

# What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Acute Myeloid Leukemia

*A CME/MOC-Accredited Virtual Event*

**Wednesday, December 14, 2022**

**5:00 PM – 6:00 PM ET**

## **Faculty**

**Courtney D DiNardo, MD, MSCE**

**Mark Levis, MD, PhD**

## **Moderator**

**Neil Love, MD**

# Faculty



**Courtney D DiNardo, MD, MSCE**

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



**Andrew H Wei, MBBS, PhD**

Professor, Department of Haematology  
Peter MacCallum Cancer Centre and  
Royal Melbourne Hospital  
University of Melbourne  
Walter and Eliza Hall Institute of Medical Research  
Melbourne, Australia



**Mark Levis, MD, PhD**

Director, Adult Leukemia Program  
Co-Division Director, Hematologic Malignancies  
Professor of Oncology  
The Sidney Kimmel Comprehensive Cancer Center  
Johns Hopkins University  
Baltimore, Maryland



**MODERATOR**

**Neil Love, MD**

Research To Practice

## Commercial Support

This activity is supported by an educational grant from Genentech, a member of the Roche Group.

## Dr Love — Disclosures

**Dr Love** is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, BeyondSpring Pharmaceuticals Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma Corp, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Corporation, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Kronos Bio Inc, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc and Zymeworks Inc.

# Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

## Dr DiNardo — Disclosures

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<b>Data and Safety Monitoring Board/Committee</b>	Genmab

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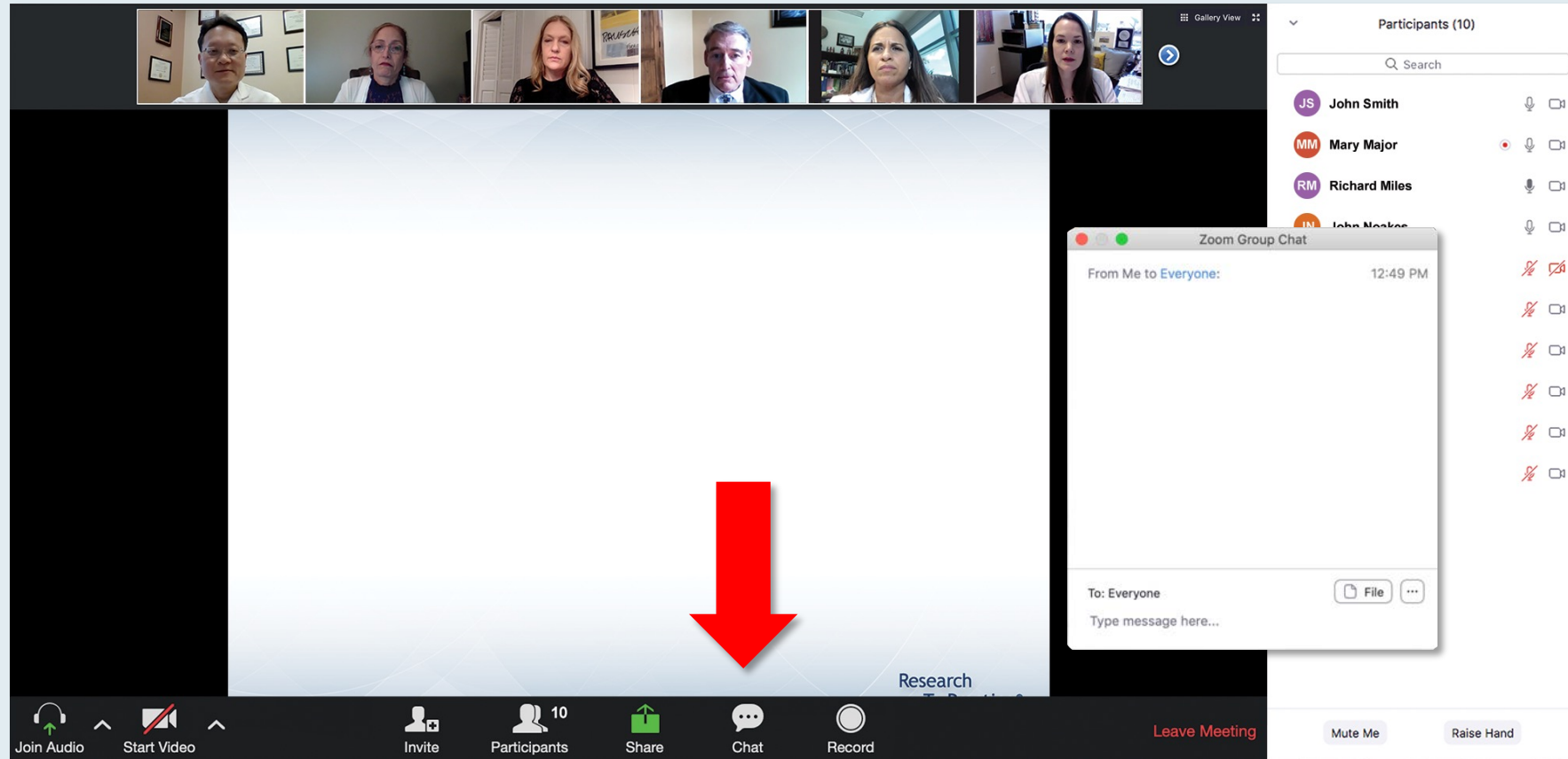
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<b>Contracted Research</b>	Astellas

# Prof Wei — Disclosures

<b>Advisory Committee</b>	AbbVie Inc, Agios Pharmaceuticals Inc, Amgen Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Gilead Sciences Inc, Janssen Biotech Inc, MacroGenics Inc, Novartis, Pfizer Inc, Roche Laboratories Inc, Servier Pharmaceuticals LLC, Shoreline Biosciences
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<b>Speakers Bureau</b>	AbbVie Inc, Astellas, Bristol-Myers Squibb Company, Novartis, Servier Pharmaceuticals LLC
<b>Nonrelevant Financial Relationship</b>	Prof Wei is an employee of the Walter and Eliza Hall Institute (WEHI). WEHI receives milestone and royalty payments related to the development of venetoclax. Current and past employees of WEHI may be eligible for financial benefits related to these payments. Prof Wei receives such a financial benefit.



# We Encourage Clinicians in Practice to Submit Questions



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

# Familiarizing Yourself with the Zoom Interface

## Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a slide titled "Meet The Professor Program Participating Faculty" featuring six faculty members with their photos and titles. To the right is a chat window titled "Chat" with two messages from "Me to Panelists" and "Me to Panelists and Attendees". At the bottom of the chat window is a submission box with a dropdown menu set to "Panelists and Attendees" and a text input field. A red arrow points to the white line above the submission box, indicating where to drag to expand the chat area.

