down”
- Antibiotics for presumed infection are not effective
- Biopsy of lymph nodes in her neck → Stage II classical Hodgkin lymphoma
  - Bulky bilateral neck, supraclavicular, axillary lymphadenopathy

Case Presentation – A 27-year-old woman with Hodgkin lymphoma (Part 2)

Ms Moran

- Patient notices lumps in her neck, feels “run down”
- Antibiotics for presumed infection are not effective
- Biopsy of lymph nodes in her neck → Stage II classical Hodgkin lymphoma
  - Bulky bilateral nodes in neck, supraclavicular, axillary
- ***ABVD x 6 – “cruised right through it”***
  - ***End of therapy PET: residual disease in the mediastinum biopsy-proven HL***

Case Presentation – A 27-year-old woman with Hodgkin lymphoma (Part 3)

Ms Moran

- Patient notices lumps in her neck, feels “run down”
- Antibiotics for presumed infection are not effective
- Biopsy of lymph nodes in her neck → Stage II classical Hodgkin lymphoma
  - Bulky bilateral nodes in neck, supraclavicular, axillary
- ABVD x 6 – “cruised right through it”
  - End of therapy PET: residual disease in the mediastinum biopsy-proven HL
- ***Currently, on maintenance brentuximab vedotin (mild peripheral neuropathy)***

Patient education regarding brentuximab vedotin

Robin Klebig, APRN, CNP, AOCNP

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Based on the results of the Phase III ECHELON-1 trial, which of the following regimens resulted in a progression-free survival advantage over standard ABVD as first-line therapy for patients with Stage III or IV classical Hodgkin lymphoma (HL)?

1. ABVD + bendamustine
2. ABVD + nivolumab
3. AVD + brentuximab vedotin
4. Brentuximab vedotin + nivolumab
5. I don’t know

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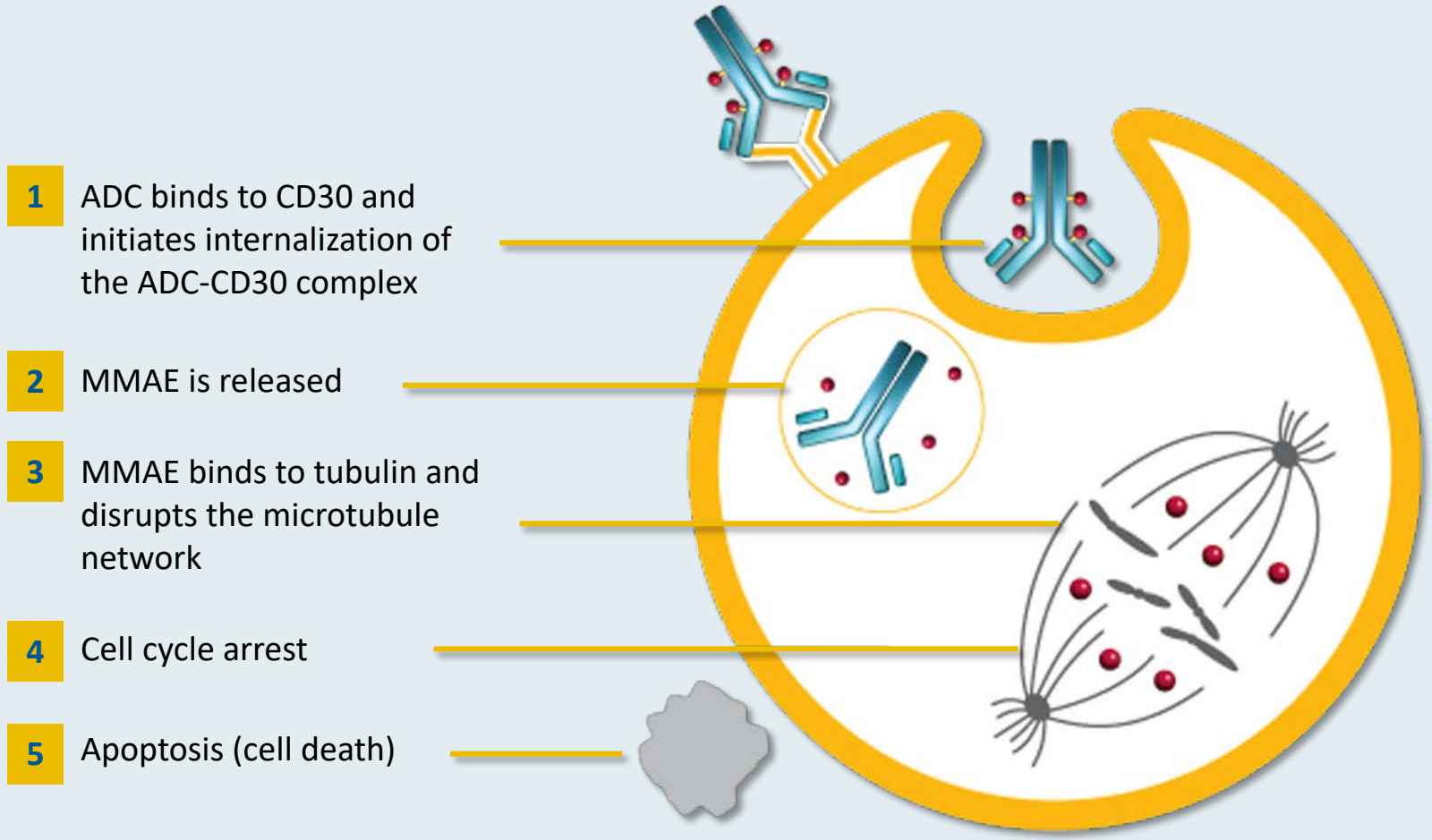
Patients at high risk for disease progression after undergoing transplant for relapsed HL may receive 1 year of consolidation treatment with…

1. Nivolumab
2. Brentuximab vedotin
3. Nivolumab + brentuximab vedotin
4. Chemotherapy
5. Other
6. I don’t know

Mechanism of Action of Brentuximab Vedotin

Brentuximab vedotin is an antibody-drug conjugate (ADC) targeted to cells expressing CD30 on their surface



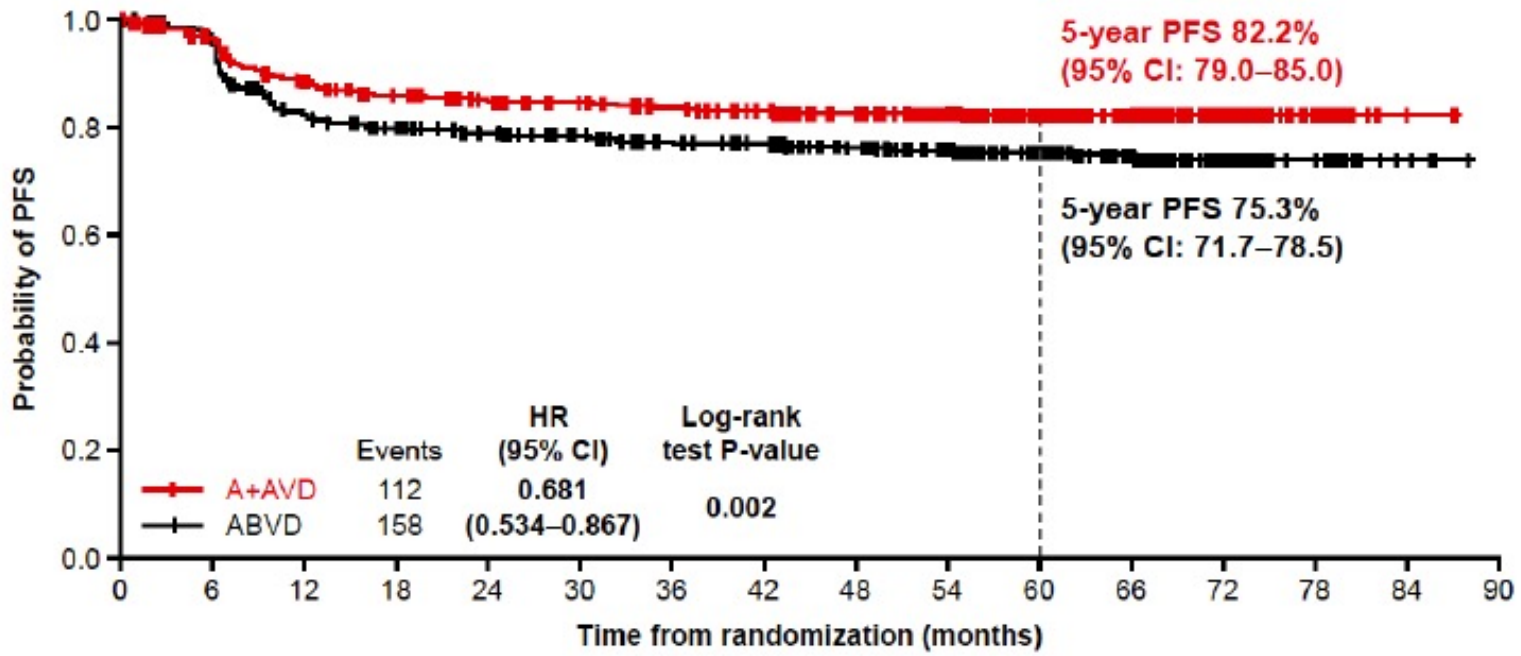
Courtesy of Julie M Vose, MD, MBA.

Brentuximab Vedotin with Chemotherapy for Patients with Previously Untreated, Stage III/IV Classical Hodgkin Lymphoma: 5-Year Update of the ECHELON-1 Study

Straus DJ et al.

ASH 2020;Abstract 2973.

ECHELON-1: PFS per investigator at 5 years' follow-up*



Number of patients at risk

A+AVD	664	620	562	535	518	505	492	474	446	414	333	201	102	38	2	0
ABVD	670	613	521	500	478	456	432	423	397	360	292	179	73	22	4	0

- As of the 5-year follow-up, the prespecified number of events required to trigger an OS analysis have not been reached.
- OS was a prespecified key secondary endpoint.

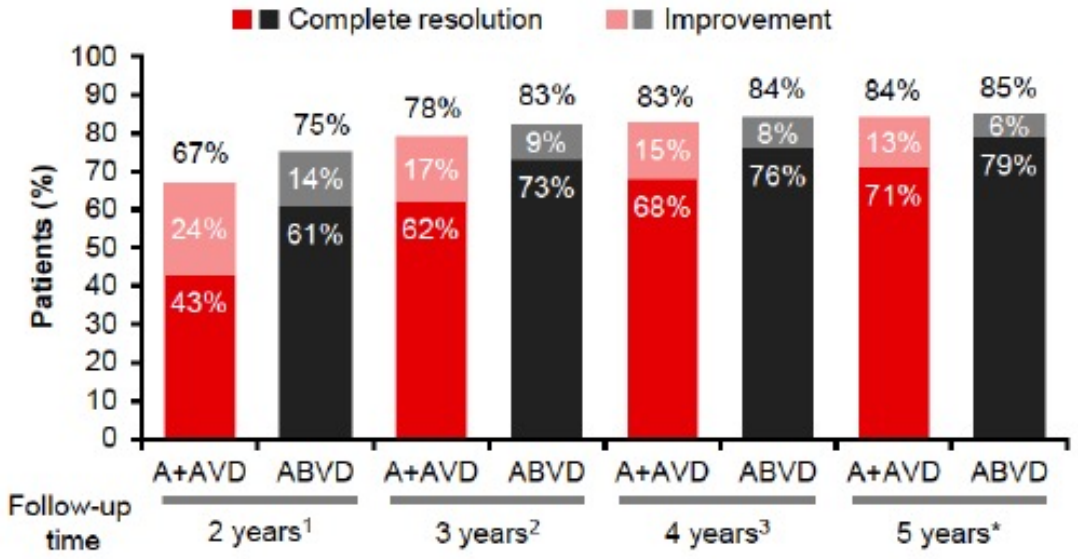
*September 14, 2020 data cut-off.

