13th Annual Oncology Grand Rounds

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

Acute Myeloid Leukemia

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

Medical Oncologists

Courtney D DiNardo, MD, MSCE
Eytan M Stein, MD

Oncology Nurse Practitioners

Ilene Galinsky, NP
Sonia Glennie, ARNP, MSN, OCN

Moderator

Neil Love, MD

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Medical Oncologists

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

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

Oncology Nurse Practitioners

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

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

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Commercial Support

This activity is supported by educational grants from AbbVie Inc and Genentech, a member of the Roche Group.

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Dr Love — Disclosures

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Dr DiNardo — Disclosures

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Ms Galinsky — Disclosures

No relevant conflicts of interest to disclose

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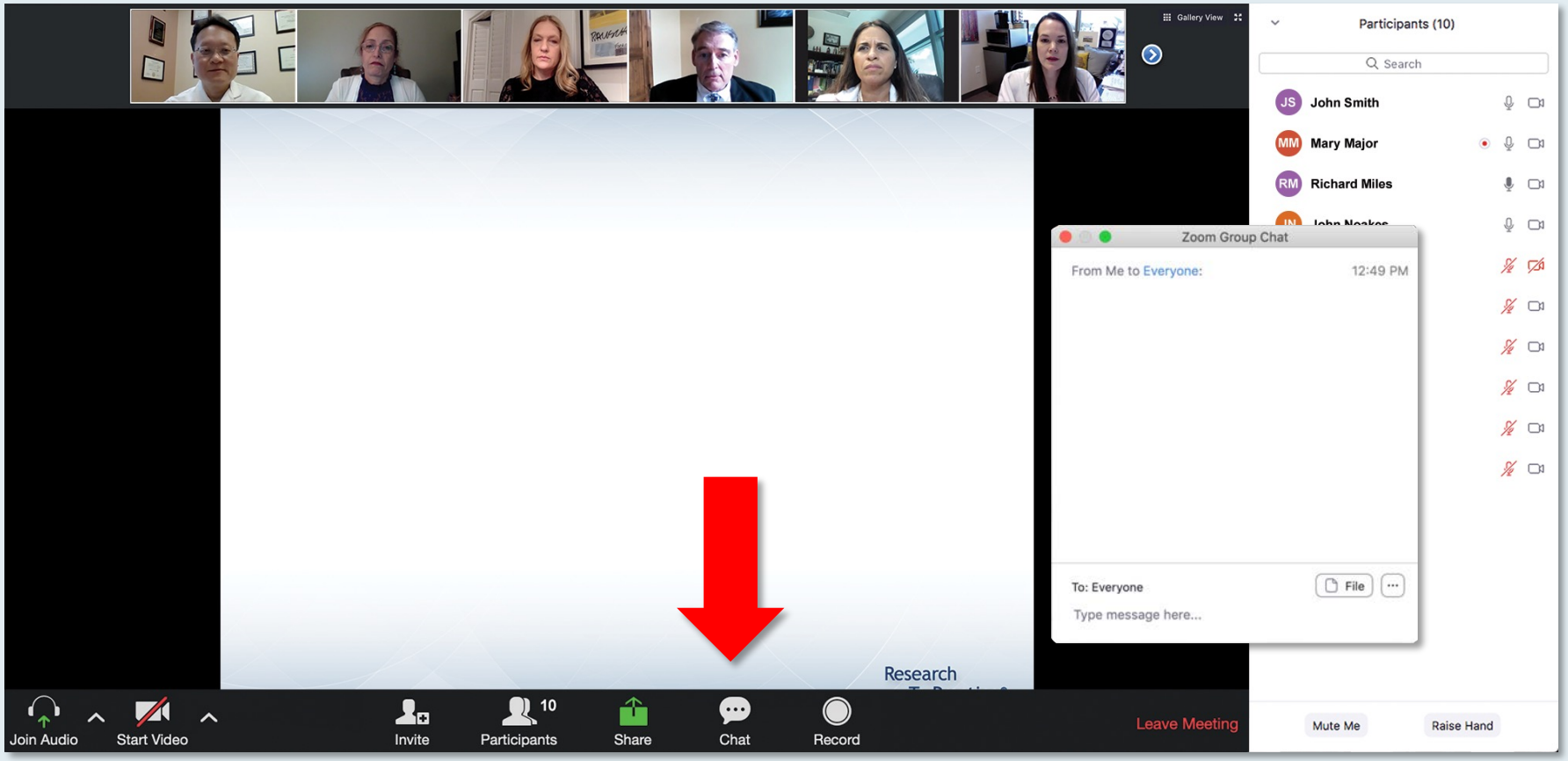
Ms Glennie — Disclosures

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

We Encourage Clinicians in Practice to Submit Questions



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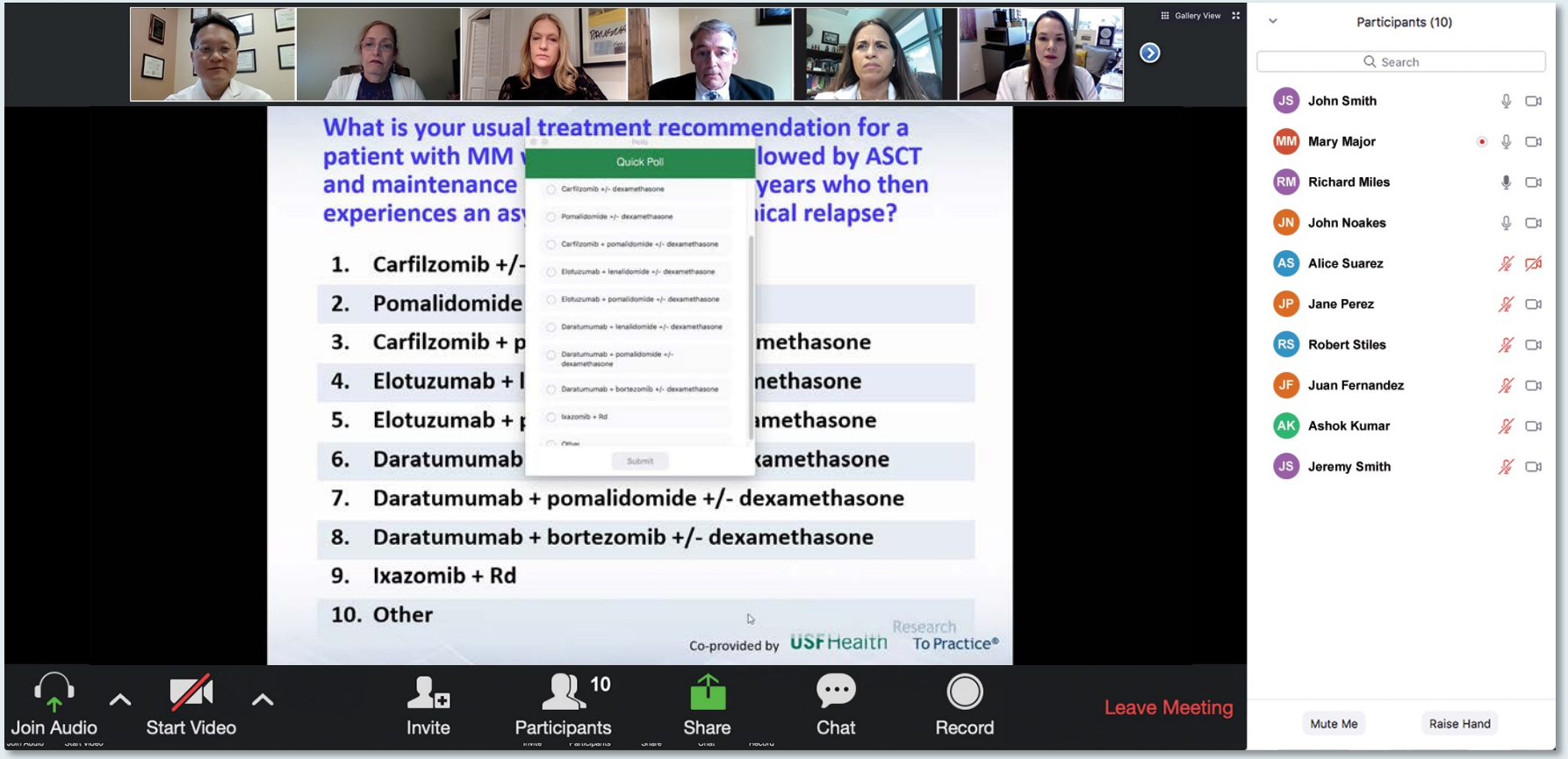
Familiarizing Yourself with the Zoom Interface

How to answer poll questions



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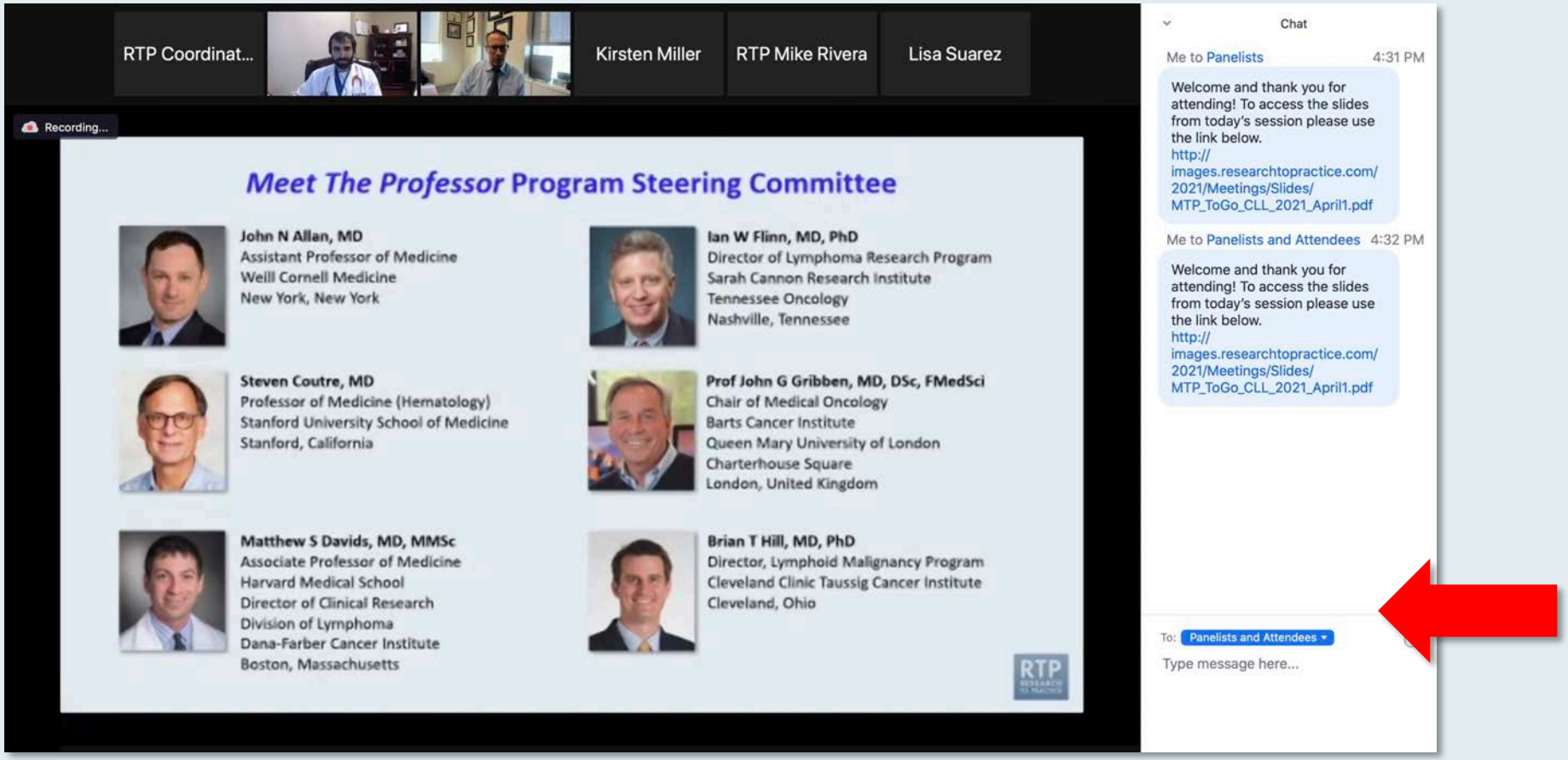
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