**Meet The Professor Program Participating Faculty**

**Nancy L Bartlett, MD**  
Professor of Medicine  
Koman Chair in Medical Oncology  
Washington University School of Medicine  
St Louis, Missouri

**Jonathan W Friedberg, MD, MMSc**  
Samuel E Durand Professor of Medicine  
Director, James P Wilmot Cancer Institute  
University of Rochester  
Rochester, New York

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

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

**Christopher R Flowers, MD, MS**  
Chair, Professor  
Department of Lymphoma/Myeloma  
The University of Texas MD Anderson Cancer Center  
Houston, Texas

**Brad S Kahl, MD**  
Professor of Medicine  
Washington University School of Medicine  
Director, Lymphoma Program  
Siteman Cancer Center  
St Louis, Missouri

**Chat**

Me to Panelists 4:31 PM

Welcome and thank you for attending! To access the slides from today's session please use the link below.  
[http://images.researchtopractice.com/2021/Meetings/Slides/MTP\\_ToGo\\_CLL\\_2021\\_April1.pdf](http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April1.pdf)

Me to Panelists and Attendees 4:32 PM

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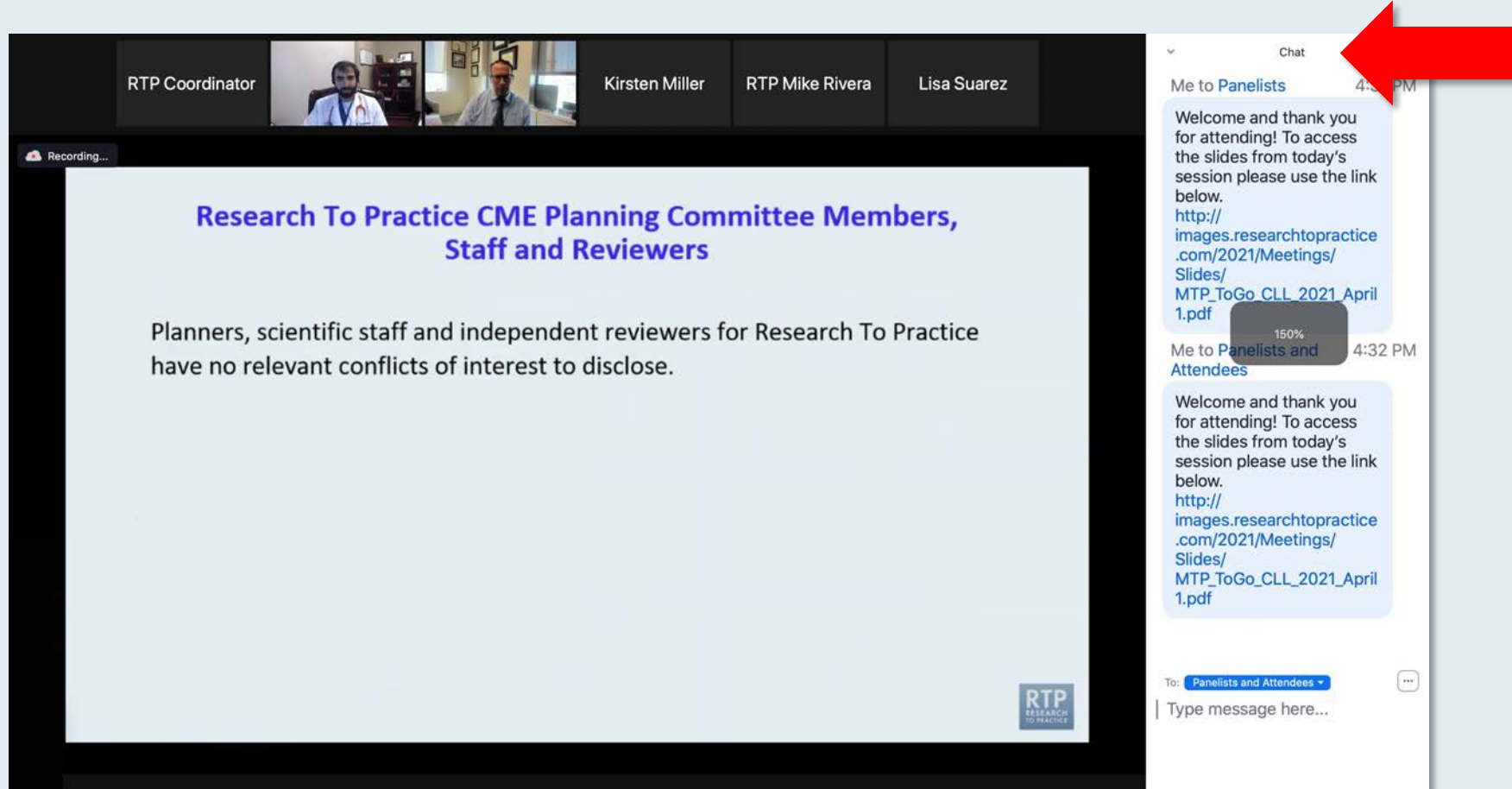
To: Panelists and Attendees

Type message here...

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

# 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.**

# Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys

The screenshot shows a Zoom meeting window. At the top, a row of seven participant video thumbnails is visible. The main content area on the left displays a presentation slide with the following text:   
**Meet The Professionals**  
**Optimizing the Selection and Timing of Therapy for Patients with Gastrointestinal Cancer**  
Wednesday, August 25, 2022  
5:00 PM – 6:00 PM EST  
Faculty  
Wells A Messersmith, MD  
Moderator  
Neil Love, MD  
The RTP Research to Practice logo is in the bottom right corner of the slide. A 'Quick Survey' pop-up window is centered over the slide, listing several treatment combinations with radio button options. To the right of the main window is a 'Participants (10)' sidebar showing a list of names with their respective status icons (microphone, video, chat). At the bottom of the Zoom window is a toolbar with icons for 'Join Audio', 'Start Video', 'Invite', 'Participants', 'Share', 'Chat', 'Record', and a 'Leave Meeting' button.

**Quick Survey**

- ☐ Ceritinib +/- dexamethasone
- ☐ Pomalidomide +/- dexamethasone
- ☐ Ceritinib + pomalidomide +/- dexamethasone
- ☐ Elotuzumab + lenalidomide +/- dexamethasone
- ☐ Elotuzumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + lenalidomide +/- dexamethasone
- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Isosorbide + Rd
- ☐ Other

**Participants (10)**

- JS John Smith
- MM Mary Major
- RM Richard Miles
- JN John Noakes
- AS Alice Suarez
- JP Jane Perez
- RS Robert Stiles
- JF Juan Fernandez
- AK Ashok Kumar
- JS Jeremy Smith

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**Regulatory and reimbursement issues aside, which treatment would you recommend for a 65-year-old patient with clear cell renal cell carcinoma (ccRCC) if follow-up 3 years later is found to have asymptomatic (PS 0)?**  
A numbered list of treatment options is shown:   
1. Nivolumab/ipilimumab  
2. Avelumab/axitinib  
3. Pembrolizumab/axitinib  
4. Pembrolizumab/lenvatinib  
5. Nivolumab/cabozantinib  
6. Tyrosine kinase inhibitor (TKI) monotherapy  
7. Anti-PD-1/PD-L1 monotherapy  
8. Other  
The RTP Research to Practice logo is in the bottom right corner of the slide. A 'Quick Poll' pop-up window is centered over the slide, listing the same treatment options with radio button options. To the right of the main window is a 'Participants (10)' sidebar showing a list of names with their respective status icons. At the bottom of the Zoom window is a toolbar with icons for 'Join Audio', 'Start Video', 'Invite', 'Participants', 'Share', 'Chat', 'Record', and a 'Leave Meeting' button.