Straus DJ et al. ASH 2020;Abstract 2973.

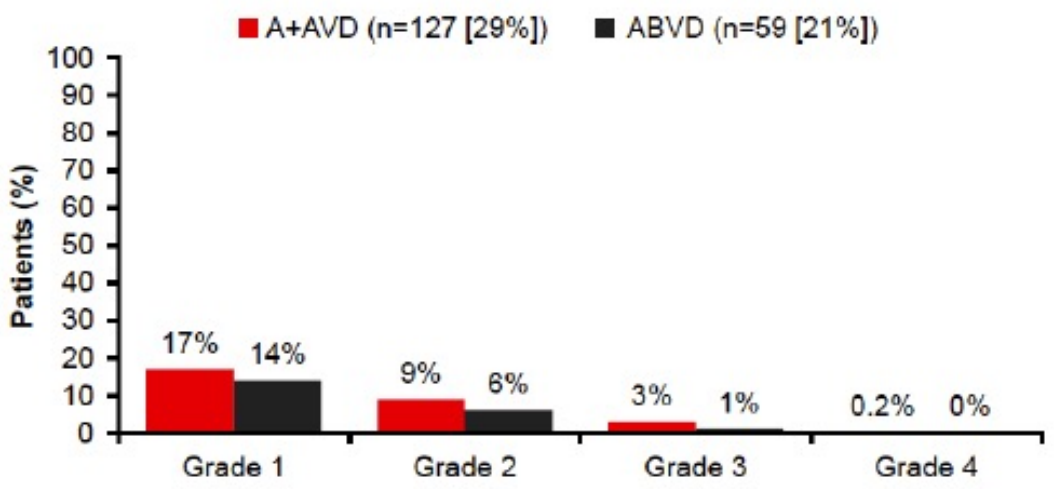
ECHELON-1: PN resolution and improvement

- At the primary analysis, 442 and 286 patients in A+AVD and ABVD arms, respectively, had experienced PN.

Patients with complete resolution or improvement of PN over time (%)*



Patients with ongoing PN by grade at last follow-up†



Resolution was defined as event outcome of "resolved" or "resolved with sequelae"; Improvement was defined as "improved by ≥1 grade from worst grade as of the latest assessment"; *Percentages rounded to nearest integer; †Median follow-up 236.9 weeks (range: 0–344); Assessment of ongoing PN with maximum severity of grade 3/4 was confounded in 12 of the 15 A+AVD patients by death prior to resolution (n=3), loss to follow-up (n=4), and withdrawal from study (n=5); Among the ABVD patients with grade 3 PN, two were lost to follow-up and two died prior to resolution of PN.

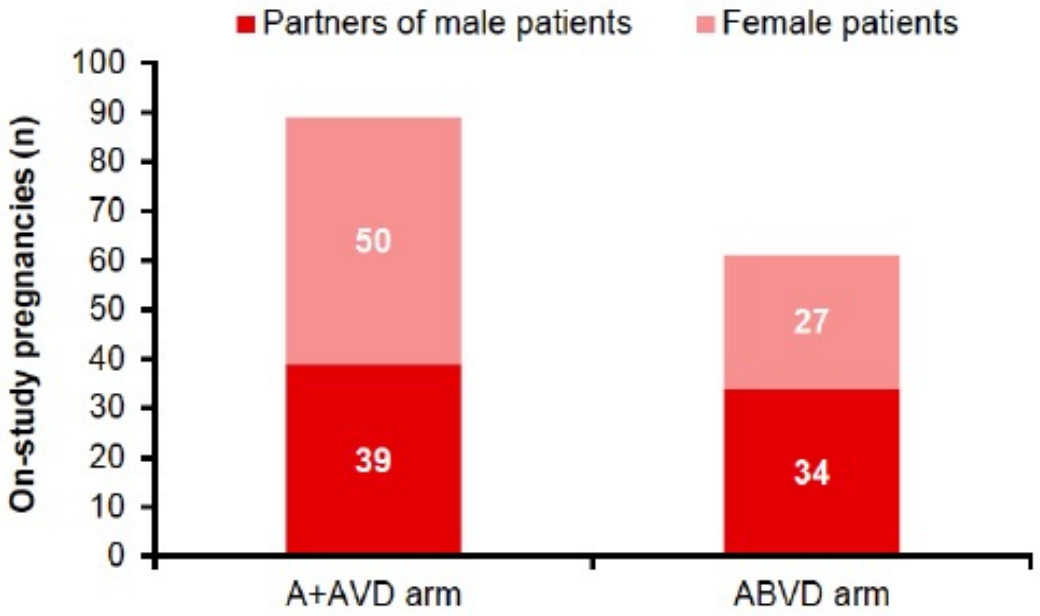
1. Connors JM, et al. N Engl J Med 2018;378:331–44;
2. Straus DJ, et al. Blood 2020;135:735–42;
3. Bartlett NL, et al. Blood 2019;134 (Suppl. 1):4026.

Straus DJ et al. ASH 2020;Abstract 2973.

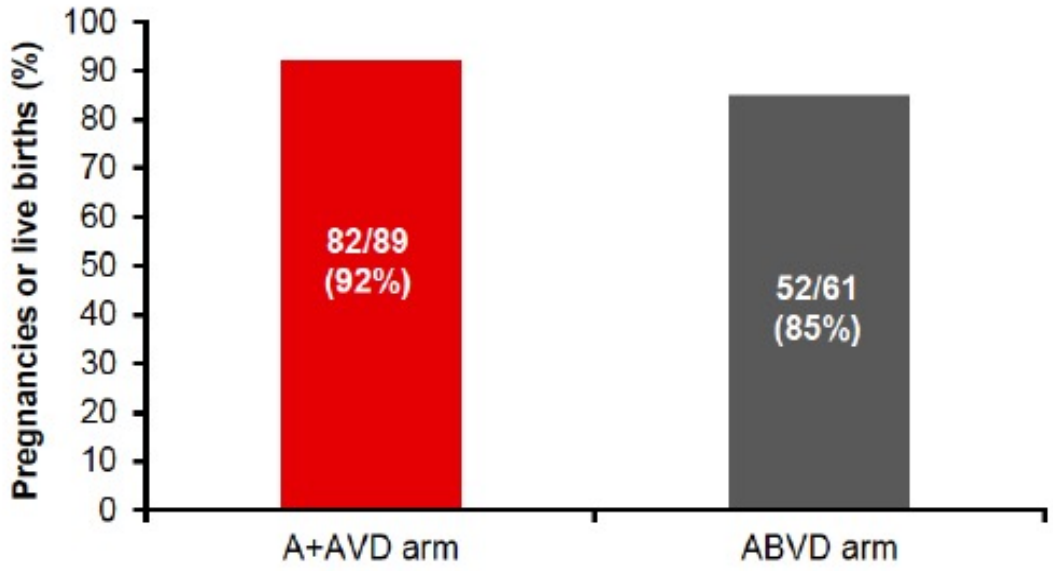
ECHELON-1: Pregnancies

- A total of 150 pregnancies were reported among study participants and their partners.

On-study pregnancies in patients or their partners

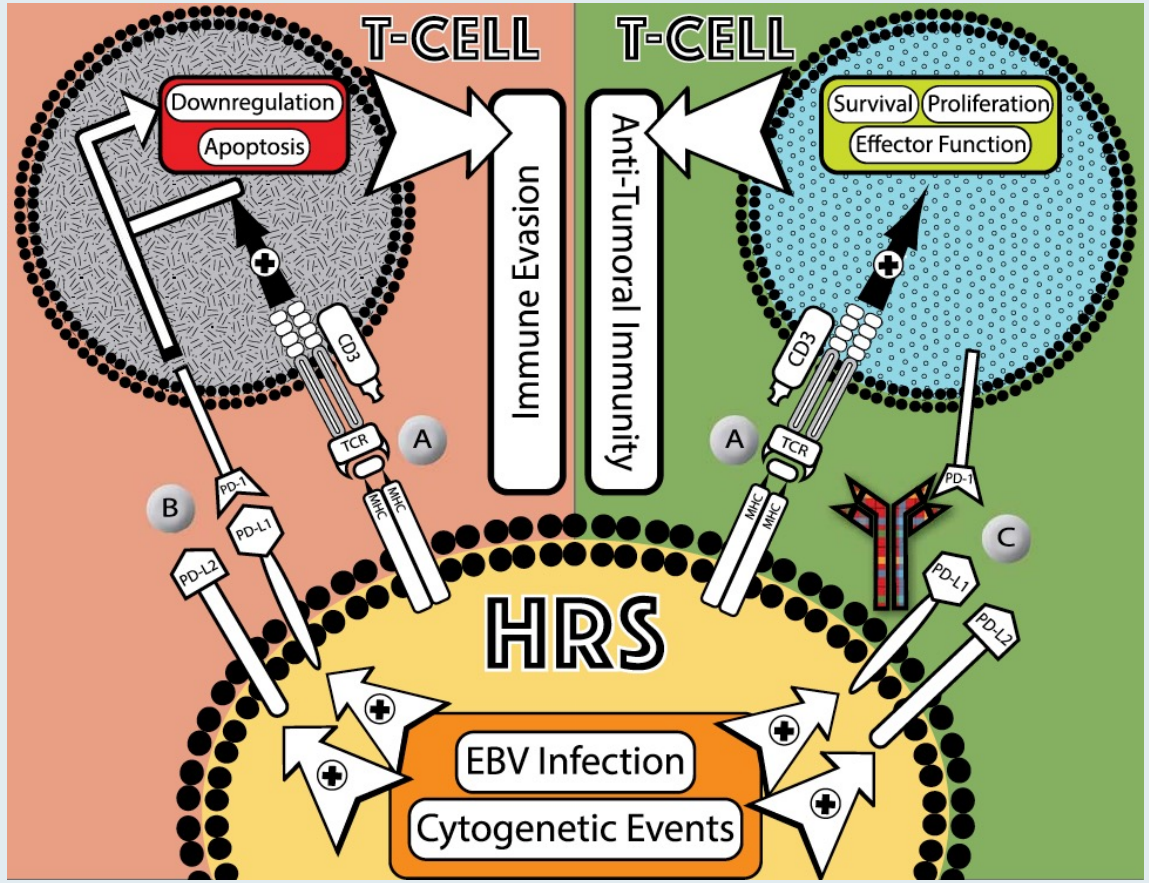


Ongoing pregnancies or live births



Straus DJ et al. ASH 2020;Abstract 2973.