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

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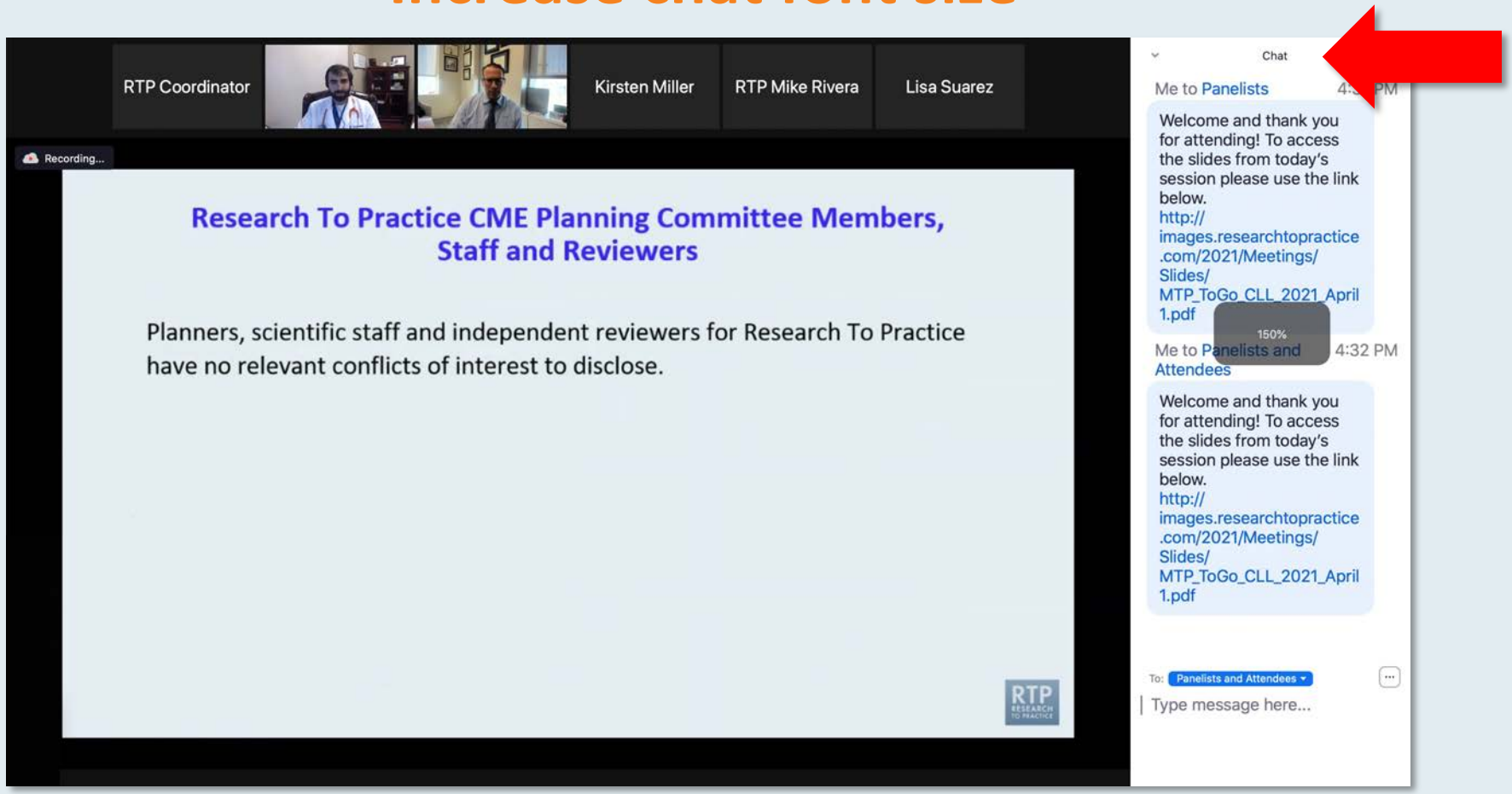

Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

ONCOLOGY TODAY

WITH DR NEIL LOVE

Key Presentations on Acute Myeloid Leukemia and Myelodysplastic Syndromes from the 2020 ASH Annual Meeting

DR HARRY ERBA
DUKE UNIVERSITY

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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

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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
5:00 PM – 6:30 PM ET

Multiple Myeloma
Tuesday, April 27, 2021
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Urothelial Bladder Carcinoma
Wednesday, April 28, 2021
12:00 PM – 1:00 PM ET

Chronic Lymphocytic Lymphoma
Thursday, April 29, 2021
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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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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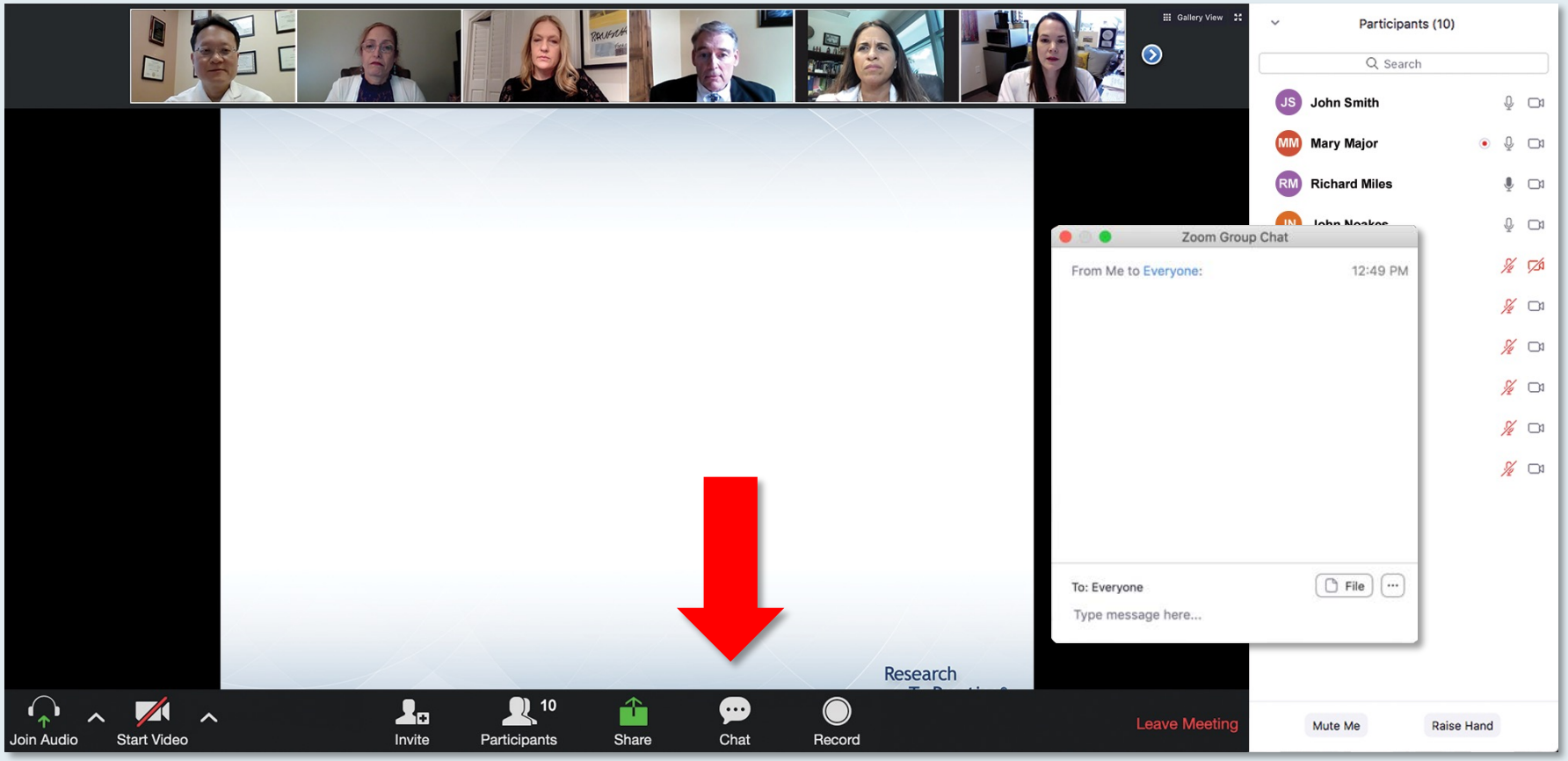

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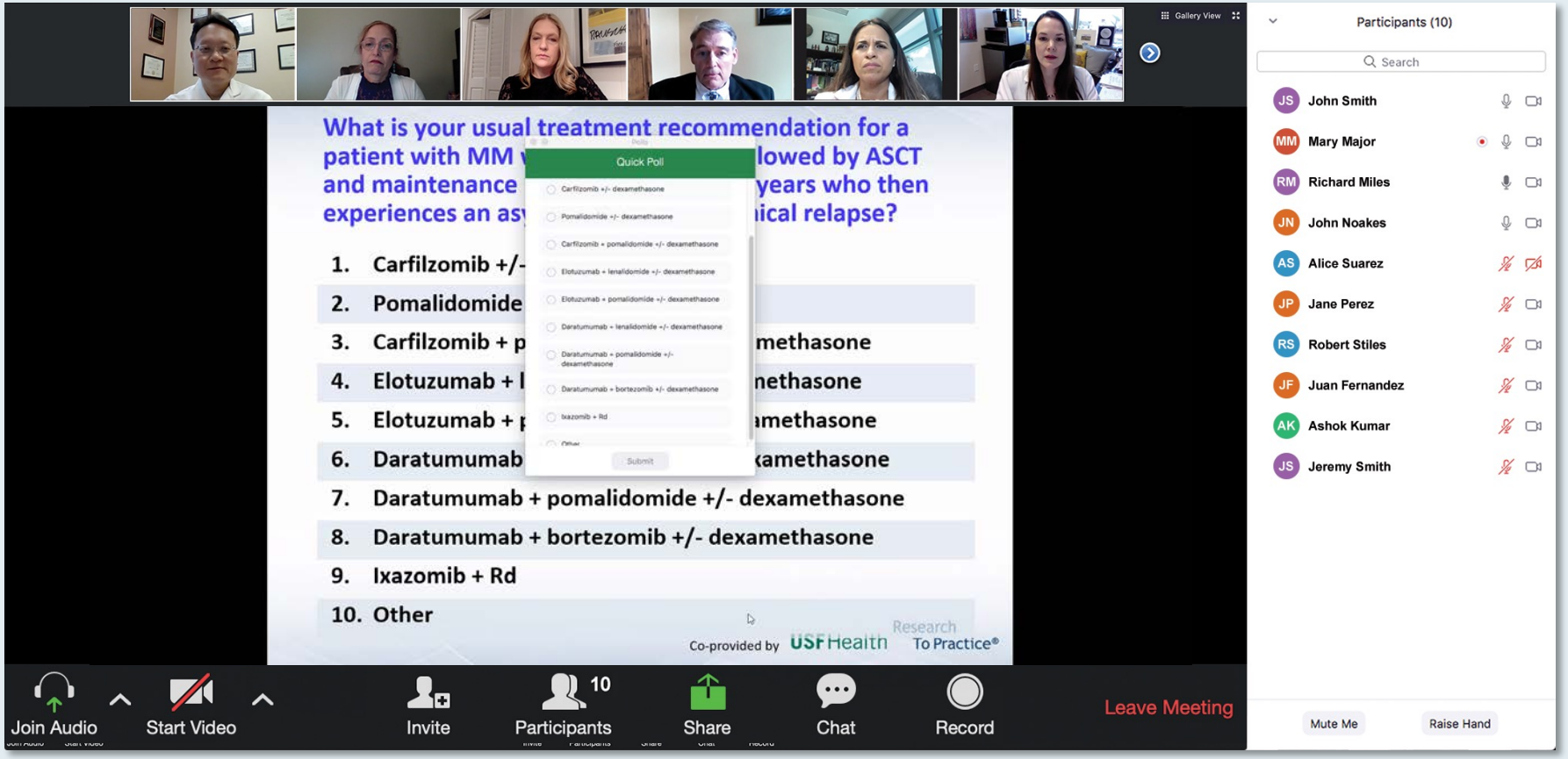