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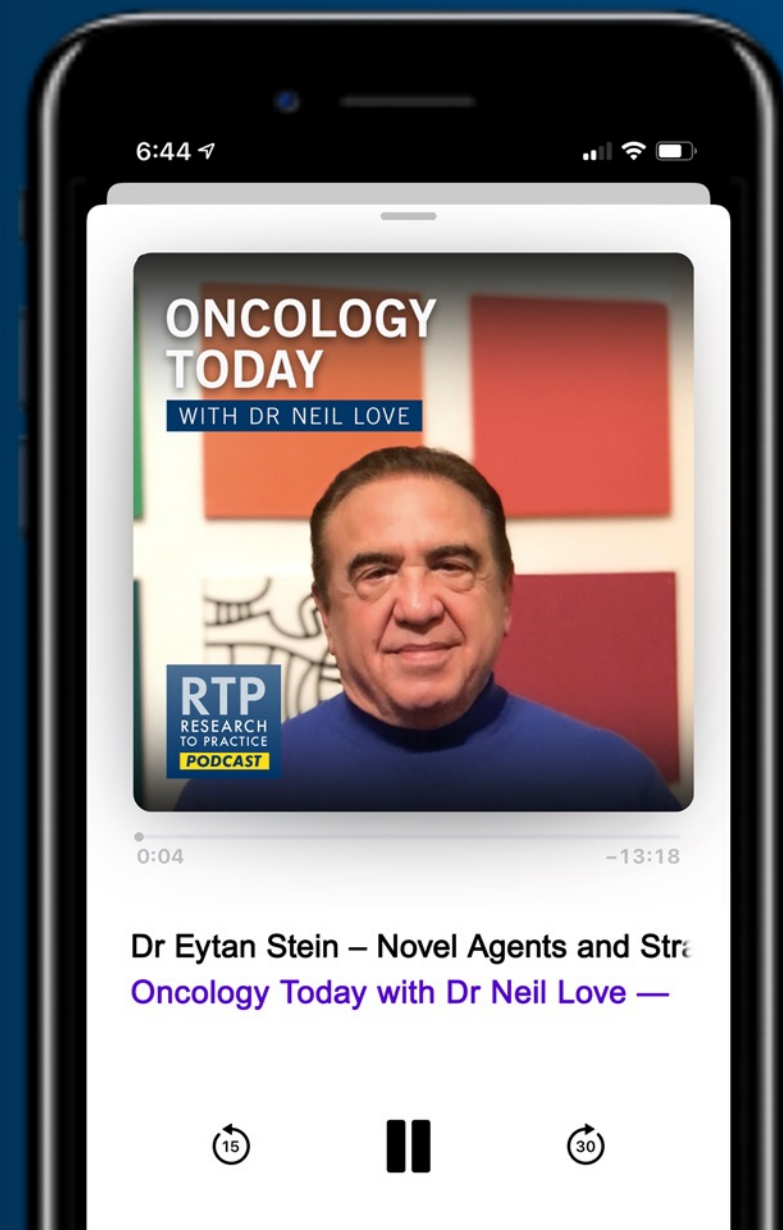
# ONCOLOGY TODAY

WITH DR NEIL LOVE

## Novel Agents and Strategies in AML



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# ***Meet The Professor***

## **Optimizing the Management of Multiple Myeloma**

**Thursday, December 15, 2022  
5:00 PM – 6:00 PM ET**

**Faculty**

**Shaji K Kumar, MD**

**Moderator**

**Neil Love, MD**

# **Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology**

## **Breast Cancer**

*A Multitumor CME/MOC-Accredited Live Webinar Series*

**Wednesday, January 4, 2023**

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**Joyce O'Shaughnessy, MD**

**Professor Peter Schmid, FRCP, MD, PhD**

### **Moderator**

**Neil Love, MD**

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**Joseph Mikhael, MD, MEd**

**Ajay K Nooka, MD, MPH**

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## **Hepatobiliary Cancers**

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***Thank you for joining us!***

***CME and MOC credit information will be emailed  
to each participant within 5 business days.***

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**Andrew H Wei, MBBS, PhD**

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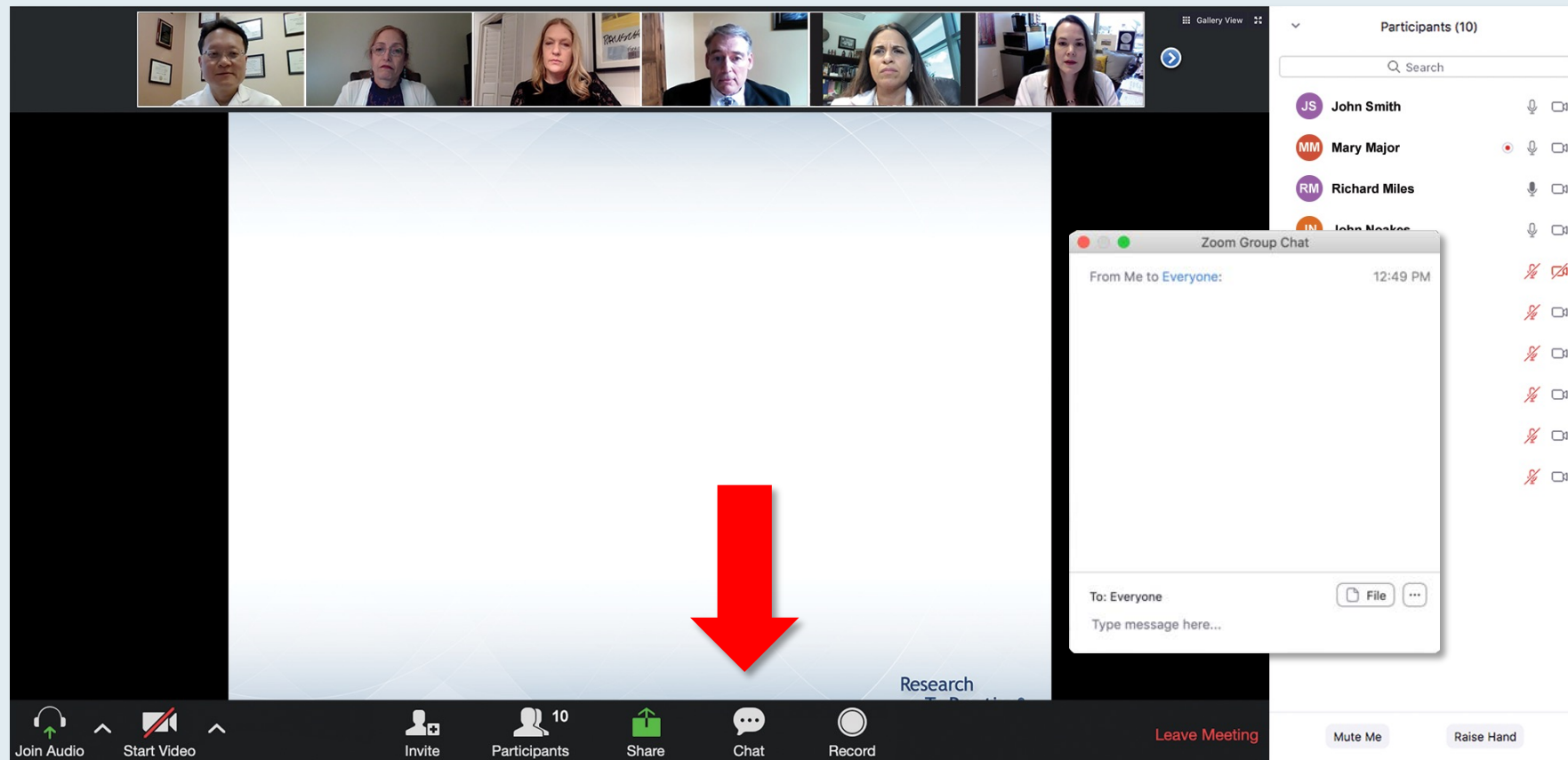