Targeting the PD-1/PD-L1 Axis in HL



- **HL characterized by small number of malignant Hodgkin Reed-Sternberg cells (HRS) surrounded by normal immune cells**
- 9p24.1 chromosomal abnormalities frequently observed in HRS
- **More than 90% of HRS have alterations in PD-L1 and PD-L2 loci**
- Malignant Hodgkin and RS cells overexpress PD-L1/L2 ligands (due to cytogenetic events, infection with EBV)

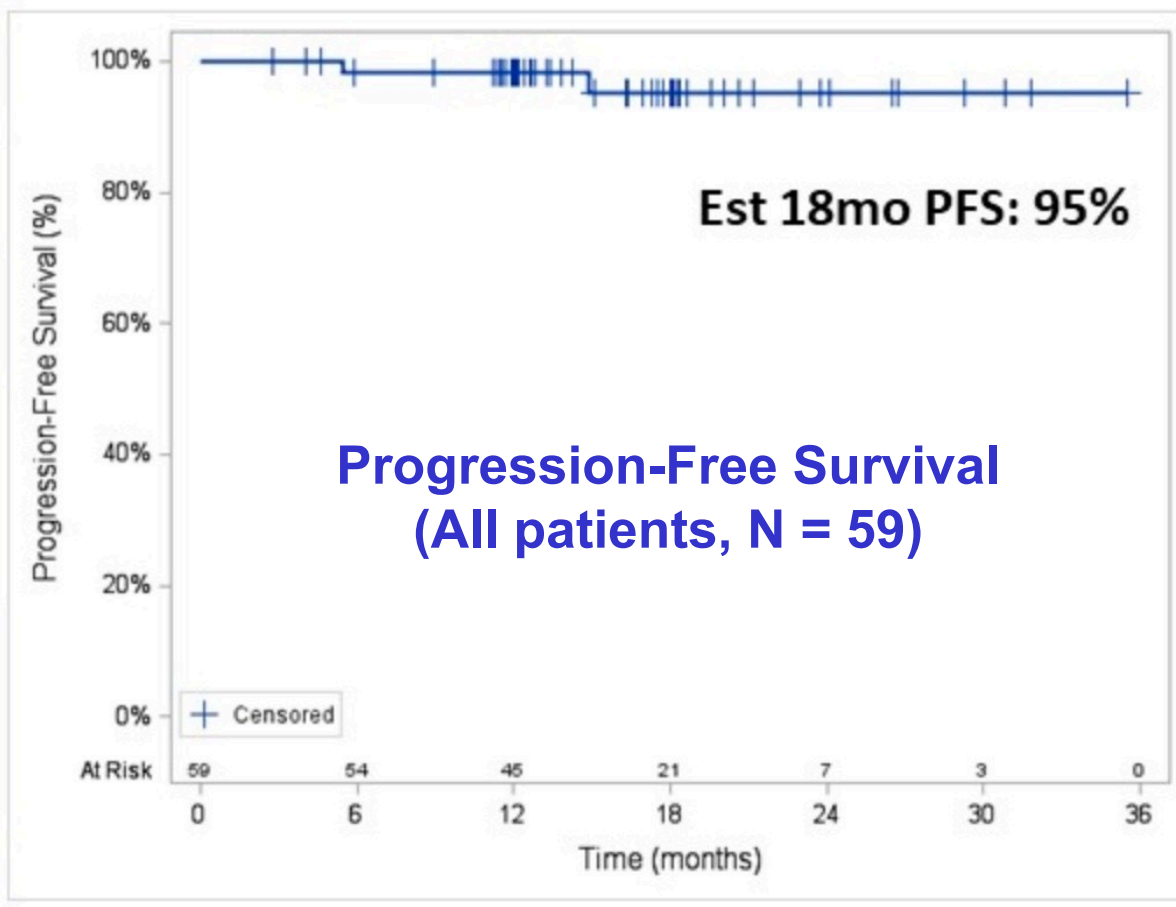
Villasboas JC, Ansell SA. *Cancer J* 2016;22(1):17-22; Roemer MGM et al. *J Clin Oncol* 2016;34(23):2690-7.

Consolidation with Nivolumab and Brentuximab Vedotin After Autologous Hematopoietic Cell Transplantation in Patients with High-Risk Hodgkin Lymphoma

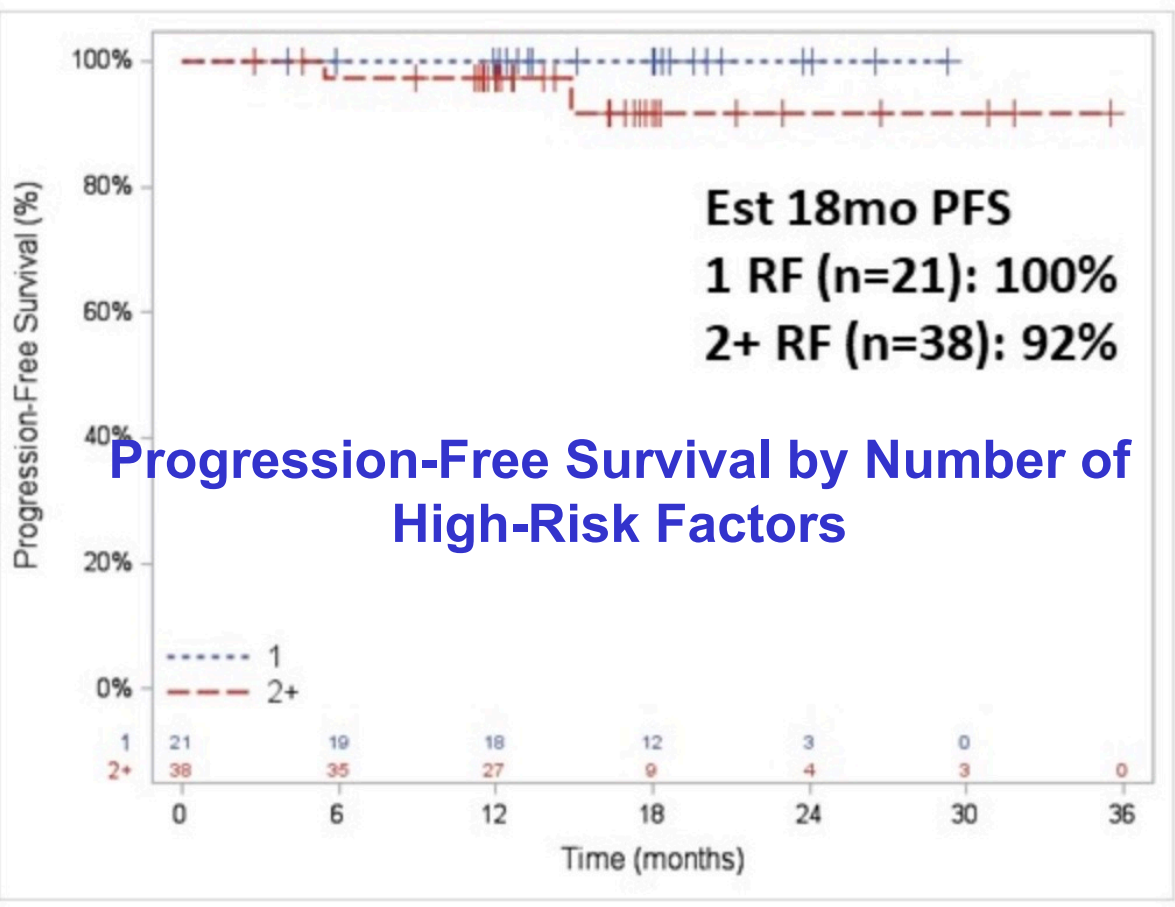
Herrera AF et al.

ASH 2020;Abstract 472.

Consolidation with Nivolumab and Brentuximab Vedotin After ASCT: Progression-Free Survival



Progression-Free Survival (All patients, N = 59)



Progression-Free Survival by Number of High-Risk Factors

Herrera AF et al. ASH 2020;Abstract 472.

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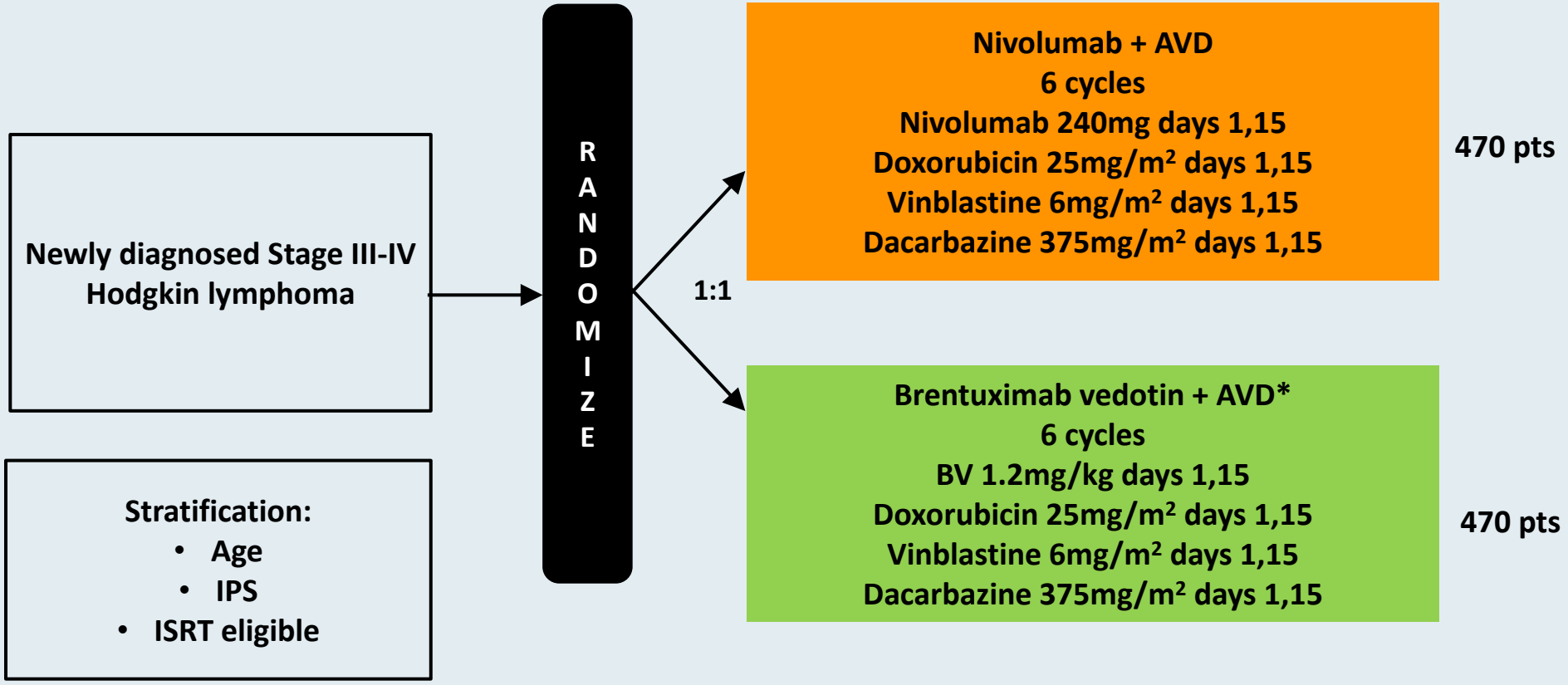
SWOG-1826: Ongoing Phase III Trial of Nivolumab or Brentuximab Vedotin with Combination Chemotherapy for Newly Diagnosed Stage III-IV Classical HL



* **G-CSF is mandatory in BV-AVD arm**, optional in N-AVD

Courtesy of Craig Moskowitz, MD.

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Case Presentation – A 76-year-old man with newly diagnosed follicular lymphoma (Part 1)

Ms Klebig

- PMH: Progressive aphasia, short-term memory loss likely due to Alzheimer's disease
- Patient is a farmer, wife is healthcare surrogate
- 9/2019: Diagnosed with Grade 1-2, Stage IV follicular lymphoma
- Lenalidomide/rituximab (R^2), with rash and neutropenia requiring dose adjustments
  - After 5 months: Complete remission (CR)
- Currently, remains in CR

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Case Presentation – A 76-year-old man with newly diagnosed follicular lymphoma (Part 2)

Ms Klebig

- PMH: Progressive aphasia, short-term memory loss likely due to Alzheimer's disease
- Patient is a farmer, wife is healthcare surrogate
- 9/2019: Diagnosed with Grade 1-2, Stage IV follicular lymphoma
- Lenalidomide/rituximab (R^2), with rash and neutropenia requiring dose adjustments
  - After 5 months: Complete remission (CR)
- Currently, remains in CR
- ***Neurologic condition worsenening, decrease in awareness***
- ***Counseling patient and caregiver about potential side effects***

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Which of the following regimens appears to have the same efficacy as bendamustine/rituximab (BR) as first-line treatment for symptomatic follicular lymphoma (FL)?