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Medical Oncologists

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
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

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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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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

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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RYDER TRAUMA CENTER
Jackson Memorial Hospital

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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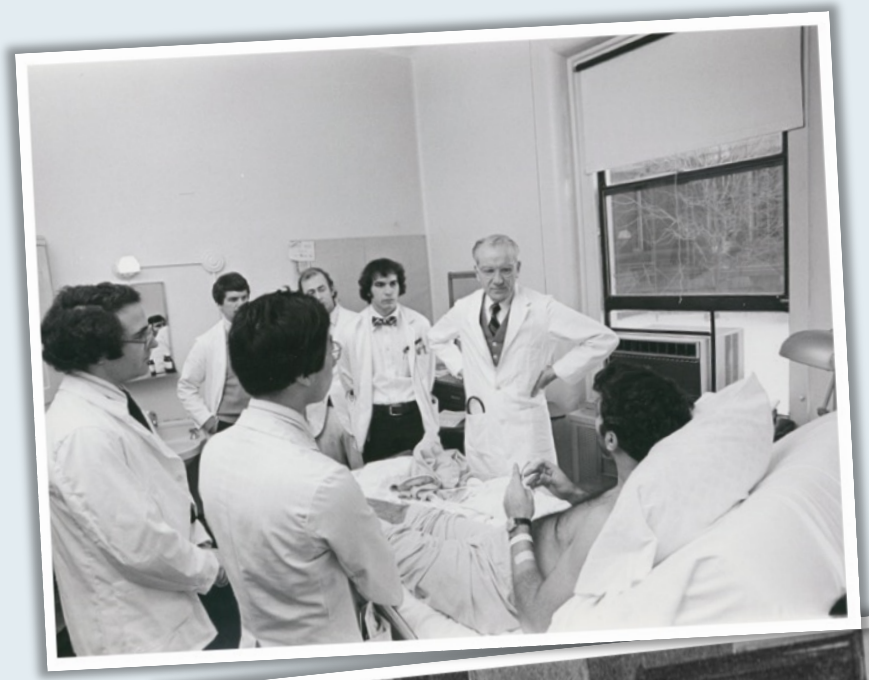

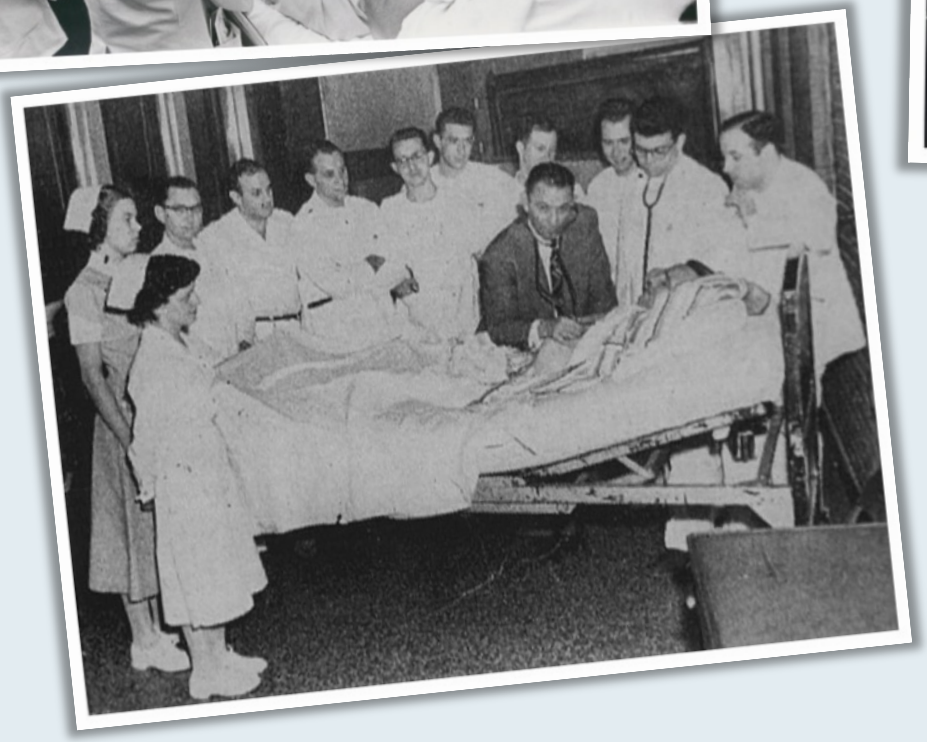


The Birmingham News

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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Neil Love, MD

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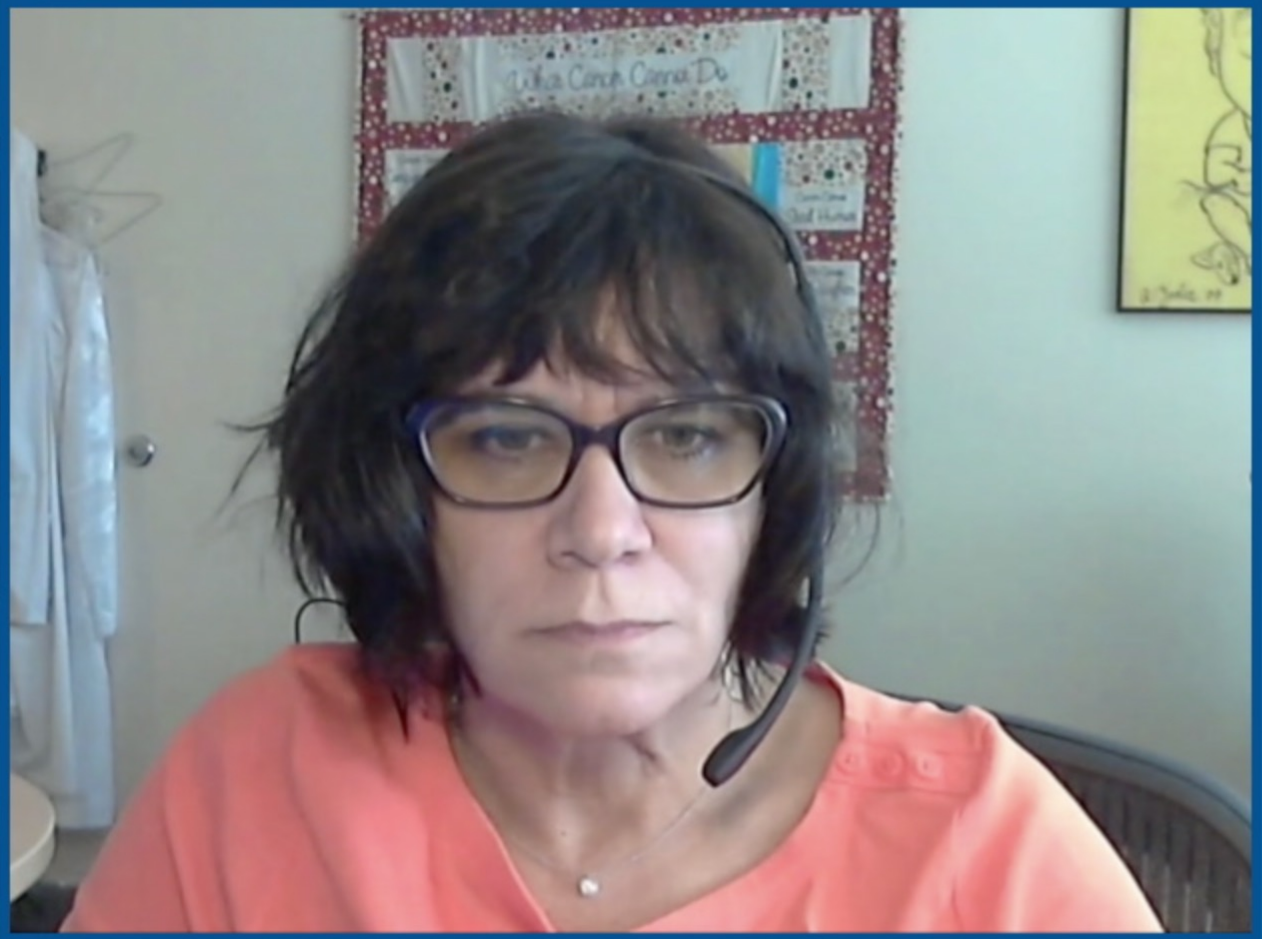

Ilene Ann Galinsky, NP

Sonia Glennie, ARNP MSN OCN

Agenda

Cases from the Practices of Ms Galinsky and Ms Glennie

- **Case 1 (Ms Galinsky): A 78-year-old woman with myelodysplastic syndrome who develops AML**
- **Case 2 (Ms Glennie): A 74-year-old woman – a Jehovah's Witness – who is diagnosed with AML**
- **Case 3 (Ms Galinsky): A 39-year-old man who develops AML with a FLT3 mutation**

Perspective on the evolution of treatments for AML

Ilene Galinsky, NP

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Agenda

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- **Case 3 (Ms Galinsky): A 39-year-old man who develops AML with a FLT3 mutation**

Case Presentation – A 78-year-old woman with myelodysplastic syndrome who develops AML (Part 1)

Ms Galinsky

- PMH: Psoriatic arthritis treated with adalimumab, ER+ breast cancer receiving letrozole
- Transfusion-dependent: darbepoetin alfa plus lenalidomide
- Azacitidine and venetoclax

Case Presentation – A 78-year-old woman with myelodysplastic syndrome who develops AML (Part 2)

Ms Galinsky

- PMH: Psoriatic arthritis treated with adalimumab, ER+ breast cancer receiving letrozole
- Transfusion-dependent: darbepoetin alfa plus lenalidomide
- Azacitidine and venetoclax
  - ***Dramatic response after cycle 2, has not required red blood transfusions***

Case Presentation – A 78-year-old woman with myelodysplastic syndrome who develops AML (Part 3)

Ms Galinsky

- PMH: Psoriatic arthritis treated with adalimumab, ER+ breast cancer receiving letrozole
- Transfusion-dependent: darbepoetin alfa plus lenalidomide
- Azacitidine and venetoclax
  - Dramatic response after cycle 2, has not required red blood transfusions
- ***Patient education regarding treatment with venetoclax and blood counts***

Impact of venetoclax and hypomethylating agents in the management of AML

Ilene Galinsky, NP

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Which of the following agents is FDA approved in combination with venetoclax for acute myeloid leukemia (AML)?