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- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Isaxozim + Rd
- ☐ Other

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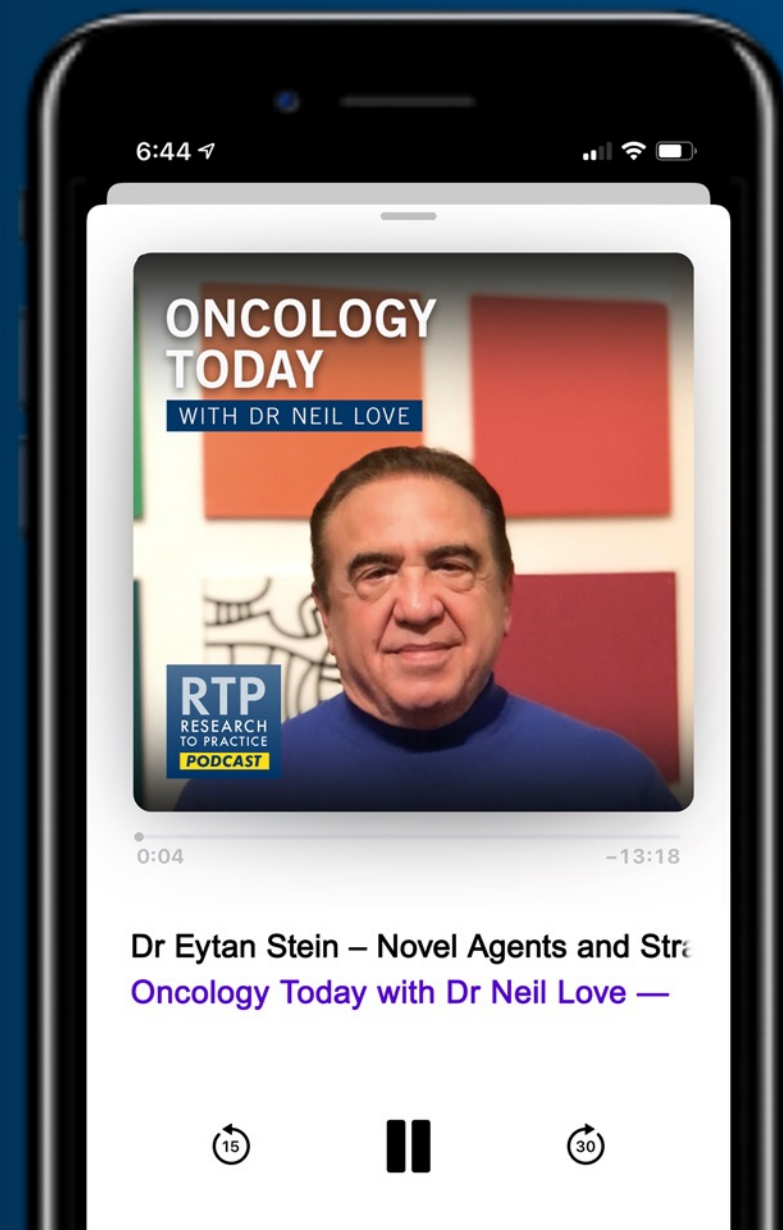
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**Spencer H Bachow, MD**  
Lynn Cancer Institute  
Boca Raton, Florida



**Ranju Gupta, MD**  
Lehigh Valley Topper Cancer Institute  
Bethlehem, Pennsylvania



**Bhavana (Tina) Bhatnagar, DO**  
West Virginia University  
Cancer Institute  
Wheeling, West Virginia



**Anna Halpern, MD**  
Fred Hutchinson Cancer  
Research Center  
Seattle, Washington



**Amany R Keruakous, MD, MS**  
Georgia Cancer Center  
Augusta University  
Augusta, Georgia



**Priya Rudolph, MD, PhD**  
Georgia Cancer Specialists  
Athens, Georgia



**Rebecca L Olin, MD, MSCE**  
University of California, San  
Francisco  
San Francisco, California



**Rajni Sinha, MD, MRCP**  
Piedmont Cancer Institute  
Atlanta, Georgia



# Selection of Therapy for Patients with AML

Courtney DiNardo  
Dept of Leukemia  
MD Anderson Cancer Center



## Treatment of AML with Targetable Mutations



Andrew Wei  
Peter MacCallum Cancer Centre  
Royal Melbourne Hospital  
Melbourne, Australia



# Agenda

**MODULE 1: Case Presentations – Part 1**

**MODULE 2: Selection of Therapy for Patients with AML**

**MODULE 3: Case Presentations – Part 2**

**MODULE 4: Treatment of AML with Targetable Mutations**



# Agenda

## **MODULE 1: Case Presentations – Part 1**

- Dr Olin: 80-year-old man with newly diagnosed AML with significant comorbidities is treated with decitabine/venetoclax
- Dr Bachow: 54-year-old man s/p 7 + 3 → allogeneic SCT presents with myeloid sarcoma
- Dr Gupta: 78-year-old man s/p 7 + 3 → allogeneic SCT presents with myeloid sarcoma
- Dr Halpern: 39-year-old man with core binding factor AML s/p induction FLAG-M + gemtuzumab ozogamicin (GO) → high-dose cytarabine x 4
- Dr Bhatnager: 64-year-old woman with newly diagnosed del(5q) AML with monocytic differentiation and multiple mutations (GATA2, BCOR, NF1 and RUNX1) receives azacitidine and venetoclax

## **MODULE 2: Selection of Therapy for Patients with AML**

## **MODULE 3: Case Presentations – Part 2**

## **MODULE 4: Treatment of AML with Targetable Mutations**

# Case Presentation: 80-year-old man with newly diagnosed AML with significant comorbidities is treated with decitabine/venetoclax



**Dr Rebecca Olin (San Francisco, California)**



**Dr Spencer Bachow**  
**(Boca Raton, Florida)**

**Case Presentation: 54-year-old man s/p 7 + 3 →  
allogeneic SCT presents with myeloid sarcoma**



**Dr Ranju Gupta**  
**(Bethlehem, Pennsylvania)**

**Case Presentation: 78-year-old man s/p 7 + 3 →  
allogeneic SCT presents with myeloid sarcoma**

**Case Presentation: 39-year-old man with core binding factor  
AML s/p induction CLAG-M + gemtuzumab ozogamicin (GO)  
→ high-dose cytarabine x 4**



**Dr Anna Halpern (Seattle, Washington)**

## Questions and Comments: De-escalation of therapy



**Prof Andrew Wei (Melbourne, Australia)**



**Case Presentation: 64-year-old woman with newly diagnosed del(5q) AML with monocytic differentiation and multiple mutations (GATA2, BCOR, NF1 and RUNX1) receives azacitidine and venetoclax**



**Dr Tina Bhatnagar (Wheeling, West Virginia)**

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# Selection of Therapy for Patients with AML