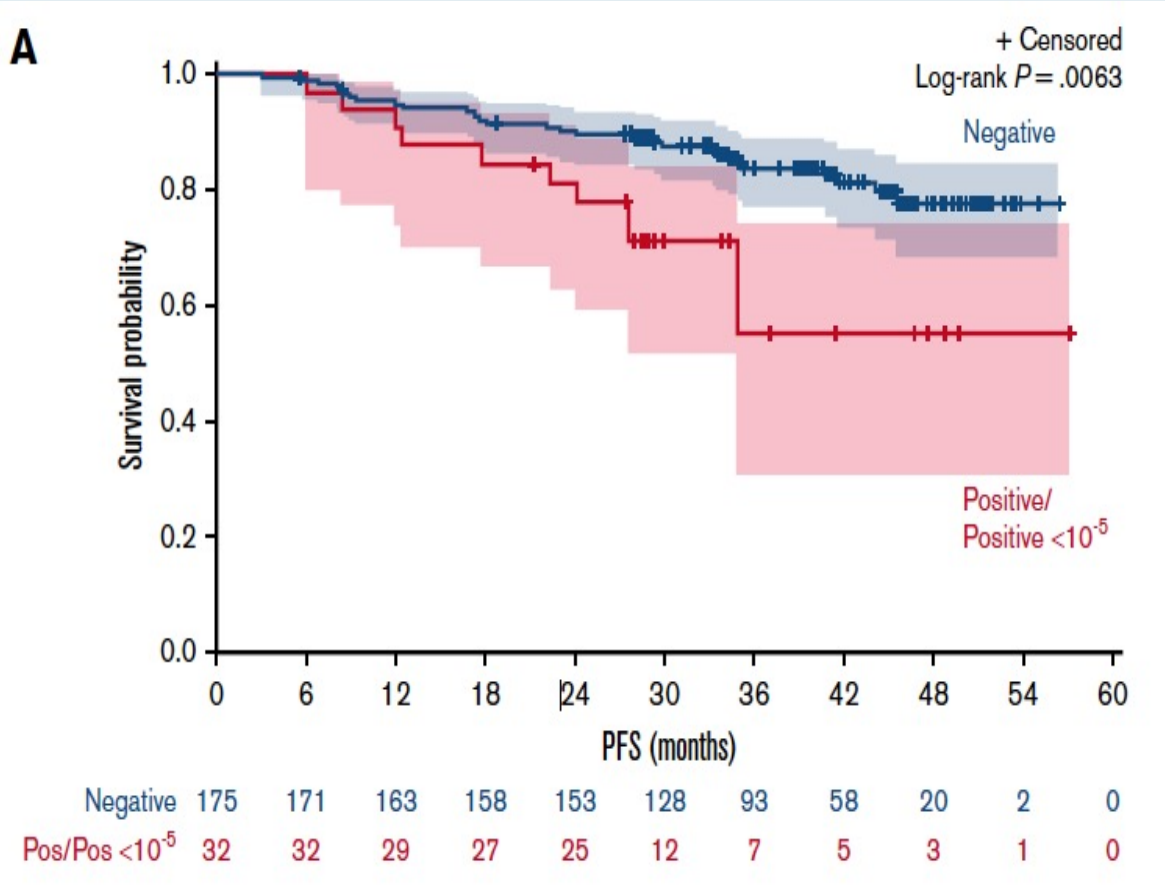
1. Rituximab alone
2. Lenalidomide/rituximab
3. Obinutuzumab
4. R-CHOP
5. None of the above
6. I don’t know

What is the usual second-line therapy for a patient with FL who experiences disease progression on first-line BR?

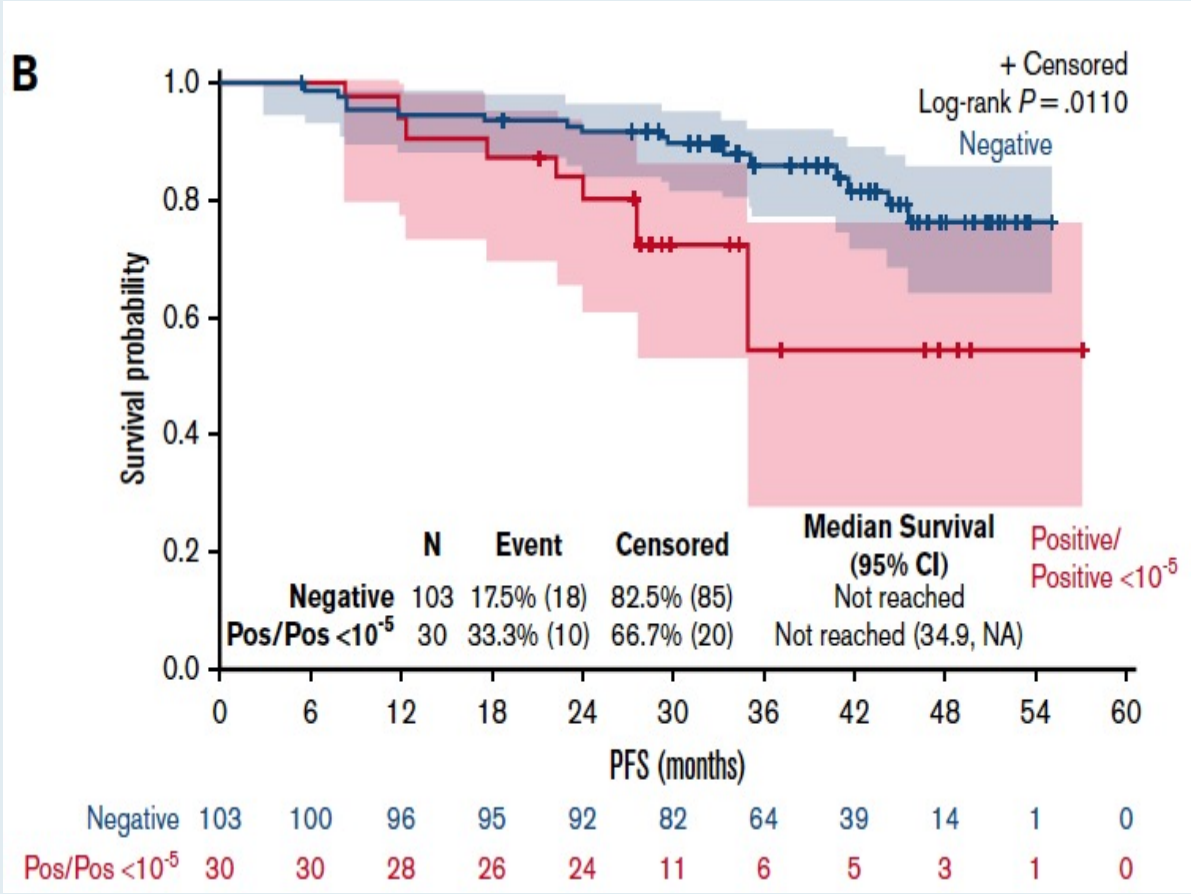
1. Re-treatment with BR
2. Obinutuzumab/bendamustine
3. Rituximab/lenalidomide
4. A PI3K inhibitor (eg, idelalisib, copanlisib, duvelisib, umbralisib)
5. I don’t know

RELEVANCE Trial: R^2 Induces High Molecular Response in Untreated FL

Impact of positive MRD at week 24 on PFS in PB and/or BM



Impact of positive MRD at week 24 on PFS in BM



Delfau-Larue MH et al. *Blood Adv* 2020;4(14):3217-23.

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Approved PI3K inhibitors in R/R Follicular Lymphoma

	Idelalisib	Copanlisib	Duvelisib	Umbralisib
FDA approval	Jul 29, 2014	Sep 14, 2017	Sep 24, 2018	Feb 5, 2021
Isoforms	PI3K delta	Pan-PI3K	PI3K delta/gamma	PI3K-delta and CK1-epsilon
Formulation	150 mg **PO** BID	60 mg **IV** Q weekly 3 wks on, 1 wk off	25 mg **PO** BID	800 mg **PO** QD
Indication in FL	Relapsed after at least two prior systemic therapies	Relapsed after at least two prior systemic therapies	Relapsed after at least two prior systemic therapies	Relapsed after at least three prior systemic therapies
Pivotal trial	Study 101-09	CHRONOS-1	NCT02204982	UTX-TGR-205
Results	iNHL, n=125 **ORR 57%, CR 6%**	FL, n=104 **ORR 59%, CR 14%**	FL, n=83 **ORR 42%, 1 CR**	FL, n = 117 **ORR 43%, CR 3%**
	mDOR 12.5 mo	**mDOR 12.2 mo**	**43% maintained responses for ≥6mo, 17% maintained responses for ≥12mo**	**mDOR 11.1 mo**
Side effects	**Pneumonitis, transaminitis, colitis**	**Hyperglycemia, hypertension**, infections, neutropenia	**Infection, diarrhea or colitis, pneumonia**	**Infection, neutropenia, diarrhea or noninfectious colitis**

S deVos Sep 2019 (Gopal A, et al. NEJM 2014; 370:1008-18)

(https://www.fda.gov/Drugs/Information)

FDA Grants Accelerated Approval to Tazemetostat for Follicular Lymphoma

Press Release – June 18, 2020

"The Food and Drug Administration granted accelerated approval to tazemetostat, an EZH2 inhibitor, for adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, and for adult patients with R/R FL who have no satisfactory alternative treatment options.

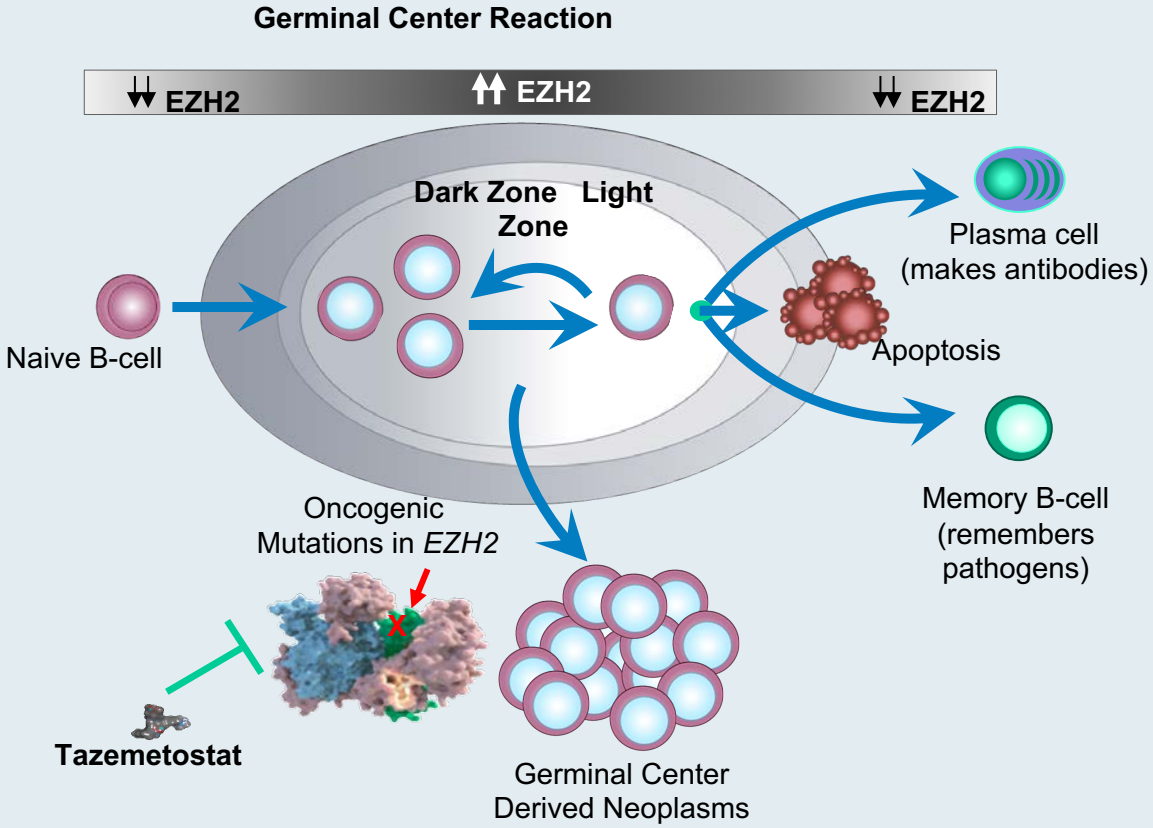
Today, the FDA also approved the cobas® EZH2 Mutation Test as a companion diagnostic for tazemetostat.