1. Decitabine
2. Azacitidine
3. Low-dose cytarabine
4. All of the above
5. Only 1 and 2
6. I don’t know

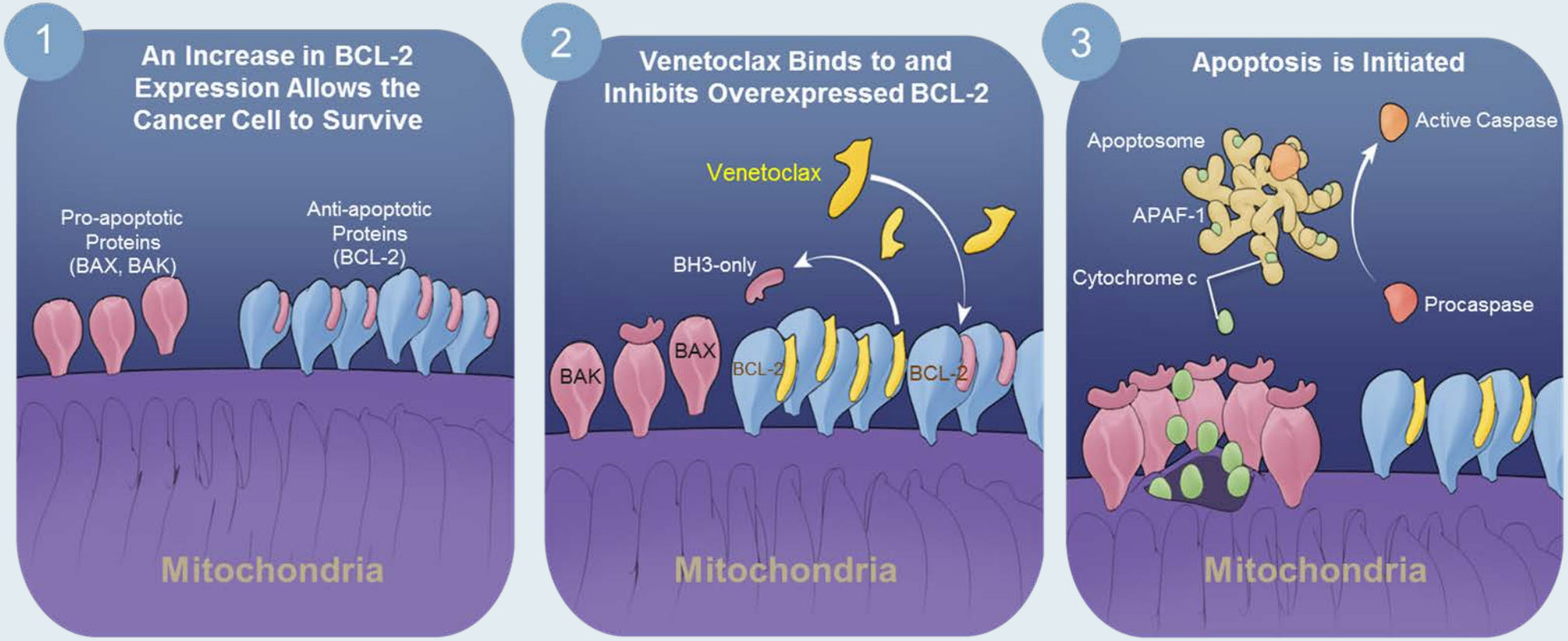
Venetoclax-based combination regimens are currently approved for AML in…

1. All patients
2. Patients who are not candidates for intensive chemotherapy
3. I don’t know

What is the most common side effect associated with venetoclax that leads to dose reduction or withholding therapy?

1. GI toxicity
2. Cytopenias
3. Renal dysfunction
4. Peripheral neuropathy

Venetoclax Mechanism of Action



- Cancer cells increase the expression of anti-apoptotic proteins to offset the increase in pro-apoptotic proteins, tipping the balance toward cell survival
- The large # of pro-apoptotic proteins bound and sequestered by Bcl-2 in AML make them “primed” for death

Kumar S et al. ASCO 2015;Abstract 8576.

FDA Grants Regular Approval to Venetoclax in Combinations for Untreated Acute Myeloid Leukemia

Press Release – October 16, 2020

"The Food and Drug Administration granted regular approval to venetoclax in combination with azacitidine, decitabine, or low-dose cytarabine (LDAC) for newly-diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities precluding intensive induction chemotherapy.

Venetoclax was initially granted accelerated approval for this indication in November 2018.

Efficacy was confirmed in two randomized, double-blind, placebo-controlled trials in patients with AML described above.

In VIALE-A (NCT02993523), patients were randomized to receive venetoclax plus azacitidine (n=286) or placebo plus azacitidine (n=145). Efficacy was established based on an improvement in overall survival (OS).

In VIALE-C (NCT03069352), patients were randomized to receive venetoclax plus LDAC (n=143) or placebo plus LDAC (n=68). Efficacy was based on CR rate and duration of CR."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-regular-approval-venetoclax-combination-untreated-acute-myeloid-leukemia

N Engl J Med 2020;383:617-29.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 13, 2020 VOL. 383 NO. 7

Azacitidine and Venetoclax in Previously Untreated Acute Myeloid Leukemia

C.D. DiNardo, B.A. Jonas, V. Pullarkat, M.J. Thirman, J.S. Garcia, A.H. Wei, M. Konopleva, H. Döhner, A. Letai, P. Fenaux, E. Koller, V. Havelange, B. Leber, J. Esteve, J. Wang, V. Pejsa, R. Hájek, K. Porkka, Á. Illés, D. Lavie, R.M. Lemoli, K. Yamamoto, S.-S. Yoon, J.-H. Jang, S.-P. Yeh, M. Turgut, W.-J. Hong, Y. Zhou, J. Potluri, and K.W. Pratz

VIALE-A Study Design

(NCT02993523)

Eligibility

Inclusion

- Patients with newly diagnosed confirmed AML
- Ineligible for induction therapy defined as **either**
  - ❖ ≥75 years of age
  - ❖ 18 to 74 years of age with at least one of the comorbidities:
    - CHF requiring treatment or Ejection Fraction ≤50%
    - Chronic stable angina
    - DLCO ≤65% or FEV_1 ≤65%
    - ECOG 2 or 3

Exclusion

- Prior receipt of any HMA, venetoclax or chemotherapy for myelodysplastic syndrome
- Favorable risk cytogenetics per NCCN
- Active CNS involvement

Randomization 2:1
N = 433*

Treatment

Venetoclax + Azacitidine
(n = 286)
Venetoclax 400 mg PO, daily, days 1–28 +
Azacitidine 75 mg/m² SC /IV days 1–7

Placebo + Azacitidine
(n = 145)
Placebo daily, days 1–28
+ Azacitidine 75 mg/m² SC /IV days 1–7

Endpoints

Primary

- Overall survival

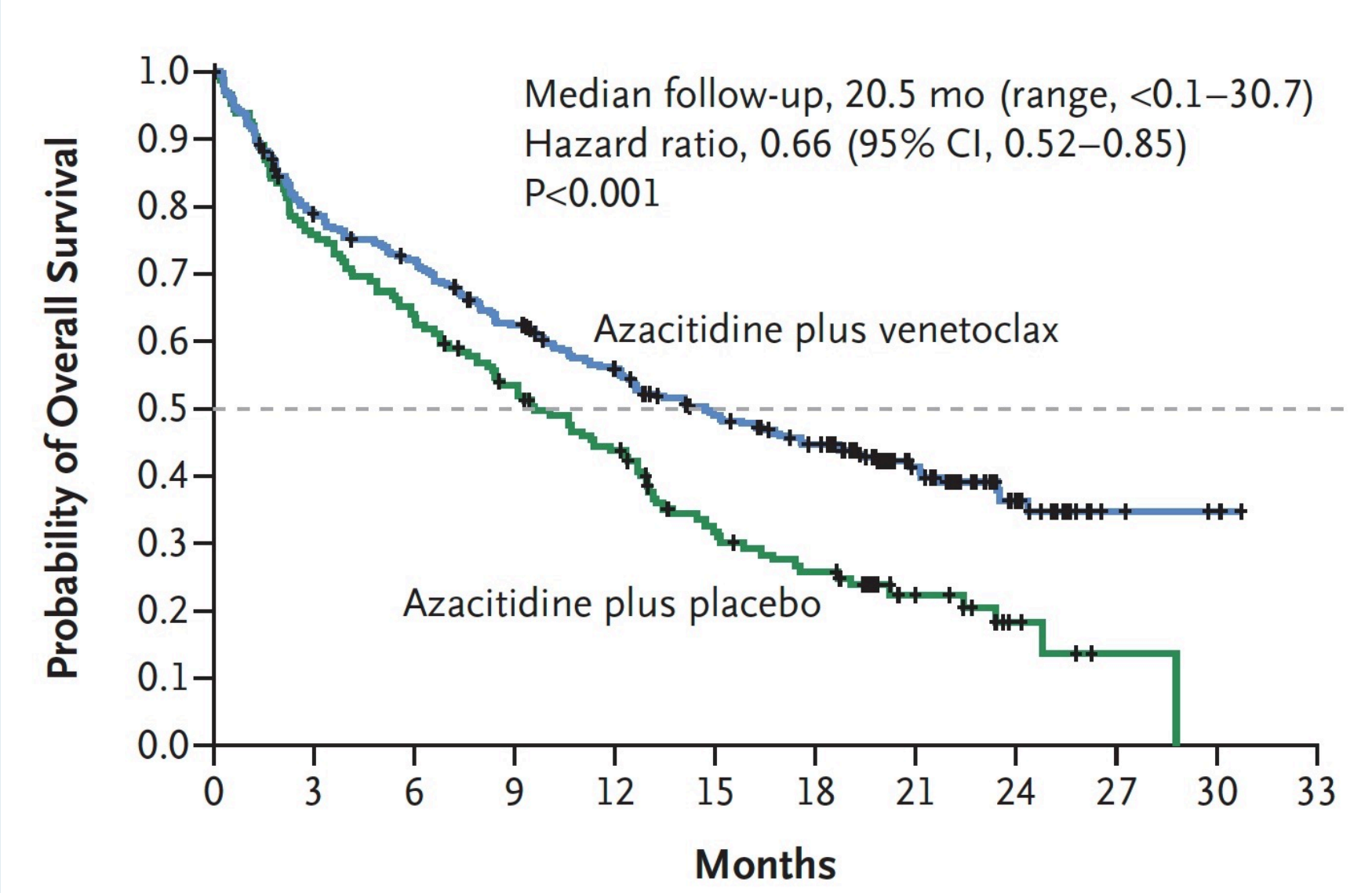
Secondary

- CR+CRi rate
- CR+CRh rate
- CR+CRi and CR+CRh rates by initiation of cycle 2
- CR rate
- Transfusion independence
- CR+CRi rates and OS in molecular subgroups
- Event-free survival

Randomization stratification factors	Age (<75 vs ≥75 years); Cytogenetic risk (intermediate, poor); Region
Venetoclax dosing ramp-up	**Cycle 1 ramp-up** Day 1: 100 mg, Day 2: 200 mg, Day 3-28: 400 mg **Cycle 2** Day 1-28: 400 mg