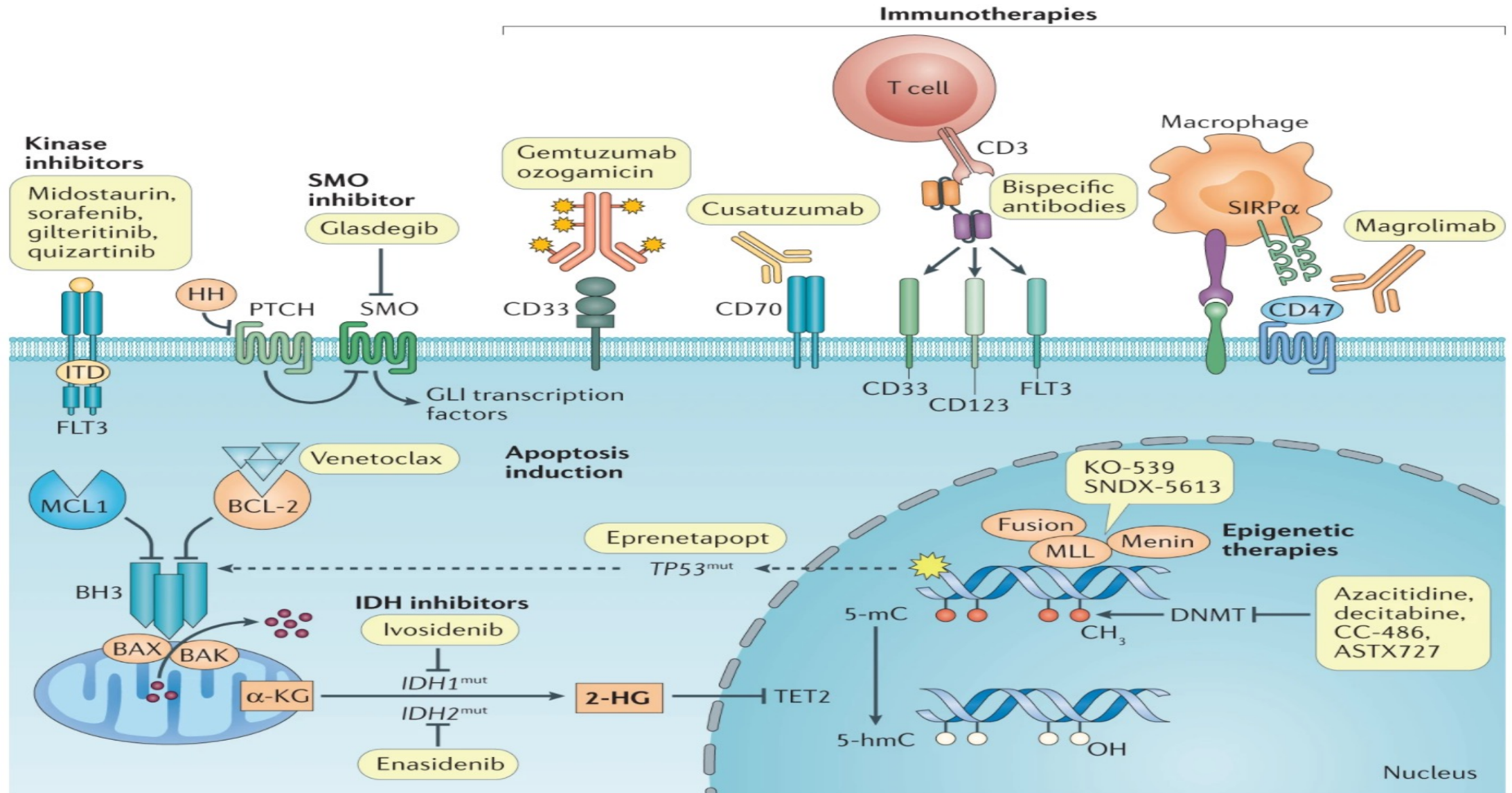
Courtney DiNardo

Dept of Leukemia

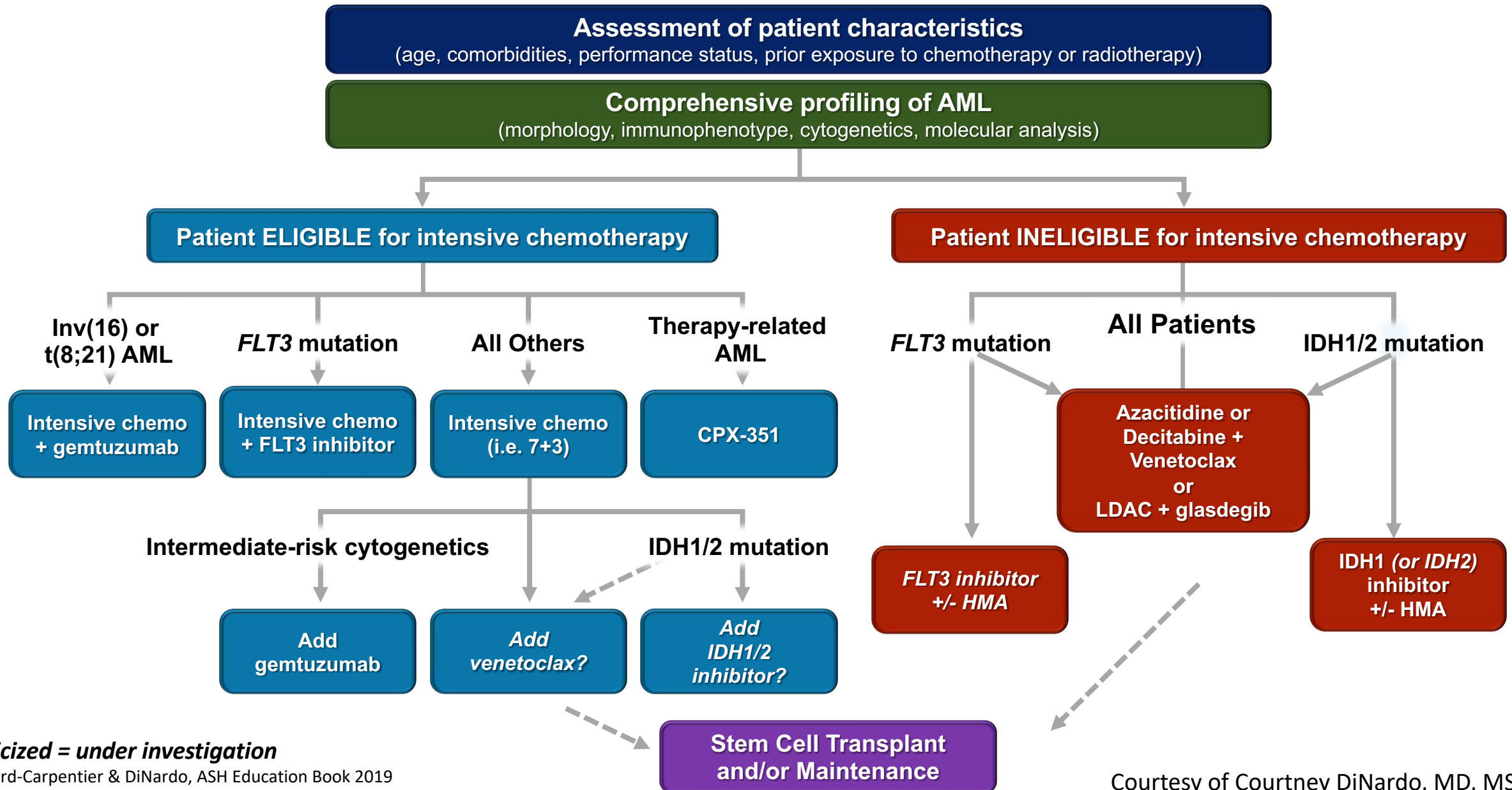
MD Anderson Cancer Center



# Novel targets for precision medicine in AML



# Evolving diagnostic and treatment paradigm for Newly Dx AML



*Italicized = under investigation*

Richard-Carpentier & DiNardo, ASH Education Book 2019

Courtesy of Courtney DiNardo, MD, MSCE

Young/Fit Newly Dx AML:  
role for addition of venetoclax to IC?