Approval was based on two open-label, single-arm cohorts (Cohort 4 - EZH2 mutated FL and Cohort 5 - EZH2 wild-type FL) of a multi-center trial (Study E7438-G000-101, NCT01897571) in patients with histologically confirmed FL after at least 2 prior systemic therapies. EZH2 mutations were identified prospectively using formalin-fixed, paraffin-embedded tumor samples, which were centrally tested using the cobas® EZH2 Mutation Test. Patients received tazemetostat 800 mg orally twice daily until confirmed disease progression or unacceptable toxicity."

https://www.fda.gov/drugs/fda-granted-accelerated-approval-tazemetostat-follicular-lymphoma

Follicular Lymphoma and EZH2

- ***EZH2*** **an epigenetic regulator of gene expression and cell fate decisions[1]**
- ***EZH2*** **is required for normal B-cell biology and germinal center formation[2]**
  - **Oncogenic mutations in *EZH2* suppress exit from germinal state and "lock" B cells in this state thereby transforming into a cancer[2]**
- ***EZH2*** **biology relevant in both mutant (MT) and wild-type (WT) *EZH2* FL**
  - **~20% of patients with FL also have *EZH2* gain of function mutations[3]**



Tazemetostat, a selective, oral inhibitor of EZH2 has shown antitumor activity in non-Hodgkin's lymphoma patients with either MT or WT EZH2[4,5]

1. Gan L, et al. *Biomark Res*. 2018;6(1):10; 2. Béguelin W, et al. *Cancer Cell*. 2013;23(5)677-692.
3. Bödör C, et al. *Blood*. 2013;122:3165-3168. 4. Italiano A, et al. *Lancet Oncol*. 2018;19(5):649-59;
5. Morschhauser F, et al. *Hematol Oncol*. 2017 Jun;35:24-5.

Courtesy of John P Leonard, MD

Analyzing Efficacy Outcomes from the Phase 2 Study of Single-Agent Tazemetostat as Third-Line Therapy in Patients with Relapsed or Refractory Follicular Lymphoma to Identify Predictors of Response

Salles G et al.

ASH 2020;Abstract 2047.

Phase 2 Efficacy Outcomes

Efficacy Outcome[a]	Combined WT and MT *EZH2* (N=99)	WT *EZH2* (n=54)[1]	MT *EZH2* (n=45)[1]
ORR, % (95% CI)	51 (40–61)	35 (23-49)	69 (53-82)
Median DOR, months (95% CI)	11 (7–19)	13 (6-NE)	11 (7-NE)
Median PFS, months (95% CI)	12 (8–15)	11 (4-15)	14 (11-22)
Median OS, months (95% CI)	NR (38–NE)	NR	NR

- The DOR was consistent between WT and MT *EZH2* groups[1]
- Consistent ORRs were also observed across high-risk subgroups, such as patients with POD24, double-refractory disease, and refractoriness to rituximab therapy, regardless of mutation status[1]

[a]ORR, DOR, and PFS are based on IRC assessments.

1. Morschhauser F, et al. *Lancet Oncology*; 2020;21(11):1433-42.

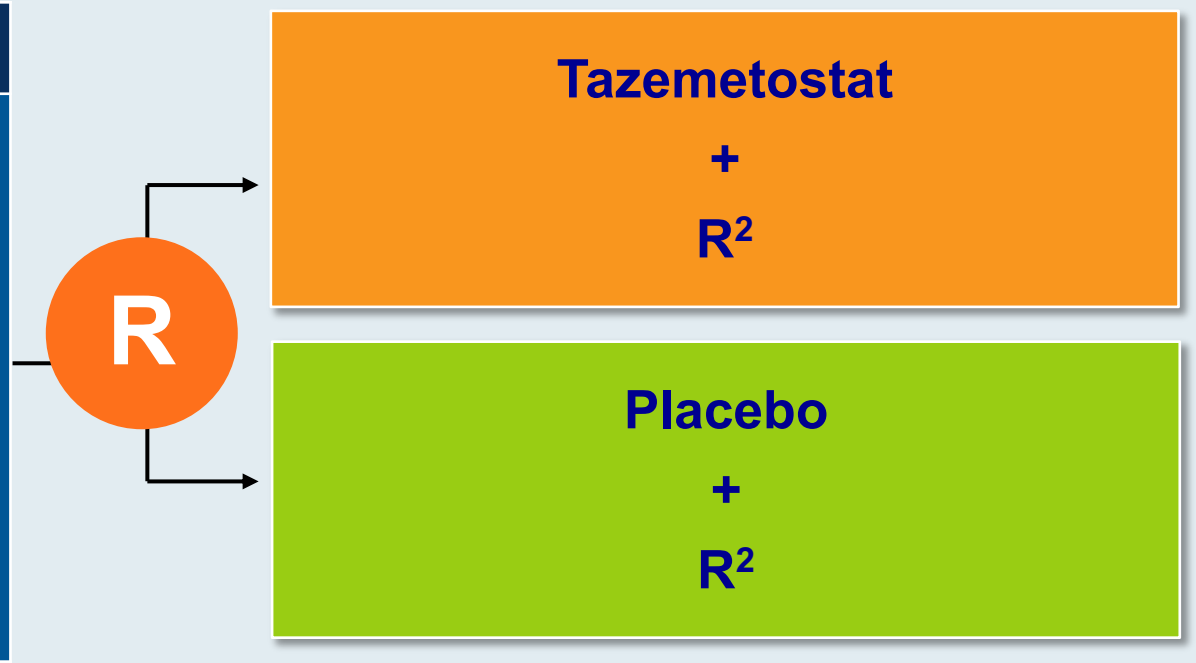
CI, confidence interval; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; EZH2, enhancer of zeste homolog 2; IRC, independent radiology committee; MT, mutant; NE, not estimable; NR, not reached; ORR, objective response rate; OS, overall survival; MT, mutant; NE, not evaluable; NR, not reached; PFS, progression-free survival; WT, wild type.

Salles G et al. ASH 2020;Abstract 2047.

Ongoing Phase Ib/III Trial of Tazemetostat + Lenalidomide/Rituximab (R^2) for R/R FL

Target accrual (N = 518)

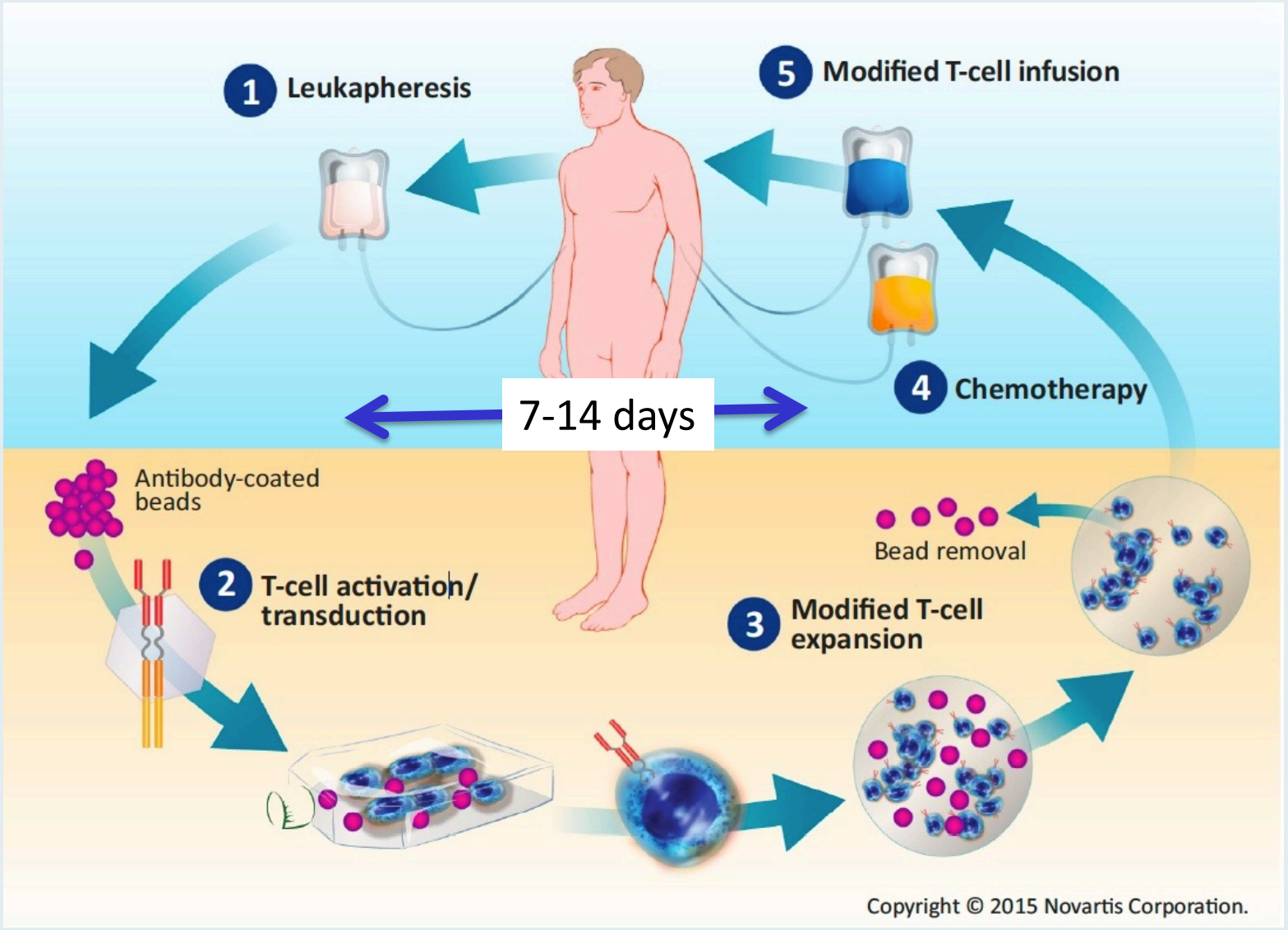
- Must have Grade I to IIIA FL
- Received at least 1 prior line of therapy
- No prior EZH2 inhibitor
- No prior lenalidomide for FL



- Primary endpoint:
  - Stage 1: RP3D of tazemetostat in combination with R^2
  - Stage 2: PFS

Batlevi CL et al. ASH 2020; Abstract 2052; Clinicaltrials.gov; NCT04224493 (Accessed January 2021).

Overview of CAR T-Cell Therapy



Modification, Courtesy, David Porter, MD

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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.

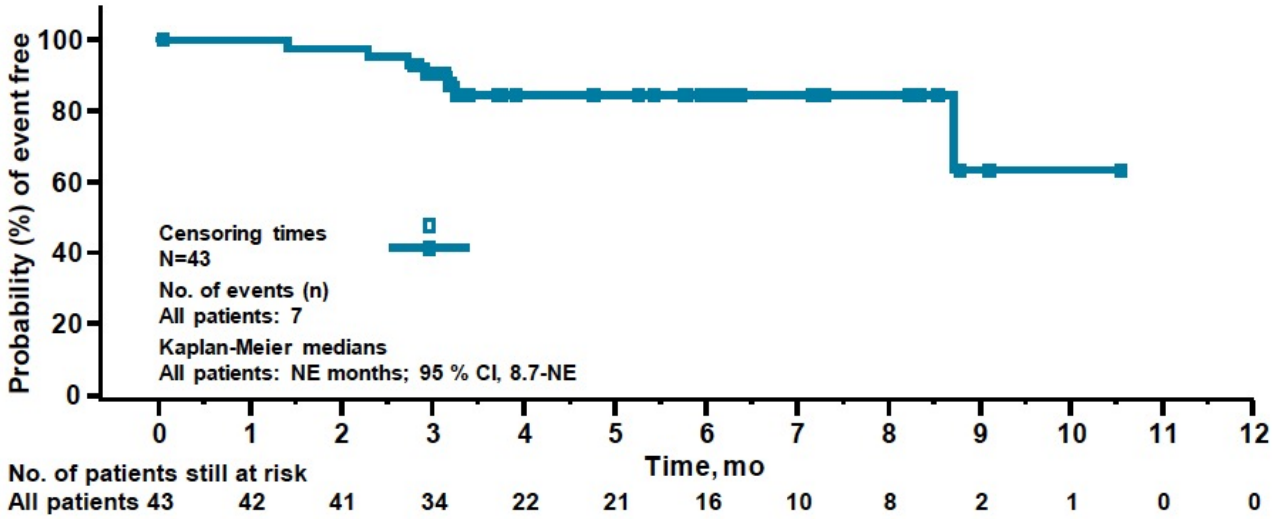
ELARA Interim Analysis: Primary CR Endpoint

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.