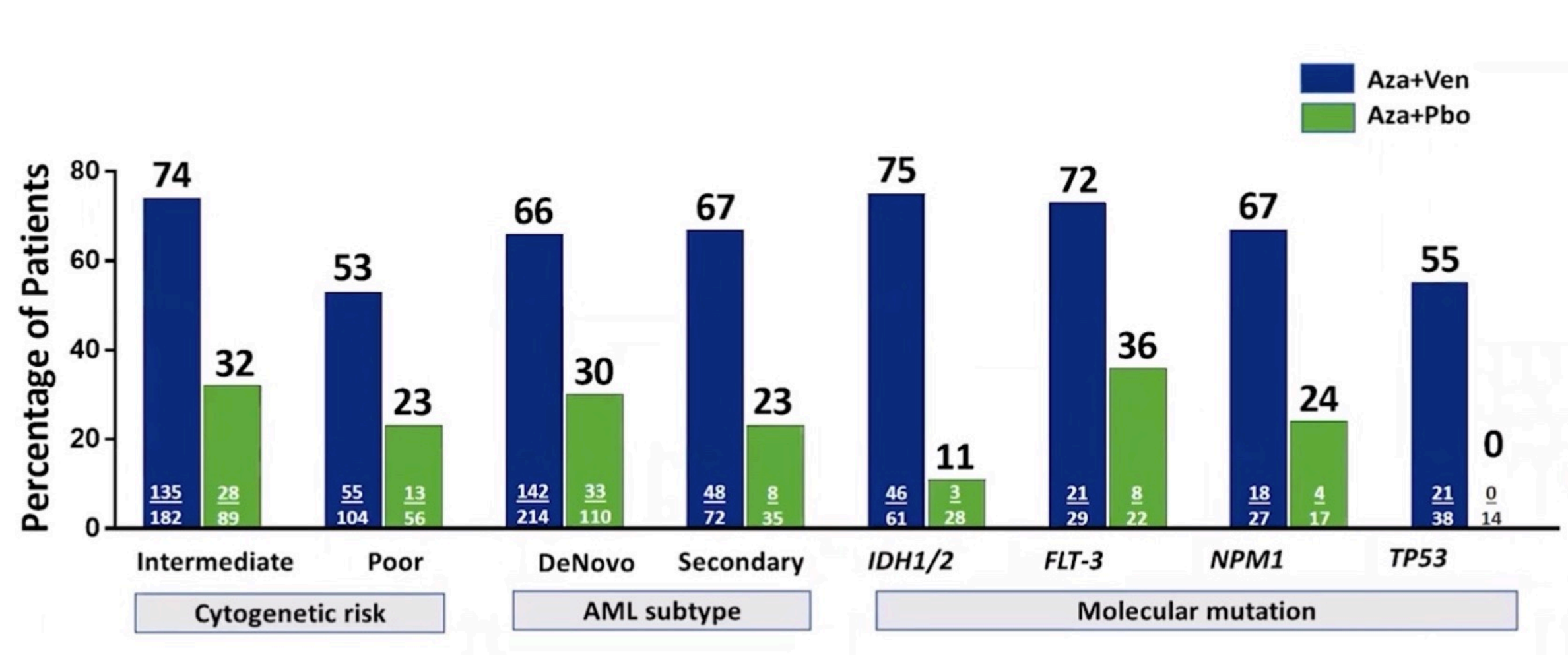
DiNardo CD et al. *N Engl J Med* 2020;383:617-29.

VIALE-A: Overall Survival (N = 431)



DiNardo CD et al. *N Engl J Med* 2020;383:617-29.

VIALE-A: Response Rates (CR + CRi) in Subgroups



DiNardo C et al. EHA 2020;Abstract LB2601.

VIALE-A: Selected Serious Adverse Events

	Azacitidine/venetoclax (n = 283)		Azacitidine/placebo (n = 144)	
	All grades	Grade ≥3	All grades	Grade ≥3
Serious AEs	83%	82%	73%	71%
Febrile neutropenia	30%	30%	10%	10%
Anemia	5%	5%	4%	4%
Neutropenia	5%	5%	2%	2%
Atrial fibrillation	5%	4%	1%	1%
Pneumonia	17%	16%	22%	22%
Sepsis	6%	6%	8%	8%

DiNardo CD et al. *N Engl J Med* 2020;383:617-29.

blood®
Regular Article

CLINICAL TRIALS AND OBSERVATIONS

Venetoclax plus LDAC for newly diagnosed AML ineligible for intensive chemotherapy: a phase 3 randomized placebo-controlled trial

Andrew H. Wei,[1,2] Pau Montesinos,[3,4] Vladimir Ivanov,[5] Courtney D. DiNardo,[6] Jan Novak,[7,8] Kamel Laribi,[9] Inho Kim,[10] Don A. Stevens,[11] Walter Fiedler,[12] Maria Pagoni,[13] Olga Samoilova,[14] Yu Hu,[15] Achilles Anagnostopoulos,[16] Julie Bergeron,[17] Jing-Zhou Hou,[18] Vidhya Murthy,[19] Takahiro Yamauchi,[20] Andrew McDonald,[21] Brenda Chyla,[22] Sathej Gopalakrishnan,[22] Qi Jiang,[22] Wellington Mendes,[22] John Hayslip,[22] and Panayiotis Panayiotidis[23]

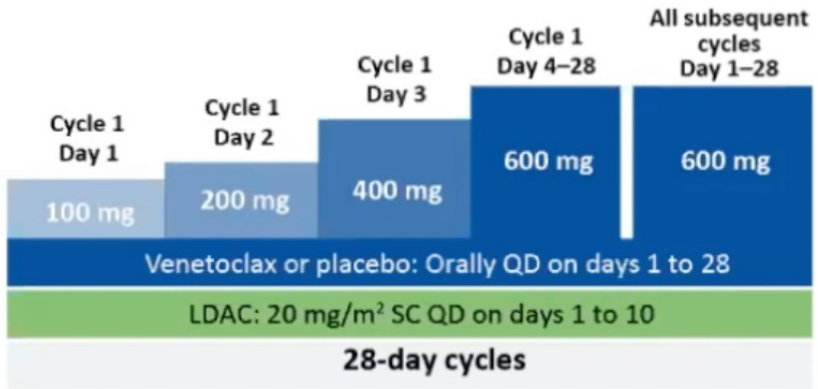
Blood 2020;135(24):2137-45.

VIALE-C Phase 3 Study Design

- Randomized 2:1, double-blind, placebo-controlled trial

Stratification factors

- AML status (secondary vs de novo)
- Age (18 to <75 vs ≥75)
- Region (US, EU, China, Japan, ROW)



Primary endpoint: overall survival

Secondary endpoints

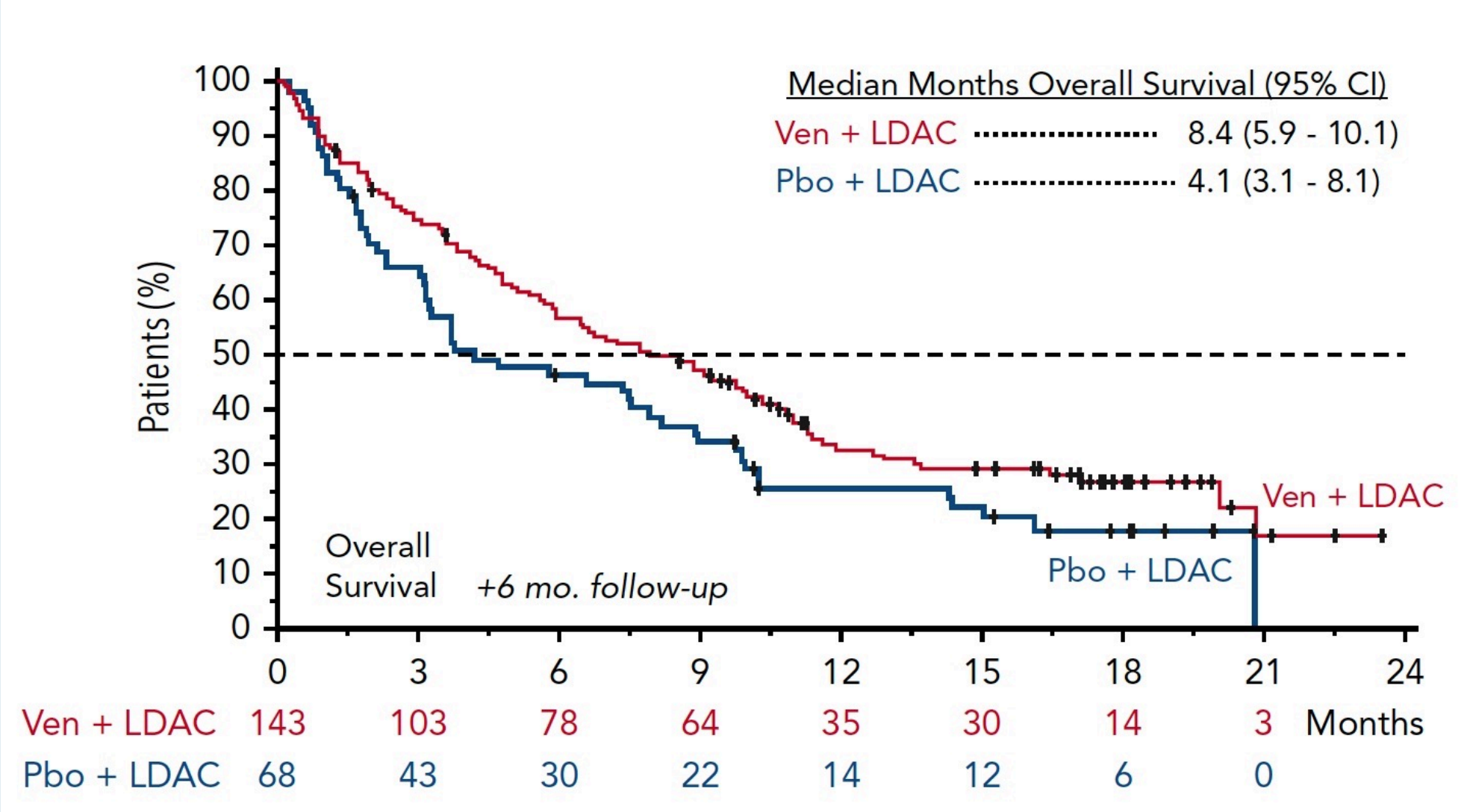
- CR, CRh, and CRi (modified IWG criteria[1])
- Rate of transfusion independence
- EFS
- MRD

Progressive disease was defined per ELN recommendations.[2]

AML, acute myeloid leukemia; CR, complete remission; CRh, CR with partial hematologic recovery; CRi, CR with incomplete blood count recovery; EFS, event-free survival; ELN, European LeukemiaNet; IRT, Interactive Response Technology; IWG, International Working Group; LDAC, low-dose cytarabine; MRD, minimal residual disease; OS, overall survival; QD, once a day; ROW, rest of world; SC, subcutaneous.

1. Cheson BD, et al. *J Clin Oncol.* 2003;21:4642-4649; 2. Döhner H, et al. *Blood.* 2017;129:424-447.

VIALE-C: Overall Survival



Wei AH et al. *Blood* 2020;135(24):2137-45.

VIALE-C: Selected Serious Adverse Events

AE	n (%)	
	Placebo + LDAC (n = 68)	Venetoclax + LDAC (n = 142)
Selected key AML serious AEs		
Febrile neutropenia	12 (18)	23 (16)
Pneumonia	7 (10)	18 (13)
Sepsis	4 (6)	8 (6)
Thrombocytopenia	2 (3)	7 (5)
Anemia	0	4 (3)
Neutropenia	0	4 (3)

Wei AH et al. *Blood* 2020;135(24):2137-45.