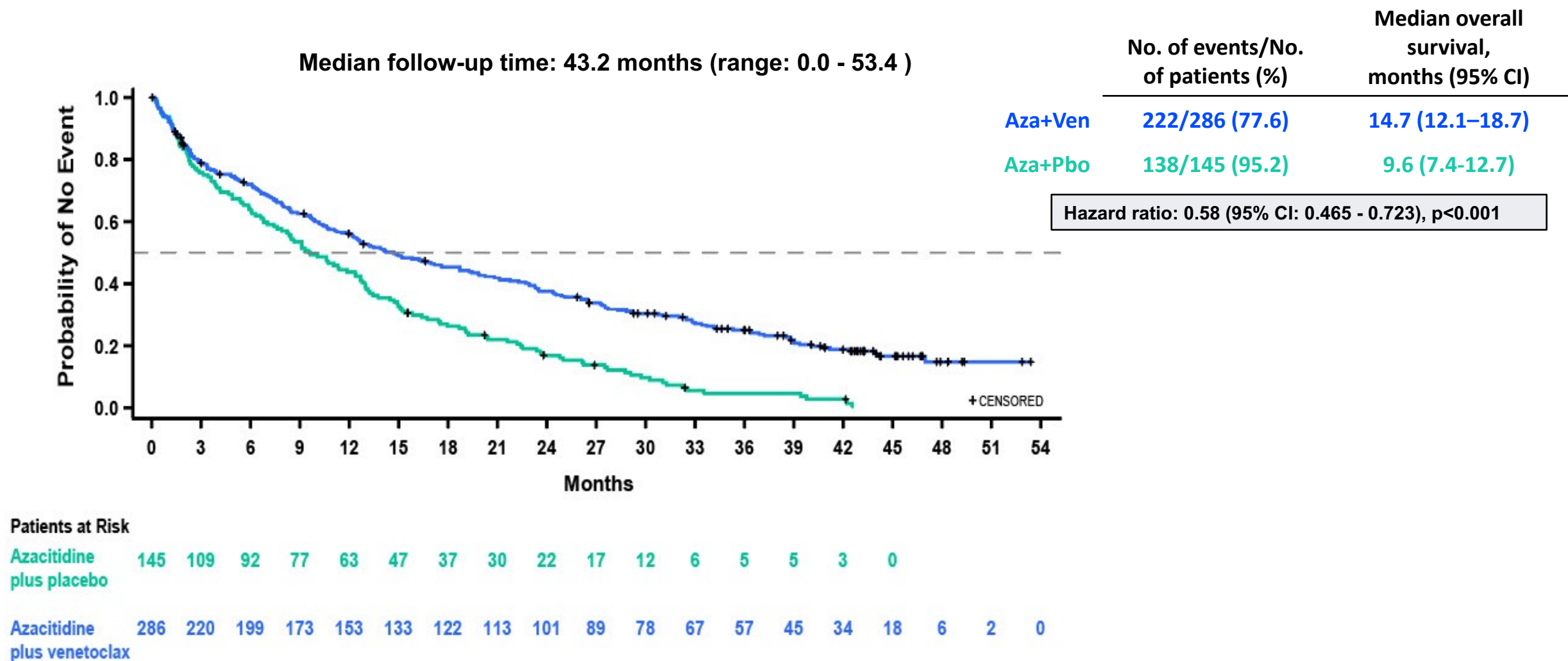
# VEN+IC in AML:

Venetoclax added to intensive chemotherapy in ND-AML:

- **Improved MRD-negative CRc (86% vs 61%)**
  - Most prominent in TP53-wild type ELN adverse-risk AML
- **Enabled more patients to transition to HSCT in CR (72% vs 58%)**
  - HSCT associated with improved EFS in ELN intermediate and adverse-risk AML
- **Improved EFS compared to our historical cohort treated with IC**
  - OS benefit also observed in ELN intermediate or adverse-risk AML
- ***TP53 mutated-AML demonstrates inferior outcomes compared to patients with wild-type TP53***