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.

FDA Grants Accelerated Approval to Axicabtagene Ciloleucel for Relapsed or Refractory Follicular Lymphoma

Press Release – March 5, 2021

"The Food and Drug Administration granted accelerated approval to axicabtagene ciloleucel for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Approval in FL was based on a single-arm, open-label, multicenter trial (ZUMA-5; NCT03105336) that evaluated axicabtagene ciloleucel, a CD19-directed chimeric antigen receptor (CAR) T cell therapy, in adult patients with relapsed or refractory FL after two or more lines of systemic therapy, including the combination of an anti-CD20 monoclonal antibody and an alkylating agent. Following lymphodepleting chemotherapy, axicabtagene ciloleucel was administered as a single intravenous infusion.

The main efficacy measures were objective response rate (ORR) and duration of response (DOR) as determined by an independent review committee. Among 81 patients in the primary efficacy analysis, the ORR was 91% with a complete remission (CR) rate of 60% and a median time-to-response of 1 month. The median DOR was not reached, and the 1-year rate of continued remission was 76.2%. For all leukapheresed patients in this trial (n=123), the ORR was 89% with a CR rate of 62%."

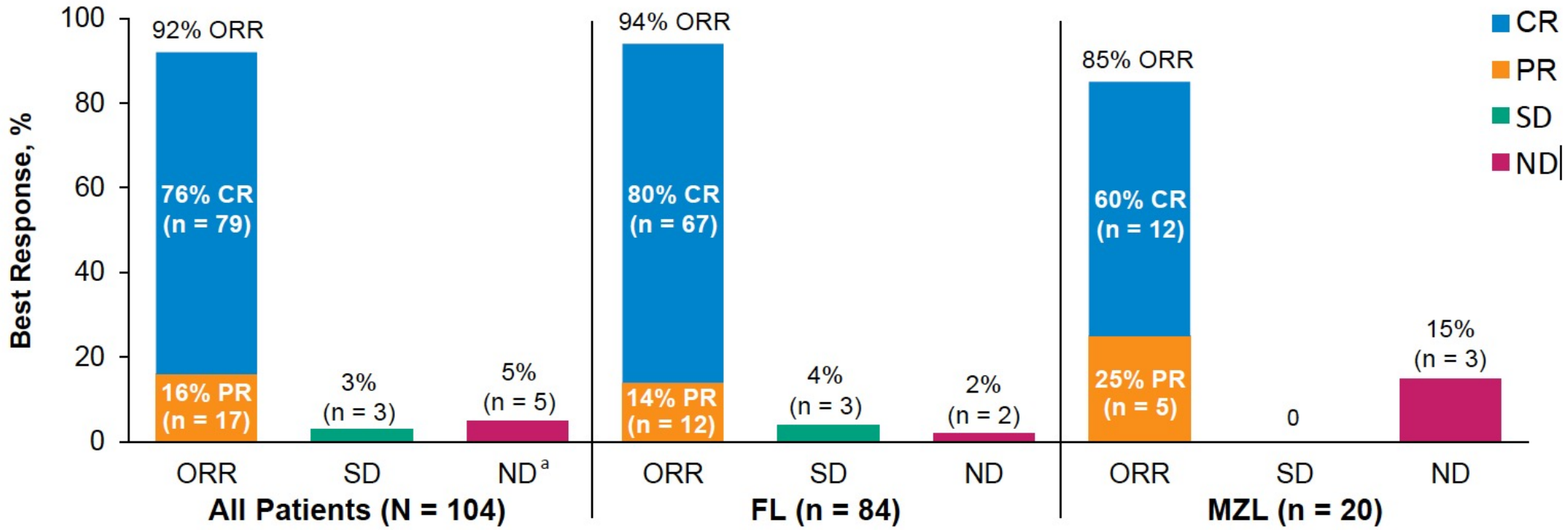
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-axicabtagene-ciloleucel-relapsed-or-refractory-follicular-lymphoma

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.

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

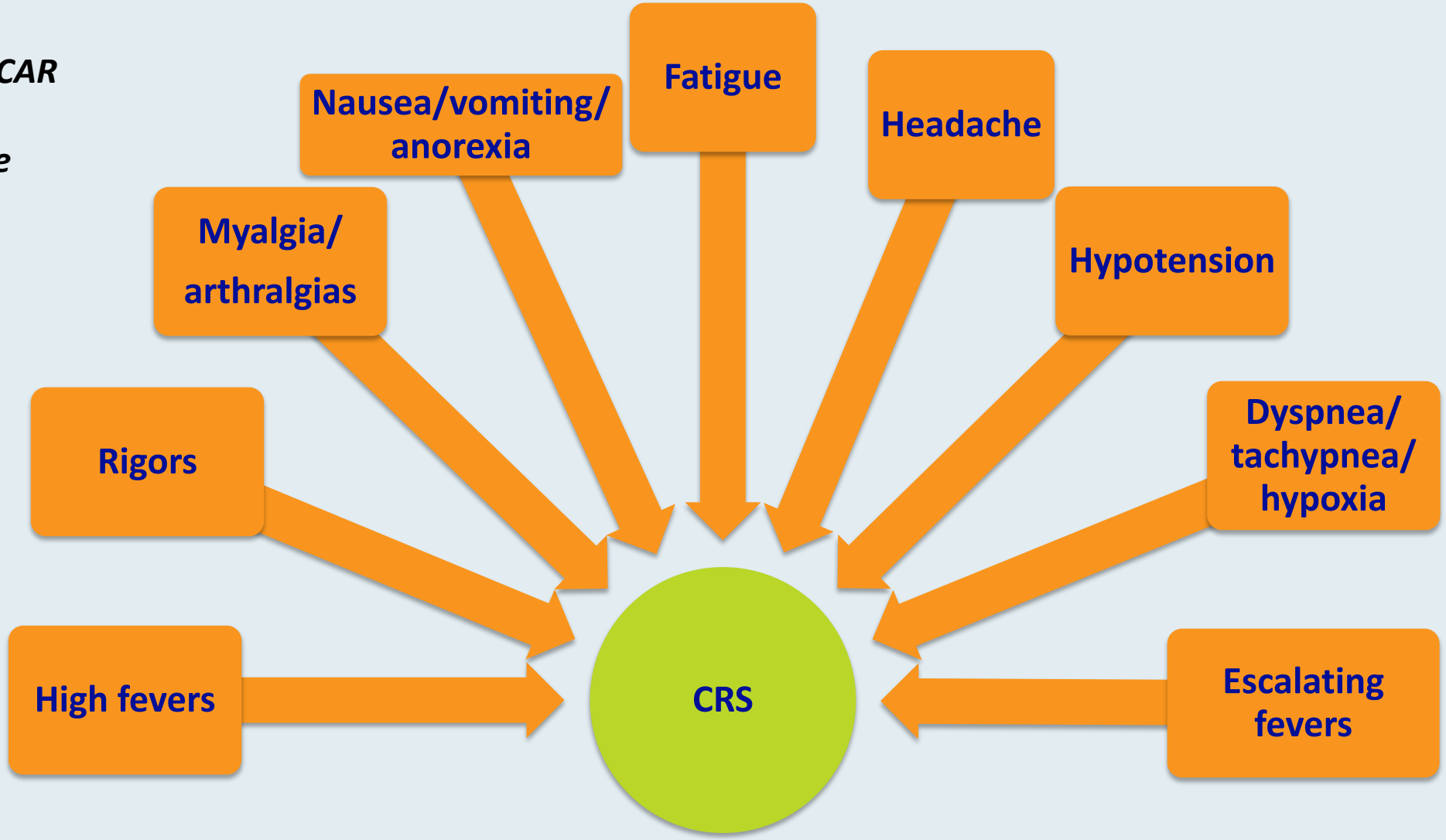
CRS — May be mild or life-threatening

- 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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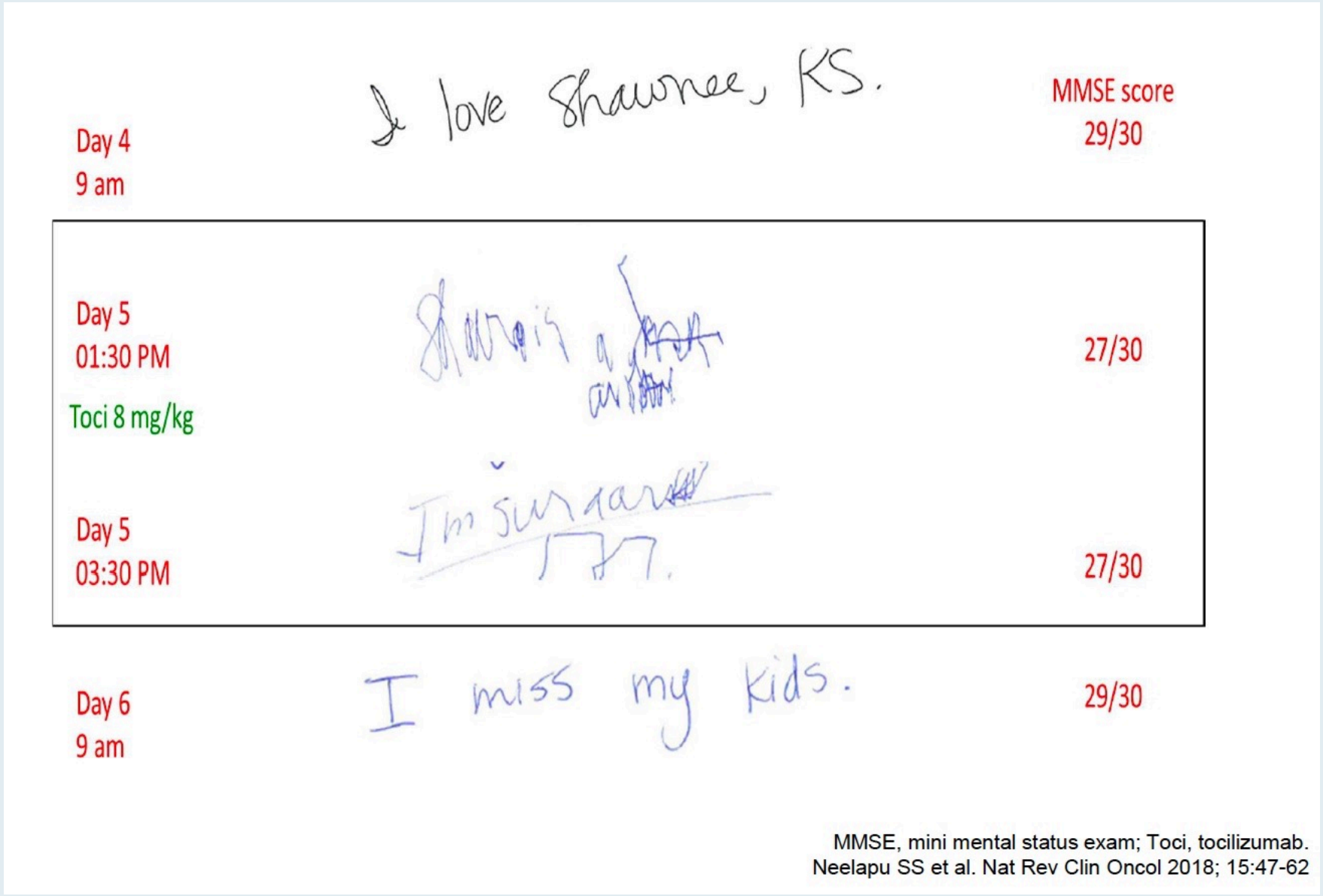
CAR T-Cell Therapy-Associated Neurologic Toxicity

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.