Agenda

Cases from the Practices of Ms Galinsky and Ms Glennie

- Case 1 (Ms Galinsky): A 78-year-old woman with myelodysplastic syndrome who develops AML
- Case 2 (Ms Glennie): A 74-year-old woman – a Jehovah's Witness – who is diagnosed with AML
- Case 3 (Ms Galinsky): A 39-year-old man who develops AML with a FLT3 mutation

Case Presentation – A 74-year-old woman – a Jehovah's Witness – who is diagnosed with AML (Part 1)

Ms Glennie

- Jehovah's Witness diagnosed with AML
- Molecular testing: No targetable mutations
- No use of blood products due to her faith
- Azacitidine dose-reduced and administered in the hospital x 1 month
  - Pancytopenia
  - Epoetin alfa, tranexamic acid, romiplostim
- Venetoclax added with cycle 3 without complication
  - Low MRD positivity

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Case Presentation – A 74-year-old woman – a Jehovah's Witness – who is diagnosed with AML (Part 2)

Ms Glennie

- Jehovah's Witness diagnosed with AML
- Molecular testing: No targetable mutations
- No use of blood products due to her faith
- Azacitidine dose-reduced and administered in the hospital x 1 month
  - Pancytopenia
  - Epoetin alfa, tranexamic acid, romiplostim
- Venetoclax added with cycle 3 without complication
  - Low MRD positivity
- ***Displayed profound faith and resolve while pancytopenic***

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Case Presentation – A 39-year-old man who develops AML with a FLT3 mutation

Ms Galinsky

- PMH: Anxiety, hypothyroidism
- Diagnosed with AML and FLT3 ITD mutation, NPM1+, DNMT3A
- Enrolled on a clinical trial: 7 + 3 and crenolanib versus midostaurin

The FLT3 inhibitors gilteritinib and midostaurin are effective against which of the following FLT3 mutation subtypes?

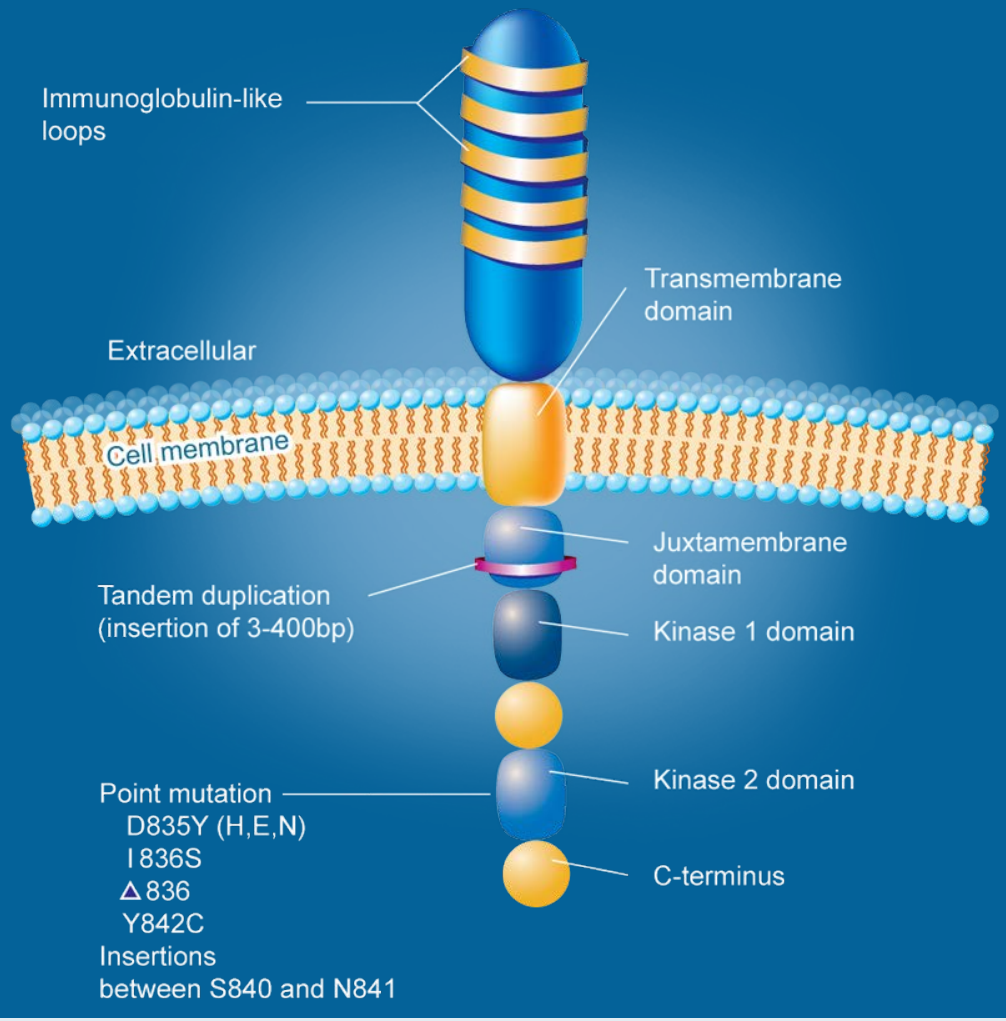
1. ITD (internal tandem duplication) mutations
2. TKD (tyrosine kinase domain) mutations
3. Both 1 and 2
4. I don’t know

FLT3 Mutations in AML

Approximately 30% of patients with AML have a FLT3 mutation

FLT3-ITD: 25% of patients with AML

FLT3-TKD: 5% of patients with AML



- **FLT3 ligand (FL) binding activates downstream pathways (↑ cell proliferation)**
- **FLT3 mutations associated with a poor prognosis**

Litzow MR. *Blood* 2005;106:3331-2; Small D. *Hematology Am Soc Hematol Educ Program* 2006:178-84; Swords R et al. *Leukemia* 2012;26(10):2176-85; Griffith J et al. *Mol Cell* 2004;13(2):169-78; Levis M. *Hematology Am Soc Hematol Educ Program* 2013;2013:220-6.

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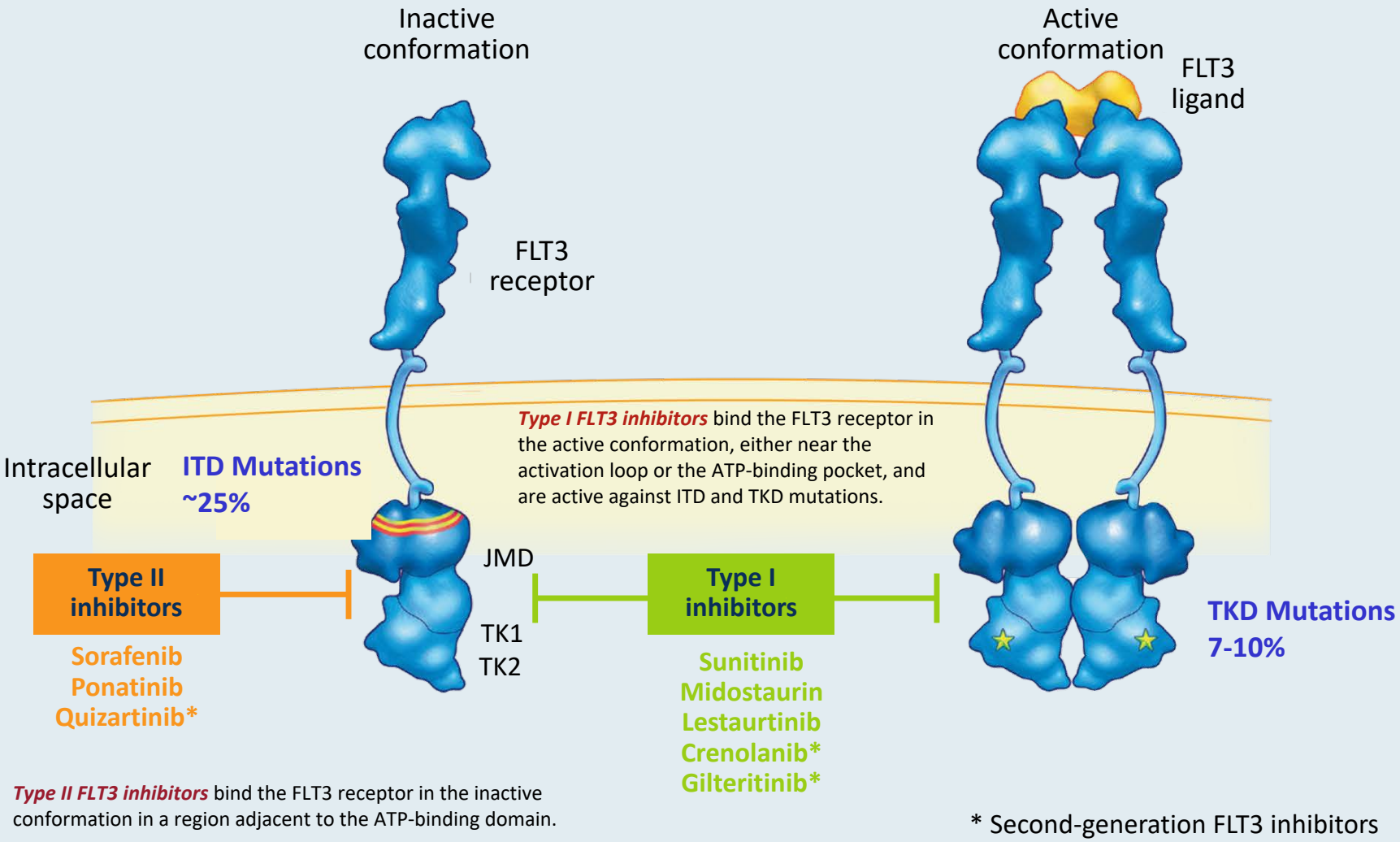
FLT3 Mutations (ITD and TKD) Occur in Approximately 30% to 35% of Patients with AML



Daver N et al. *Leukemia* 2019;33:299-312.

Characteristics of Select FLT3 Inhibitors

FLT3 inhibitor	Inhibitory type	FLT3 kinase inhibition IC50 (nmol/L)	Non-FLT3 targets	FLT3-TKD mutation activity	Major toxicities
Sorafenib 400 mg BID	II	58	c-KIT PDGFR RAF VEGFR	No	Rash Hemorrhage Myelosuppression
Midostaurin 50 mg BID	I	6.3	c-KIT PDGFR PKC VEGFR	Yes	GI toxicity Myelosuppression
Quizartinib 30 – 60 mg QD	II	1.6	c-KIT	No	QTc prolongation Myelosuppression
Gilteritinib 120 mg QD	I	0.29	AXL LTK ALK	Yes	Elevated transaminases Diarrhea