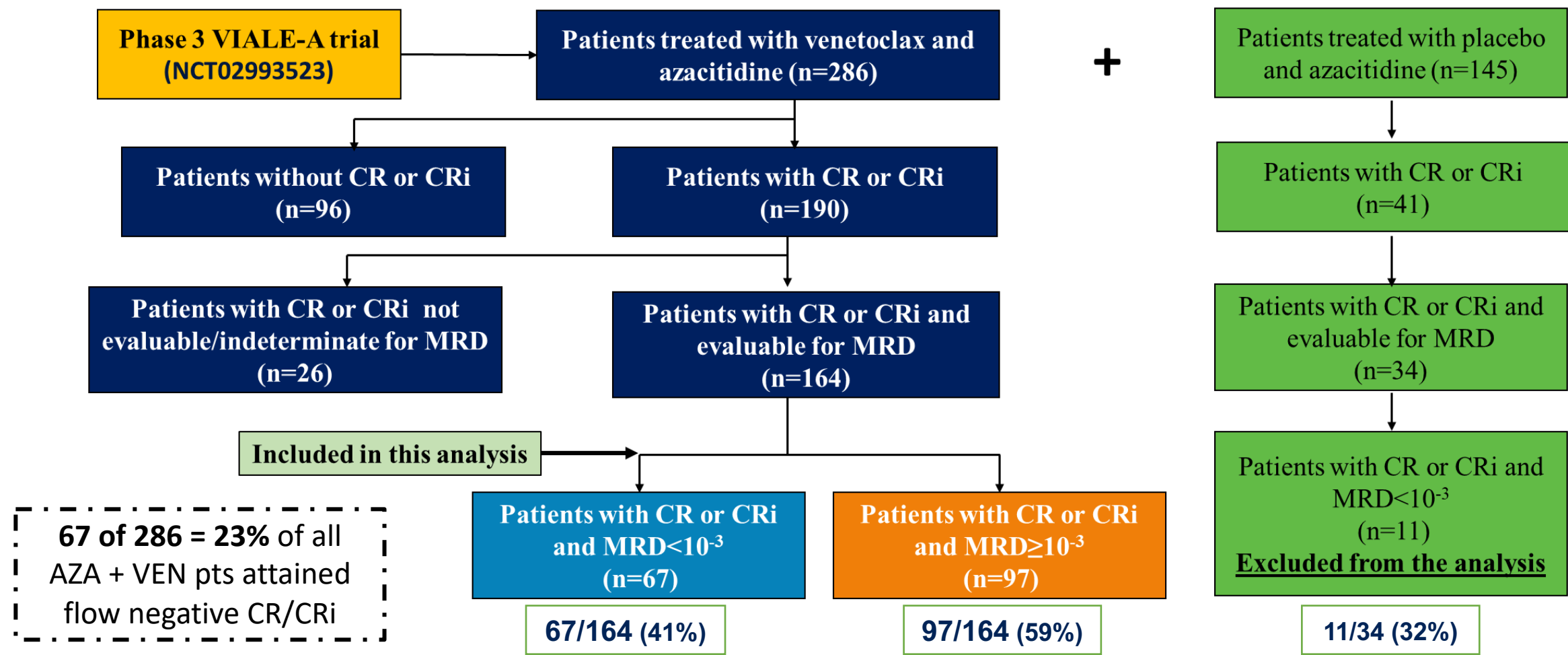
# Older AML

# Long Term Results of VIALE-A : Azacitidine ± venetoclax



# VIALE-A: Flow cytometry MRD: Response and Prognosis

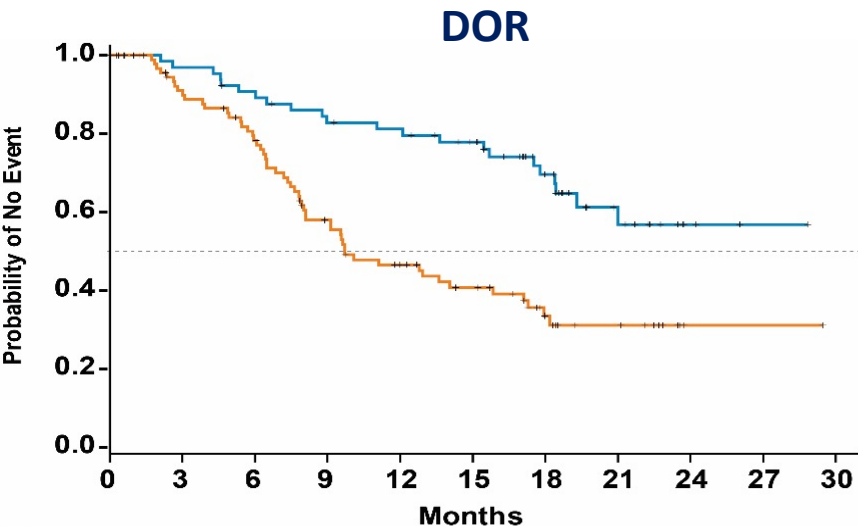
Analyzed patient population



Data cutoff: Jan 04, 2020  
CR: Complete remissions, CRi: CR with incomplete hematological recovery; MRD: Minimal residual disease  
Patients were indeterminate if the BM samples had less than a hundred thousand CD45+ leukocytes



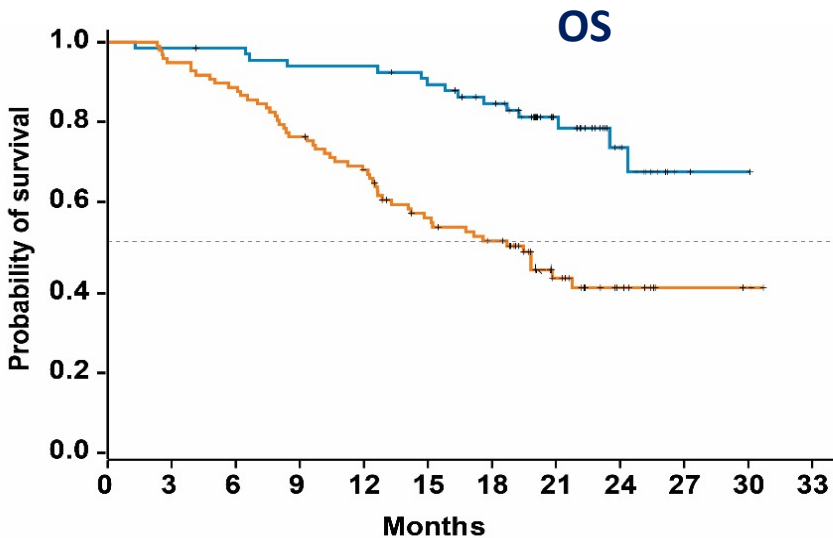
# DOR and OS in CR/CRi patients treated with AZA + VEN by MRD Status



Patients at Risk

CR+CRi+MRD<10 <sup>-3</sup>	67	63	58	52	50	44	30	14	3	1	0
CR+CRi+MRD≥10 <sup>-3</sup>	97	80	67	46	34	27	14	9	1	1	0

Duration of remission	# of events	12-month, % (95% CI)	18-month % (95% CI)	Median DoR, months (95% CI)
CR+CRi+MRD<10 <sup>-3</sup>	22	81.2 (69.3, 88.9)	69.6 (55.9, 79.8)	NR (19.3 – NR)
CR+CRi+MRD≥10 <sup>-3</sup>	54	46.6 (35.6, 56.8)	33.5 (22.9, 44.5)	9.7 (8.0 – 15.8)



Patients at Risk

CR+CRi+MRD<10 <sup>-3</sup>	67	66	65	62	62	58	52	30	13	2	1	0
CR+CRi+MRD≥10 <sup>-3</sup>	97	92	86	74	64	49	42	21	10	3	2	0

Overall survival	# of events	12-month, % (95% CI)	18-month % (95% CI)	Median OS, months (95% CI)
CR+CRi+MRD<10 <sup>-3</sup>	15	94.0 (84.7, 97.7)	84.6 (73.3, 91.4)	NR (24.4 – NR)
CR+CRi+MRD≥10 <sup>-3</sup>	52	67.9 (57.6, 76.2)	50.1 (39.6, 59.8)	18.7 (12.9 – NR)

Patients who attained an MRD response at any time received a median of 16.0 (range: 1.0 – 28.0) cycles of treatment with Ven+Aza; patients with MRD≥10<sup>-3</sup> received a median of 9.0 (range: 2.0 – 30.0) cycles .  
The median follow-up was 22.1 (range: 1.3– 30.1) months in patients with MRD<10<sup>-3</sup> and 20.8 (range: 2.3 – 30.7) months in patients with MRD ≥10<sup>-3</sup>.  
Duration of remission for CRc was defined as the number of days from the date of first response (CR or CRi) per the modified IWG criteria for AML to the earliest evidence of confirmed morphologic relapse, confirmed progressive disease, or death due to disease progression.  
OS was defined as the time from randomization to the date of death from any cause.