Example of Handwriting Deterioration Associated with Neurotoxicity from CAR T-Cell Therapy



MMSE, mini mental status exam; Toci, tocilizumab.
Neelapu SS et al. Nat Rev Clin Oncol 2018; 15:47-62

Agenda

Case 1 (Ms Moran): A 27-year-old woman with Hodgkin lymphoma

Case 2 (Ms Klebig): A 76-year-old man with newly diagnosed follicular lymphoma

Case 3 (Ms Klebig): An 83-year-old woman with relapsed DLBCL

Case 4 (Ms Gideon): A 66-year-old woman with relapsed DLBCL

Case 5 (Ms Gideon): A 70-year-old man with relapsed mantle cell lymphoma

Case Presentation – An 83-year-old woman with relapsed DLBCL

Ms Klebig

- 2018: Diagnosed with DLBCL s/p R-CHOP x 6
- 2019: Relapsed disease → Rituximab x 4 → PD 2 months later
- Tafasitamab/bendamustine on clinical trial MOR208C204
  - Treatment every 2 weeks until PD or intolerability
- Recent imaging confirms sustained remission for over 18 months

Case Presentation – A 66-year-old woman with relapsed DLBCL (Part 1)

Ms Gideon

- Healthy pilates instructor who developed hip and back pain to the point that she became debilitated by a large paraspinal mass
- Induction therapy, with a CR with relapsed disease shortly thereafter
- Depression, anxiety about upcoming treatment and hospitalization

Case Presentation – A 66-year-old woman with relapsed DLBCL (Part 2)

Ms Gideon

- Healthy pilates instructor who developed hip and back pain to the point that she became debilitated by a large paraspinal mass
- Induction therapy, with a CR with relapsed disease shortly thereafter
- Depression, anxiety about upcoming treatment and hospitalization
- ***Referred for salvage chemotherapy and ASCT versus CAR T-cell therapy***
- ***CAR T-cell therapy with axicabtagene ciloleucel***
  - ***Developed CRS 3 days after the infusion, treated with tocilizumab***

Case Presentation – A 66-year-old woman with relapsed DLBCL (Part 3)

Ms Gideon

- Healthy pilates instructor who developed hip and back pain to the point that she became debilitated by a large paraspinal mass
- Induction therapy, with a CR with relapsed disease shortly thereafter
- Depression, anxiety about upcoming treatment and hospitalization
- Referred for salvage chemotherapy and ASCT versus CAR T-cell therapy
- CAR T-cell therapy with axicabtagene ciloleucel
  - Developed CRS 3 days after the infusion, treated with tocilizumab
  - ***Discharged 12 days after the infusion, significant improvement in pain***
  - ***Near CR 30 days later***

Case Presentation – A 66-year-old woman with relapsed DLBCL (Part 4)

Ms Gideon

- Healthy pilates instructor who developed hip and back pain to the point that she became debilitated by a large paraspinal mass
- Induction therapy, with a CR with relapsed disease shortly thereafter
- Depression, anxiety about upcoming treatment and hospitalization
- Referred for salvage chemotherapy and ASCT versus CAR T-cell therapy
- CAR T-cell therapy with axicabtagene ciloleucel
  - Developed CRS 3 days after the infusion, treated with tocilizumab
  - Discharged 12 days after the infusion, significant improvement in pain
  - Near CR 30 days later
- ***Patient "shocked" about the effectiveness of treatment; patient desires to return to the pilates studio***

RTP RESEARCH TO PRACTICE

Chimeric antigen receptor (CAR) T-cell therapy is commonly associated with…

1. Cytokine release syndrome
2. Neurotoxicity
3. Rash
4. Peripheral neuropathy
5. I don’t know

A patient with DLBCL should be in adequate physical condition to undergo autologous stem cell transplant in order to be a suitable candidate for CAR T-cell therapy.

1. Agree
2. Disagree
3. I don't know

FDA Grants Accelerated Approval to Tafasitamab-cxix for Diffuse Large B-Cell Lymphoma

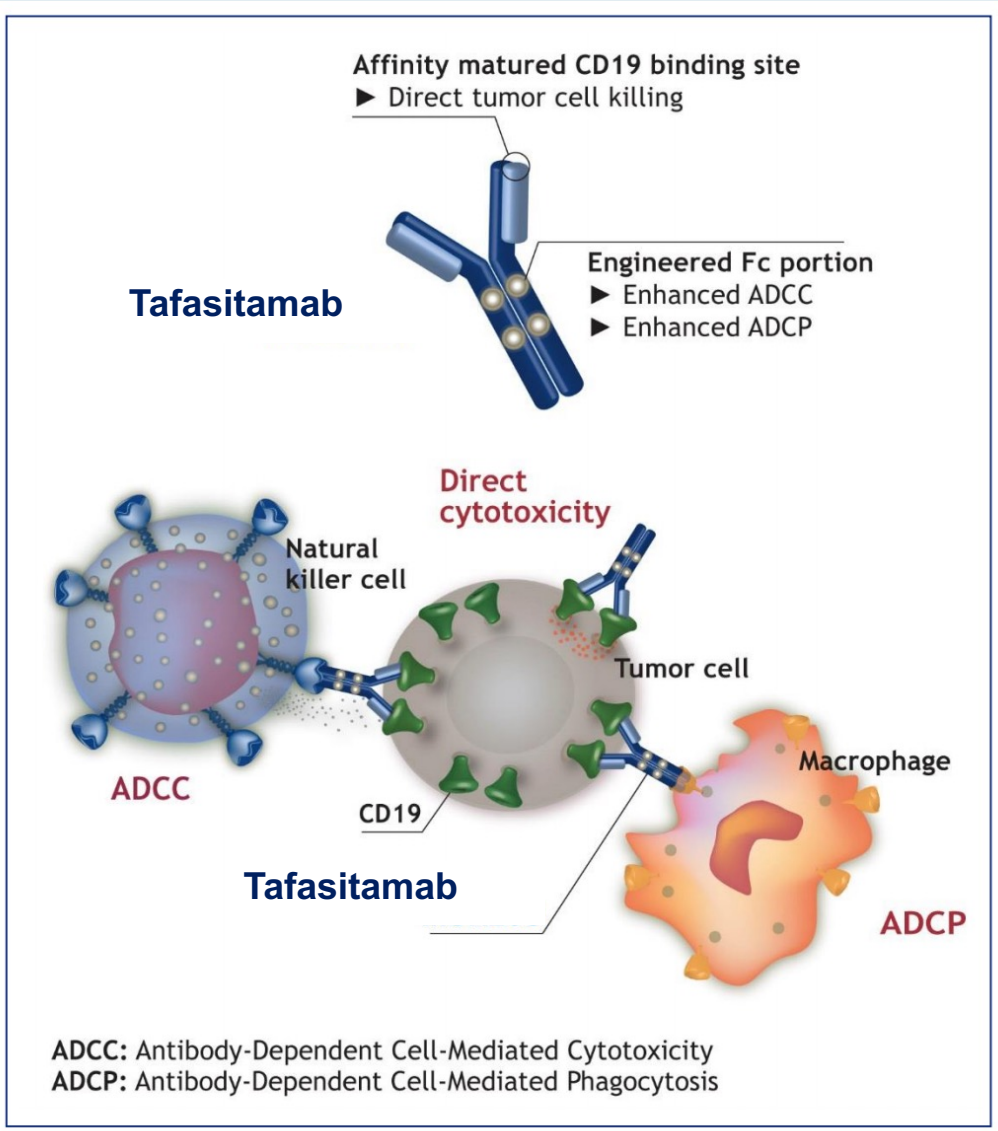
Press Release – July 31, 2020

"The Food and Drug Administration granted accelerated approval to tafasitamab-cxix, a CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant.

The efficacy of tafasitamab-cxix with lenalidomide was evaluated in L-MIND (NCT02399085), an open label, multicenter single-arm trial in 81 patients. Patients received tafasitamab-cxix 12 mg/kg intravenously with lenalidomide (25 mg orally on days 1 to 21 of each 28-day cycle) for maximum of 12 cycles, followed by tafasitamab-cxix as monotherapy."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-tafasitamab-cxix-diffuse-large-b-cell-lymphoma

Tafasitamab (MOR208)



Lenalidomide enhances NK function with enhanced ADCC in vitro

Salles et al. Lancet Onc 2020

Courtesy of Ann S LaCasce, MD, MMSc

RTP RESEARCH TO PRACTICE

Long-Term Subgroup Analyses from L-Mind, a Phase II Study of Tafasitamab (MOR208) Combined with Lenalidomide in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Maddocks KJ et al.

ASH 2020;Abstract 3021.

L-MIND: Summary

Clinical endpoint	N = 80
ORR	57.5%
CR	40.0%
Median DOR	34.6 mo
24 mo DOR rate	71.3%
24 mo OS rate	57.2%

In the subgroup analysis, patients with CR as best objective response had better outcomes than those with PR:

- Median DOR: NR vs 5.6
- 24-month DOR rate: 86.4% vs 38.5%
- 24-month OS rate: 90.6% vs 42.7%

Maddocks KJ et al. ASH 2020;Abstract 3021.

FDA Approves Selinexor for Relapsed/Refractory Diffuse Large B-Cell Lymphoma

Press Release – June 22, 2020

"The Food and Drug Administration granted accelerated approval to selinexor for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

Approval was based on SADAL (KCP-330-009; NCT02227251), a multicenter, single-arm, open-label trial in patients with DLBCL after 2 to 5 systemic regimens. Patients received selinexor 60 mg orally on days 1 and 3 of each week."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-selinexor-relapsedrefractory-diffuse-large-b-cell-lymphoma