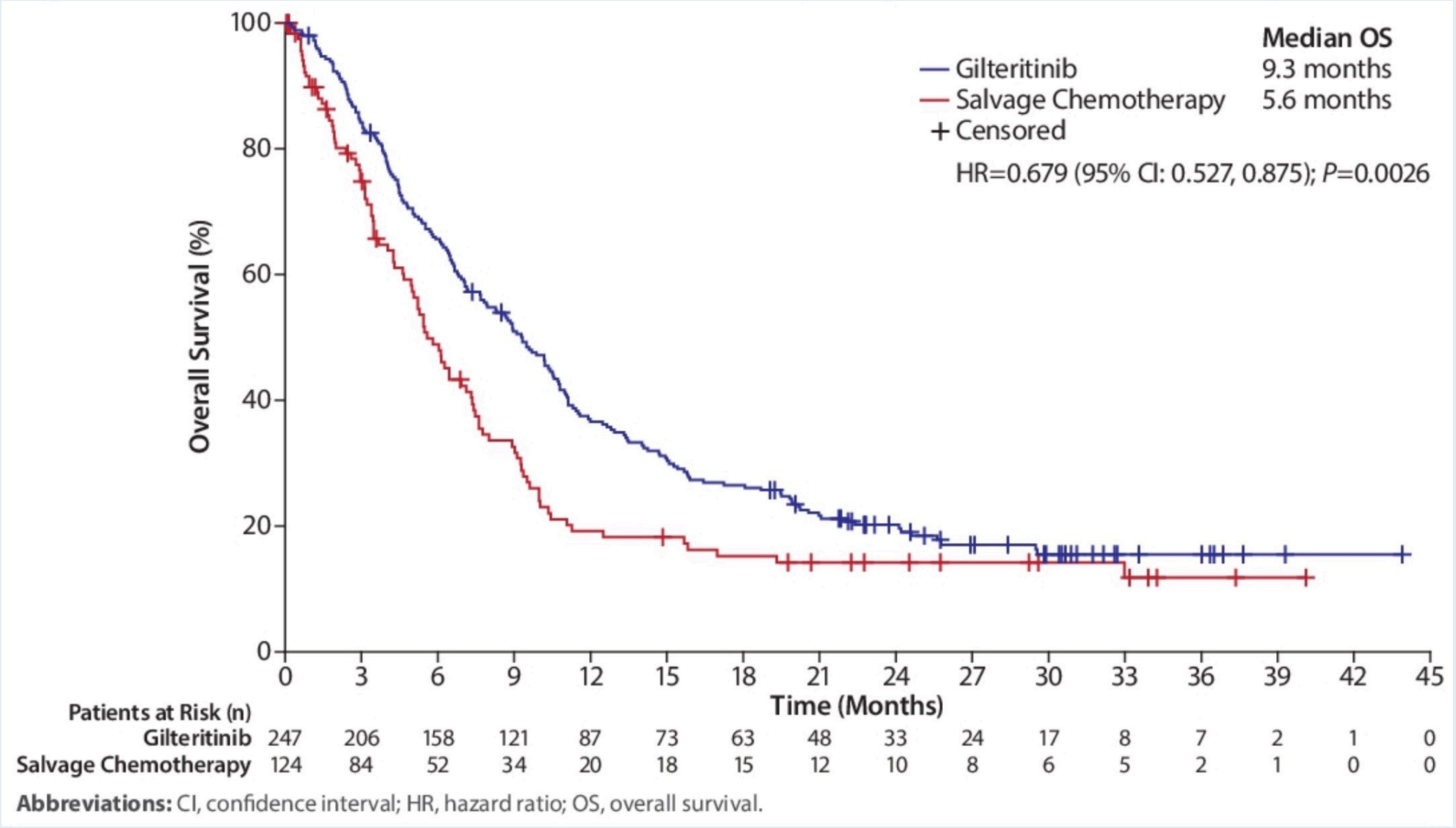
Kiyoi H et al. *Cancer Science* 2019;[Epub ahead of print];
Short NJ et al. *Ther Adv Hematol* 2019;10:2040620719827310.

Long-Term Survivors and Gilteritinib Safety Beyond One Year in *FLT3*-Mutated R/R AML: ADMIRAL Trial Follow-Up

Perl AE et al.

ASCO 2020;Abstract 7514

ADMIRAL: Overall Survival at 1 Year After the Primary Analysis



Abbreviations: CI, confidence interval; HR, hazard ratio; OS, overall survival.

Perl AE et al. ASCO 2020;Abstract 7514.

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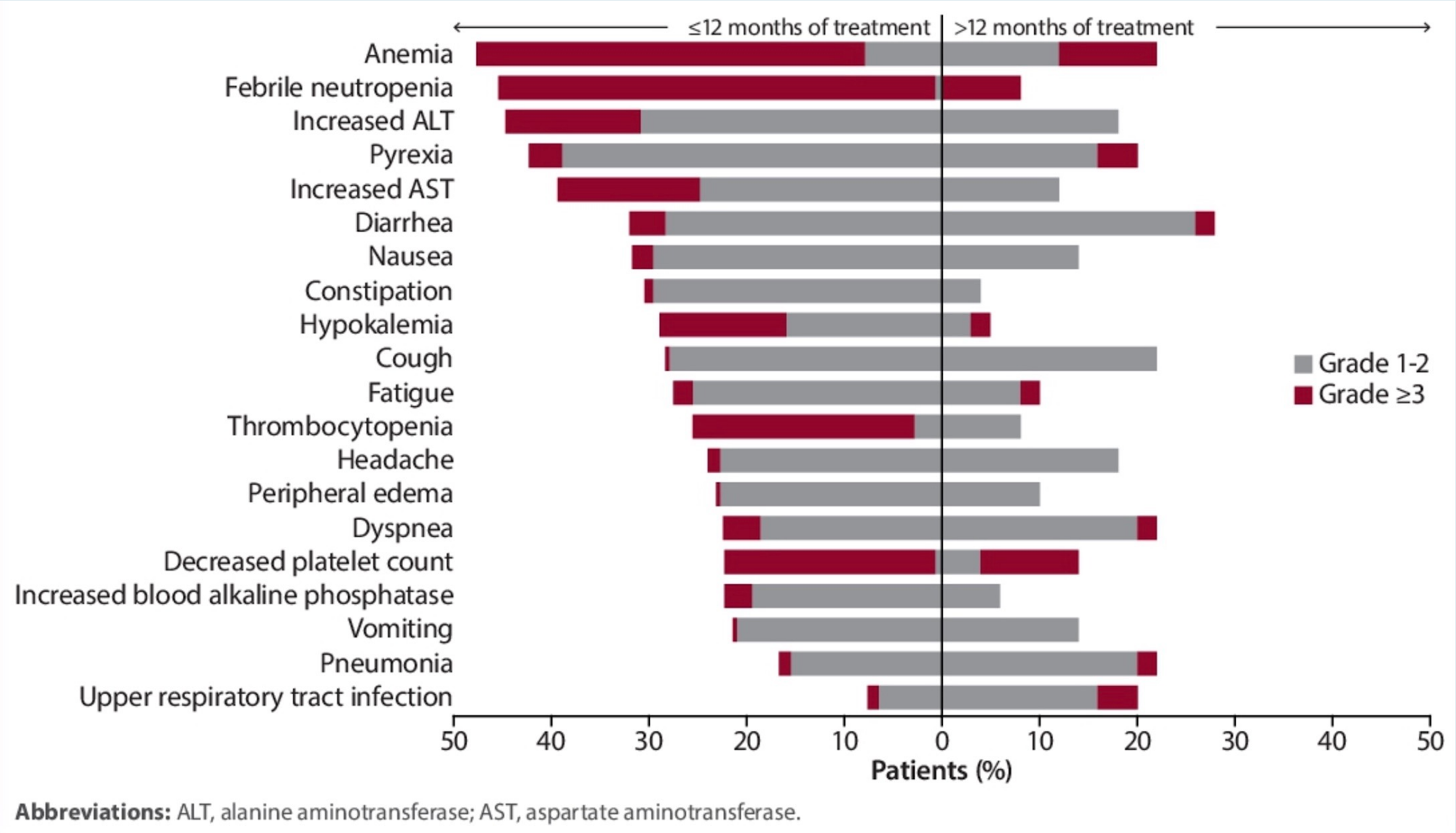
ADMIRAL: Adverse Events Occurring in ≥20% of Patients Receiving Gilteritinib



Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase.

Perl AE et al. ASCO 2020;Abstract 7514.

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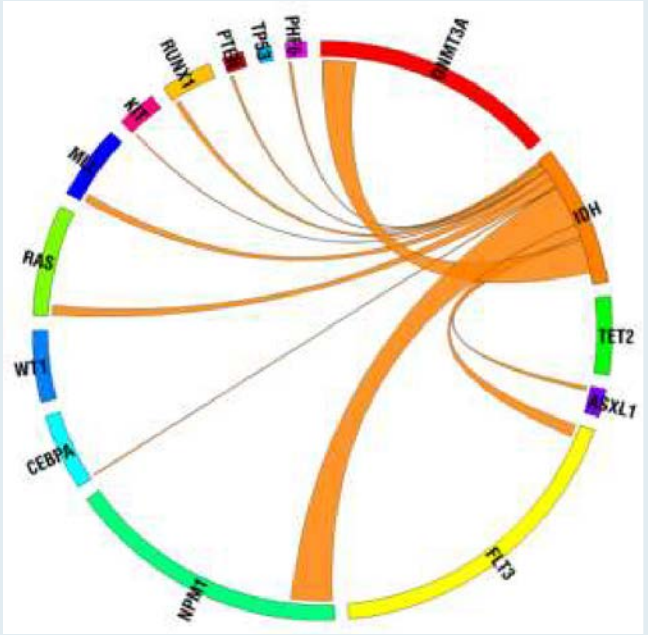
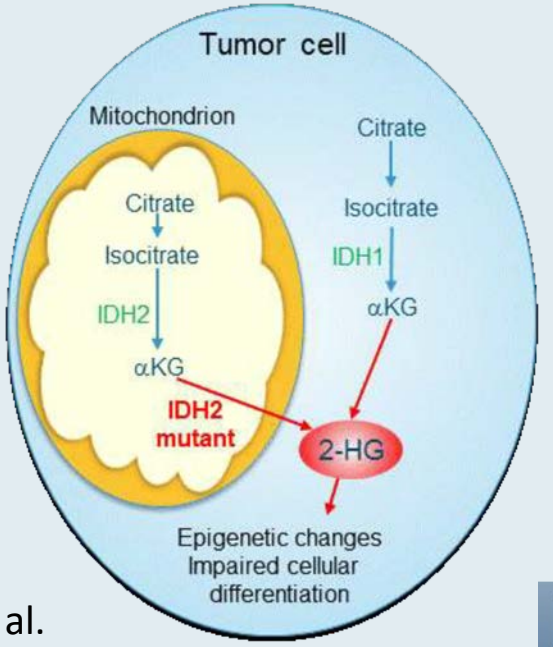
IDH Inhibitors

IDH in Leukemia

- **IDH mutations occur in ~20% of AML**
  - **Frequency: 6%-16% IDH1 and 8%-18% IDH2**
  - **Majority (85%) with diploid or +8 cytogenetics**
  - **↑ prevalence with ↑ patient age**
  - **Prognostic effect in AML remains controversial**
  - **IDH1 and IDH2 mutations may have different effects on prognosis**





Dang L et al. *Trends Mol Med* 2010;16(9):387-97. Chou WC et al. *Leukemia* 2011;25(2):246-53. Patel JP et al. *N Engl J Med* 2012;366(2):1079-89. Medeiros BC et al. *Leukemia* 2017;31:272-81.

Approved IDH Inhibitors in AML

- **Enasidenib – IDH2 inhibitor. Approved for relapsed and refractory IDH2 mutant AML.**
  - **Oral, given once daily, continuous 28 day cycles**
  - **Indirect hyperbilirubinemia**

- **Ivosidenib – IDH1 inhibitor. Approved for relapsed and refractory and newly diagnosed IDH1 mutant AML.**
  - **Oral, once daily, continuous 28 day cycles**
  - **QT prolongation**

- **In R/R AML, complete remission rates with IDH inhibitors is about 21%**

Courtesy of Eytan M Stein, MD

Frequency of Signs and Symptoms Consistent with IDH-Differentiation Syndrome

Sign or symptom	Patients with IDH-DS (N = 33)
Dyspnea	28 (85%)
Unexplained fever (body temp of 38.0°C for 2 d)	26 (79%)
Pulmonary infiltrates	24 (73%)
Hypoxia	19 (58%)
Acute kidney injury	14 (42%)
Pleural effusion	14 (42%)
Bone pain or arthralgia	9 (27%)
Lymphadenopathy	8 (24%)
Rash	8 (24%)
Disseminated intravascular coagulopathy	7 (21%)
Edema or weight gain of >5 kg from screening	7 (21%)
Pericardial effusion	5 (15%)

Fathi A et al. *JAMA Oncol* 2018;4(8):1106-10.