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

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%

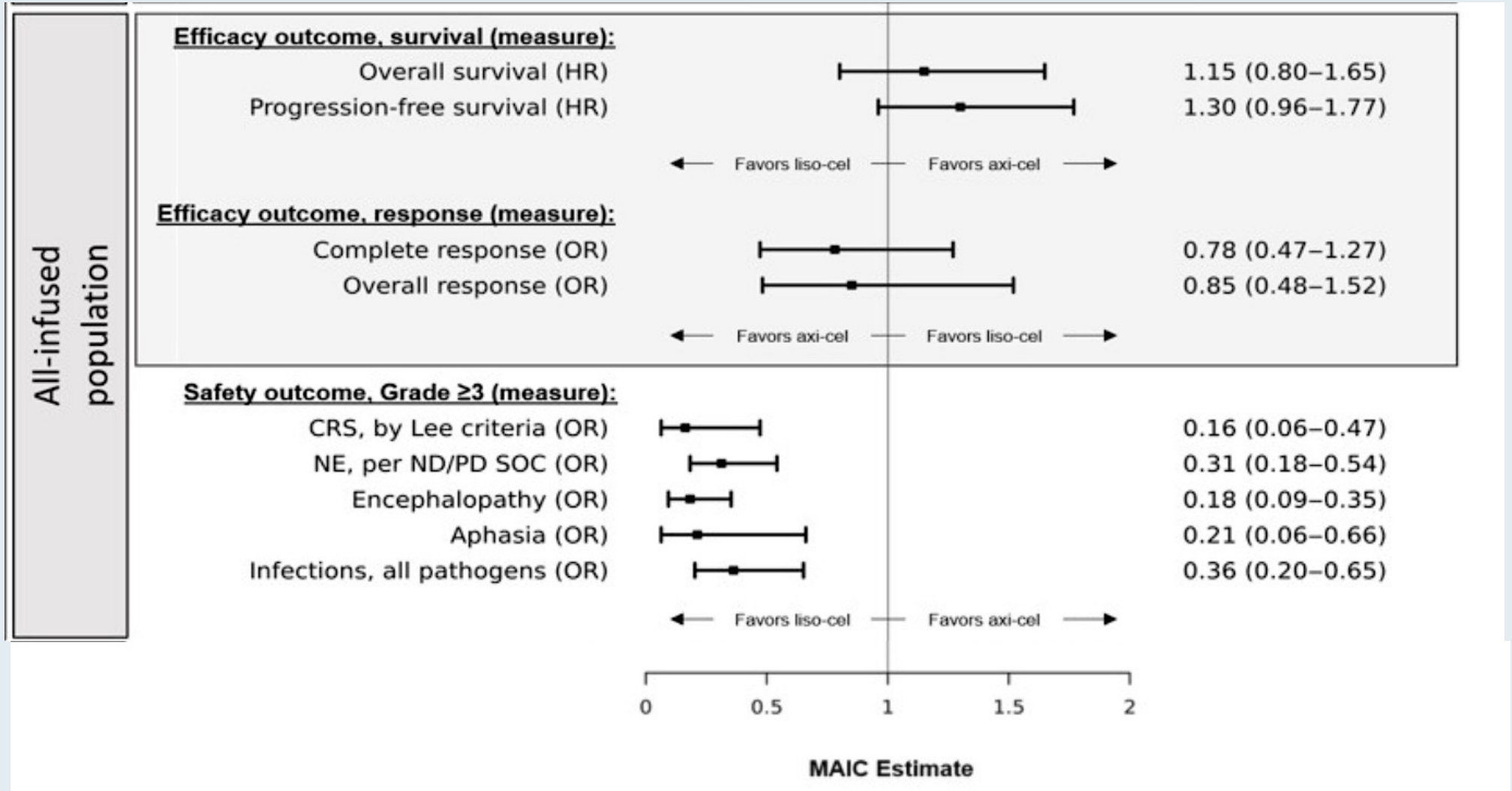
Locke F et al; ZUMA-1 Investigators. *Lancet Oncol* 2019;20(1):31-42.
Schuster SJ et al; JULIET Investigators. *N Engl J Med* 2019;380(1):45-56.
Abramson JS et al; TRANSCEND NHL 001 Investigators. *Proc ASCO* 2018;Abstract 7505.

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.

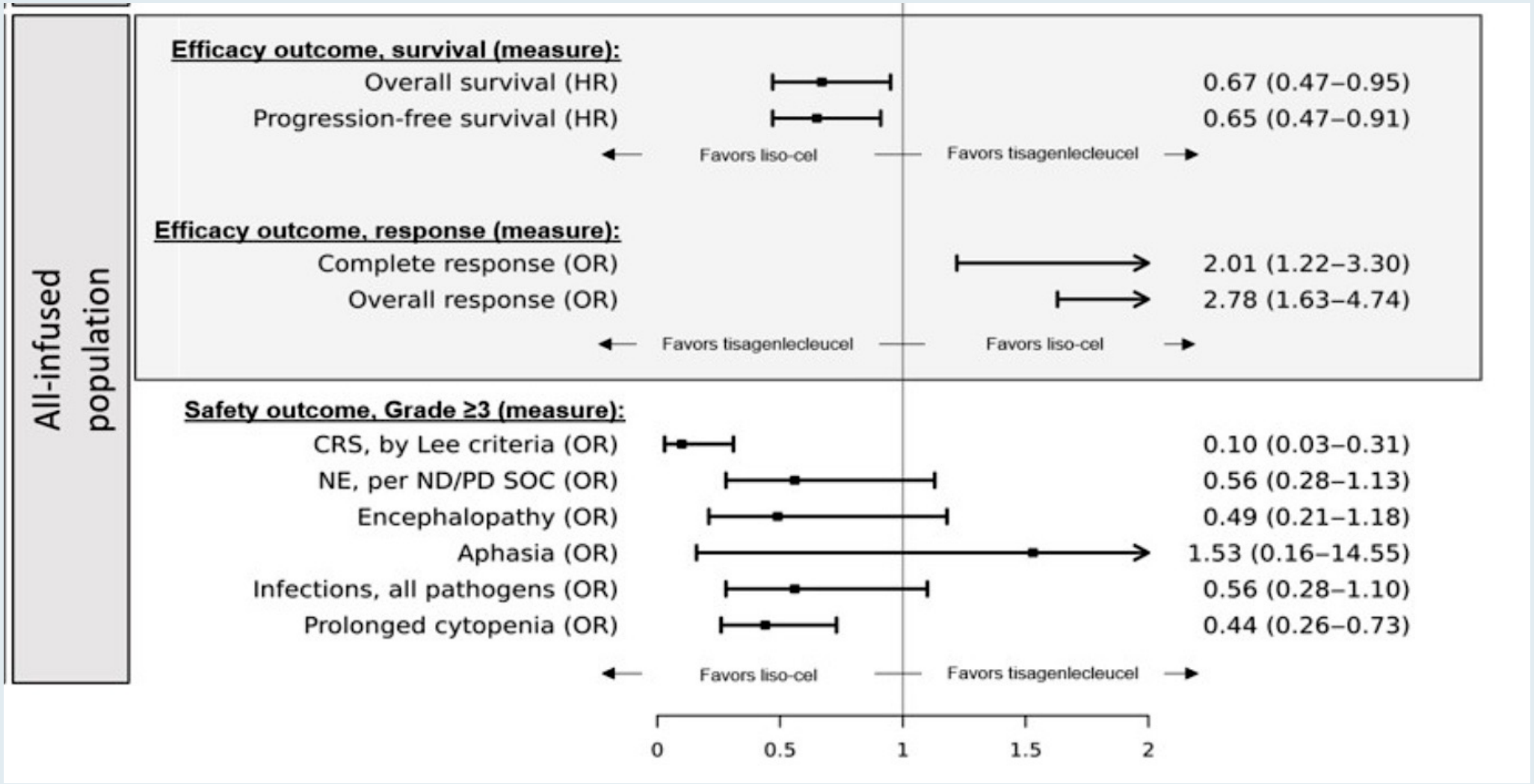
ASH 2020;Abstract 2116.

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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Agenda

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Case 5 (Ms Gideon): A 70-year-old man with relapsed mantle cell lymphoma

Case Presentation – A 70-year-old man with relapsed mantle cell lymphoma

Ms Gideon

- PMH: DM, HTN, leptomeningeal disease
- Truck driver, primary caregiver to his 92-year-old mother
- R-CHOP
- Ibrutinib/venetoclax → Symptomatic PD
- CAR T-cell therapy with brexucabtagene autoleucel
  - Grade 3 neurotoxicity for 3-4 days, requiring high-dose steroids
  - By day 30, very good PR with only inguinal adenopathy remaining

What is generally the most common second-line therapy for patients with mantle cell lymphoma who experience disease progression on first-line BR?

1. A BTK inhibitor (eg, ibrutinib, acalabrutinib, zanubrutinib)
2. Lenalidomide/rituximab
3. Bortezomib
4. Venetoclax
5. I don’t know

Acalabrutinib may result in fewer of the toxicities commonly associated with ibrutinib, but it is noteworthy for the occurrence of _____ during the first month of treatment.

1. Hair loss
2. Headache
3. Constipation
4. Visual disturbances
5. I don’t know

Overview of FDA-Approved BTK Inhibitors for MCL

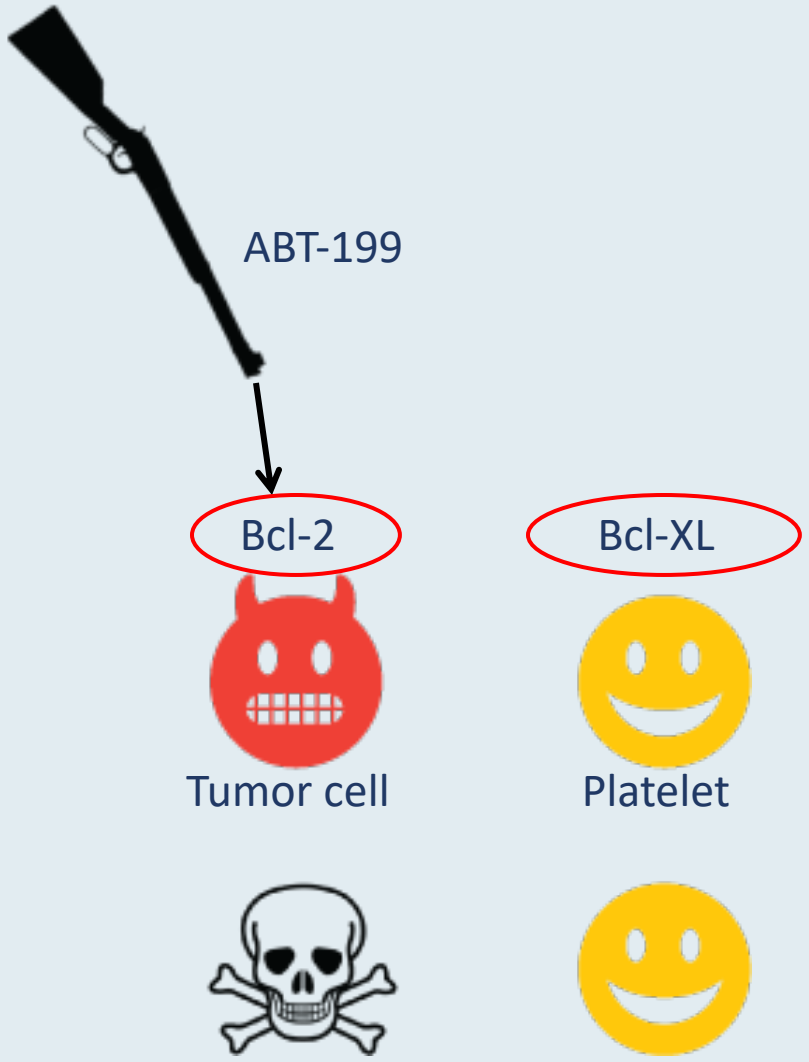
Ibrutinib, Acalabrutinib and Zanubrutinib

- **Similar overall response rates, ~70-80%**
  - **Better when used earlier (2nd or 3rd line)**
- **Improved toxicity profile for acalabrutinib and zanubrutinib**
  - **More headache with acalabrutinib, especially in first weeks of Rx – responds to caffeine**
  - **More specific BTKi inhibition (zanubrutinib similar to acalabrutinib)**
  - **Less afibrillation, bruising/bleeding, arthralgia**
  - **Prefer over ibrutinib if concurrent anticoagulation and/or anti-platelet therapy**

Herman et al, Clin Ca Res 2017

Courtesy of Michael E Williams, MD, ScM

Mechanism of Action of Venetoclax (ABT-199)



- **Bcl-2 functions to prevent cell death by apoptosis**
- **Venetoclax is specific for Bcl-2 and inhibits its function, thereby removing the block on apoptosis**

Adapted from Davids MS, Letai A. *Cancer Cell* 2013;23(2):139-41.

Venetoclax Monotherapy for BTK Inhibitor-Resistant MCL: Results Summary

Clinical endpoint	Venetoclax (N = 20)
Overall response rate (ORR) Complete response rate	60% 20%
ORR (prior response to BTKi) ORR (primary resistance to BTKi)	72.7% 44.4%
Median PFS	2.6 mo
Median OS	4.3 mo

No cases of clinical TLS were observed.

Eyre T et al. EHA 2018;Abstract S855.

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

13th Annual Oncology Grand Rounds

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

Multiple Myeloma

Tuesday, April 27, 2021
8:30 AM – 10:00 AM ET

Medical Oncologists

Shaji K Kumar, MD
Sagar Lonial, MD
Paul G Richardson, MD

Oncology Nurse Practitioners

Charise Gleason, MSN, NP-C, AOCNP
Patricia Mangan, RN, MSN, CRNP, APN, BC
Tiffany A Richards, PhD, ANP-BC, AOCNP

Moderator

Neil Love, MD

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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