CPX-351

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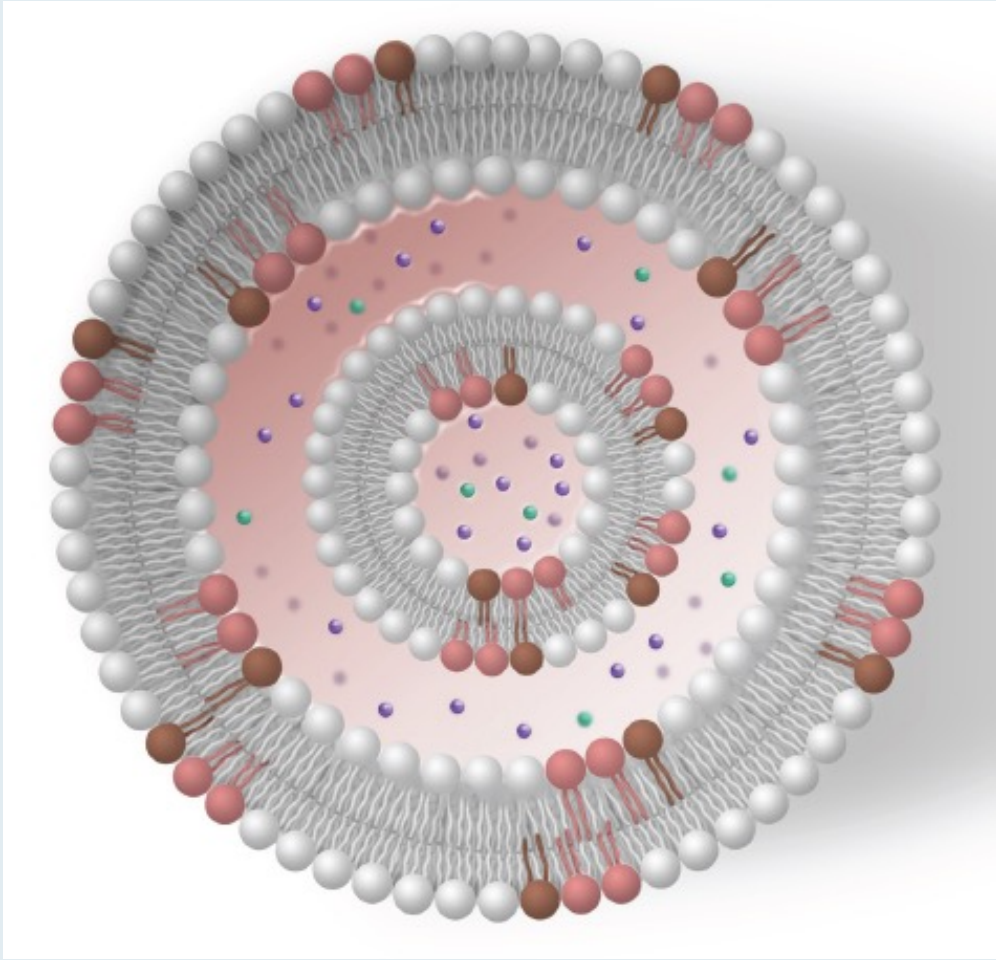
CPX-351 (liposomal cytarabine-daunorubicin) is approved for…

1. AML with a FLT3 mutation
2. Secondary AML
3. CD33-positive AML
4. I don’t know

CPX-351

- CPX-351 is a liposomal co-formulation of cytarabine and daunorubicin designed to achieve synergistic antileukemia activity
  - 5:1 molar ratio of cytarabine:daunorubicin provides synergistic leukemia cell killing *in vitro*[1]
  - In patients, CPX-351 preserved delivery of the 5:1 drug ratio for over 24 hours, with drug exposure maintained for 7 days[2]
  - Selective uptake of liposomes by bone marrow leukemia cells in xenograft models[3]



1. Tardi P et al. *Leuk Res.* 2009;33(1):129-139. 2. Feldman EJ et al. *J Clin Oncol.* 2011;29(8):979-985;
3. Lim WS et al. *Leuk Res.* 2010;34(9):1245-1223.

Oral Azacitidine

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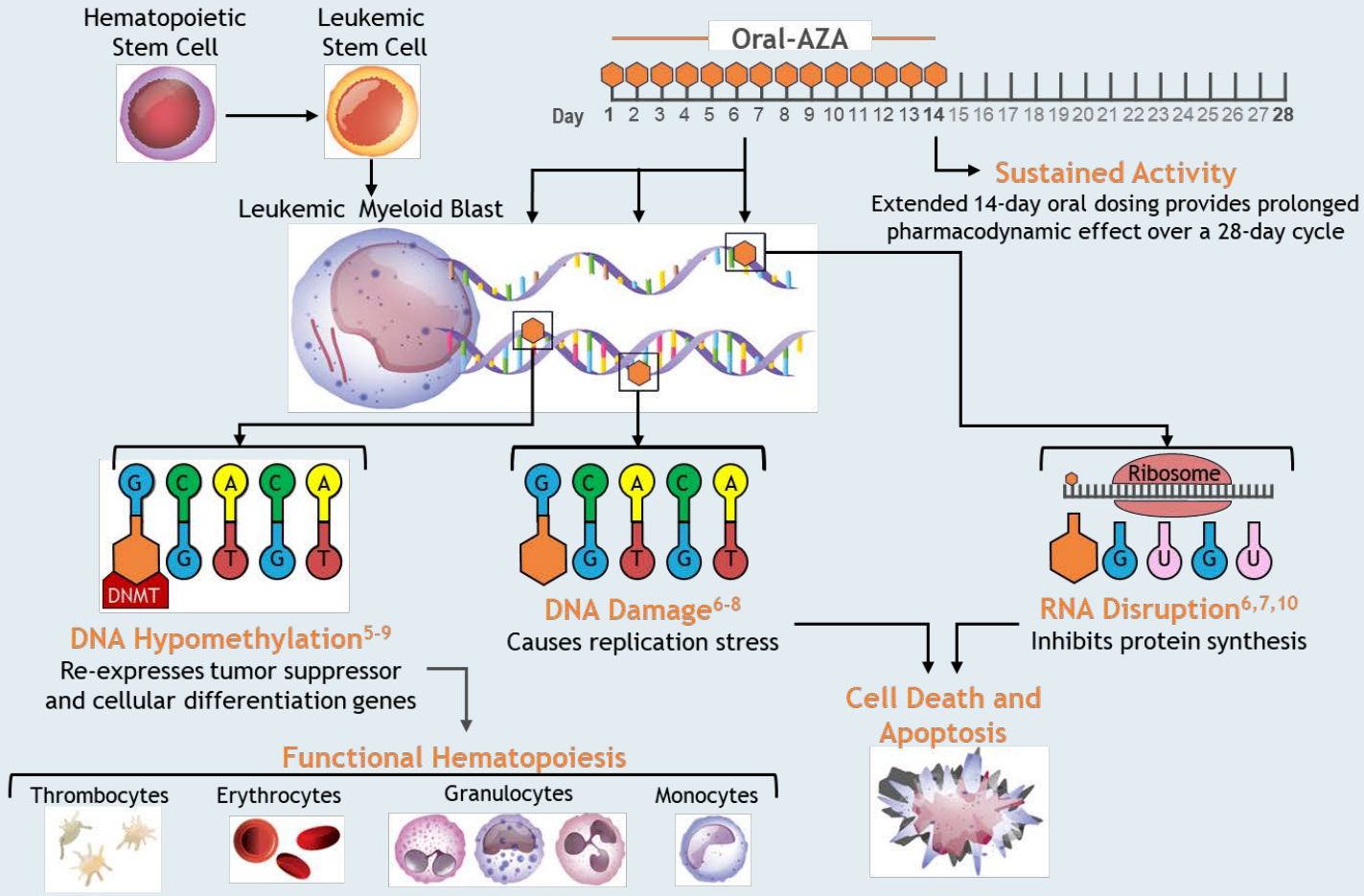
Oral Azacitidine (Oral-AZA, CC-486)

- **Oral HMA with a distinct PK/PD profile from injectable AZA; the two are not bioequivalent[1,2]**
- **Approved in the United States for continued Tx of adult pts with AML in first CR/CRi post-IC and not able to complete intensive curative therapy (eg, HSCT)[3]**
  - **Oral dosing allows for extended drug exposure during each Tx cycle to prolong AZA activity[1,2]**



1. Garcia-Manero et al. *J Clin Oncol*. 2011;29(18):2521–7. 2. Laille et al. *PLoS One*. 2015;10(8):e0135520. 3. ONUREG® (azacitidine) tablets [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; Rev. 9/2020. 4. Savona et al. *Am J Hematol*. 2018;93(10):1199–206. 5. Stresemann et al. *Mol Cancer Ther*. 2008;7:2998–3005. 6. Hollenbach et al. *PLoS One*. 2010;5(2):e9001. 7. Scott LJ. *Drugs*. 2016;76(8):889–900. 8. Stresemann C, Lyko F. *Int J Cancer*. 2008;123(1):8–13. 9. Aimiuwu et al. *Blood*. 2012;119(22):5229–38.

AML, acute myeloid leukemia; AZA, azacitidine; CR, complete remission; CRi, CR with incomplete blood count recovery; HMA, hypomethylating agent; HSCT, hematopoietic stem cell transplant; IC, intensive chemotherapy; PD, pharmacodynamic; PK, pharmacokinetic; pts, patients; Tx, treatment.

Courtesy of Richard M Stone, MD

FDA Approves Azacitidine Tablets for Acute Myeloid Leukemia

Press Release – September 1, 2020

"The Food and Drug Administration approved azacitidine tablets for continued treatment of patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

Efficacy was investigated in QUAZAR (NCT01757535), a multicenter, randomized, double-blind, placebo-controlled trial. Patients (n=472) who achieved CR or CRi with intensive induction chemotherapy with or without receiving subsequent consolidation therapy were randomized 1:1 to receive azacytidine tablets 300 mg (n=238) or placebo (n=234) orally on days 1 to 14 of each 28-day cycle."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-onureg-azacitidine-tablets-acute-myeloid-leukemia

ORIGINAL ARTICLE

Oral Azacitidine Maintenance Therapy for Acute Myeloid Leukemia in First Remission

A.H. Wei, H. Döhner, C. Pocock, P. Montesinos, B. Afanasyev,* H. Dombret, F. Ravandi, H. Sayar, J.-H. Jang, K. Porkka, D. Selleslag, I. Sandhu, M. Turgut, V. Giai, Y. Ofran, M. Kizil Çakar, A. Botelho de Sousa, J. Rybka, C. Frairia, L. Borin, G. Beltrami, J. Čermák, G.J. Ossenkoppele, I. La Torre, B. Skikne, K. Kumar, Q. Dong, C.L. Beach, and G.J. Roboz, for the QUAZAR AML-001 Trial Investigators†

N Engl J Med 2020;383:2526-37.

Impact of COVID-19 restrictions on interactions with patients and their families

Ilene Galinsky, NP

RTP RESEARCH TO PRACTICE

Coping with the practice of oncology and impact of COVID-19 on patient care

Ilene Galinsky, NP

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13th Annual Oncology Grand Rounds

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

Colorectal and Gastroesophageal Cancers

Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

Medical Oncologists

Johanna Bendell, MD
Daniel Catenacci, MD

Oncology Nurse Practitioners

Jessica Mitchell, APRN, CNP, MPH

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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