# Practical Considerations

# G-CSF Use with VEN Combinations

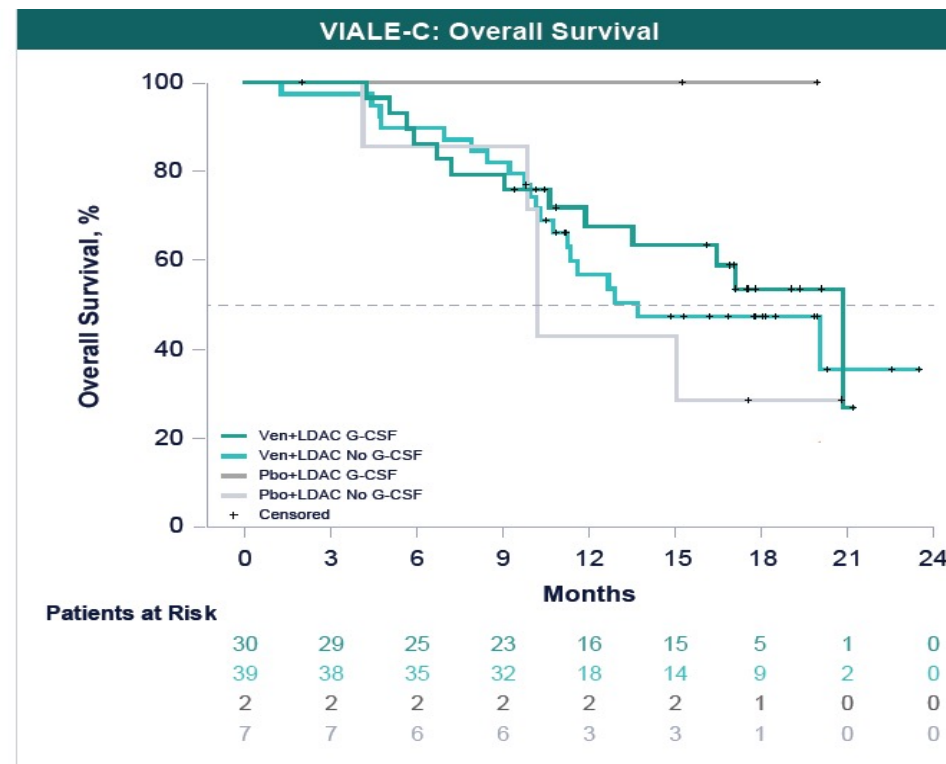
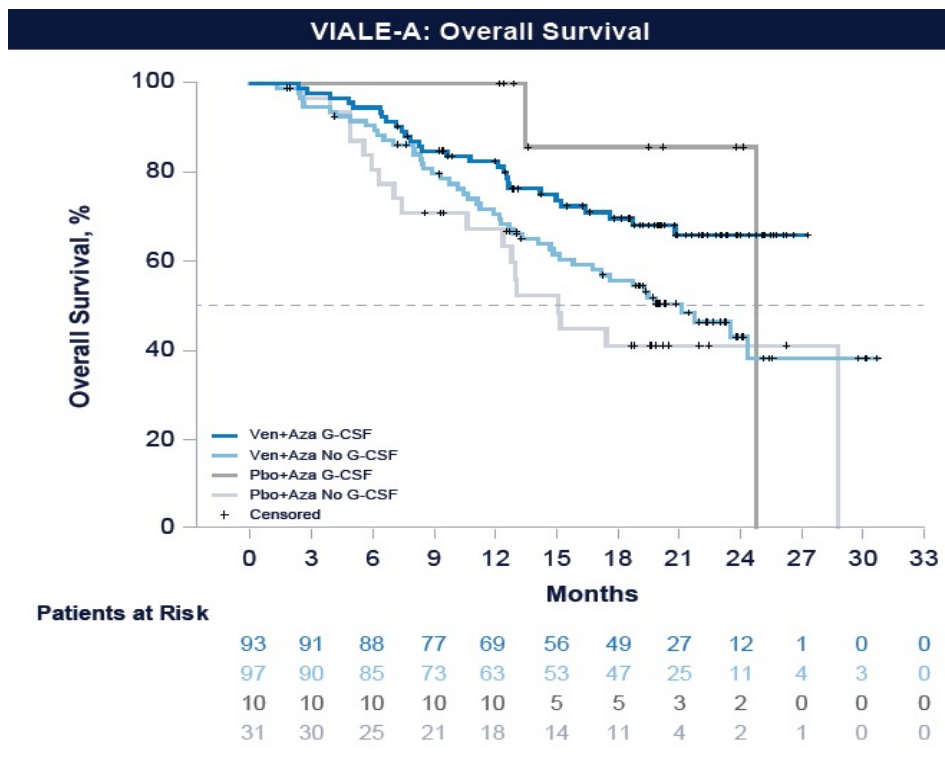
- In VIALE-A, 190/286 patients (**66%**) treated with Ven+Aza achieved CR/CRi; **49%** received G-CSF after achieving remission
- In VIALE-C, 69/143 patients (**48%**) treated with Ven+LDAC achieved CR/CRi; **43%** received G-CSF after achieving remission
- Baseline Grade  $\geq 3$  neutropenia was similar between patients who went on to receive G-CSF and those who did not

In both VIALE-A and VIALE-C, duration of post-remission Grade  $\geq 3$  neutropenia or febrile neutropenia was generally **shorter with G-CSF use than without G-CSF use**

Duration of Post-Remission Neutropenia	VIALE-A		VIALE-C	
	Ven+Aza G-CSF (n=93)	Ven+Aza No G-CSF (n=97)	Ven+LDAC G-CSF (n=30)	Ven+LDAC No G-CSF (n=39)
Median duration of post-remission Gr $\geq 3$ neutropenia (range), days	12.5 (1-696)	16 (1-648)	15 (2-419)	12.5 (5-367)
Median duration of post-remission Gr $\geq 3$ febrile neutropenia (range), days	8 (1-320)	10.5 (2-22)	6 (3-411)	29 (1-30)

# Outcome of G-CSF After VEN Combinations

Post-remission G-CSF use was NOT associated with inferior OS (or DOR) among VEN-treated patients



Overall Survival	VIALE-A		VIALE-C	
	Ven+Aza G-CSF (n=93)	Ven+Aza No G-CSF (n=97)	Ven+LDAC G-CSF (n=30)	Ven+LDAC No G-CSF (n=39)
Median (95% CI), mo	NR (NR–NR)	21.1 (15.2–NR)	20.8 (11.9–NR)	13.7 (10.8–NR)
12-mo rate (95% CI), %	83 (73–89)	71 (60–79)	68 (47–82)	57 (39–71)
18-mo rate (95% CI), %	70 (59–78)	56 (45–65)	54 (32–71)	47 (30–63)
24-mo rate (95% CI), %	66 (54–75)	43 (31–55)	NA	NA

# Anti-infectious Prophylaxis With Venetoclax: Recommended Venetoclax Dose Reductions in the VIALE Studies and US and European Labels

Venetoclax dose reductions  
with VEN + AZA and VEN + LDAC VIALE-A and VIALE-C<sup>1,2</sup>

Standard venetoclax dose	Moderate CYP3Ai/P-gpi (eg, isavuconazole, ciprofloxacin)	Strong CYP3Ai (eg, posaconazole, voriconazole)
100 mg	50 mg	10 mg
200 mg	100 mg	20 mg
400 mg	≤200 mg	50 mg
600 mg*	≤300 mg	50 mg

- Consider antibacterial, antiviral, antifungal prophylaxis
- Note that azoles interact with venetoclax
- Real-world data show efficacy of venetoclax dosed with antifungal agents<sup>5</sup>

Venetoclax dose reductions USPI<sup>3</sup>

Day	Moderate CYP3Ai/P-gpi	Strong CYP3Ai	Posaconazole
Day 1	Reduce the dose by at least 50%	10 mg	10 mg
Day 2		20 mg	20 mg
Day 3		50 mg	50 mg
Day 4		100 mg	70 mg

Venetoclax dose reductions EMA SmPC<sup>4</sup>

Day	Moderate CYP3Ai/P-gpi	Strong CYP3Ai
Day 1	Reduce the dose by at least 50%	10 mg
Day 2		20 mg
Day 3		50 mg
Day 4		100 mg or less

\*For VEN + LDAC only.

Aza, azacitidine; CYP3Ai, CYP3A inhibitor; LDAC, low-dose cytarabine; P-gpi, P-glycoprotein inhibitor; Ven, venetoclax.

1. Wei AH, et al. *Blood*. 2020;135(24):2137-2145 (incl. suppl); 2. DiNardo CD, et al. *N Engl J Med*. 2020;383(7):617-629 (incl. suppl); 3. Venclexta (venetoclax tablets) [prescribing information]. North Chicago, IL: AbbVie Inc; 2022; 4. Venclyxto [summary of product characteristics]. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG; 2018; 5. Rausch CR, et al. *Blood*. 2019;134(suppl 1): abstract 2640.

Courtesy of Courtney DiNardo, MD, MSCE

# Practical Take-Homes on VEN + AZA Therapy in AML

- VEN/AZA remains the optimal approach for newly diagnosed AML not suitable for intensive therapy, irrespective of cytogenetic or molecular features at this time
  - Generally well tolerated, with 30-day mortality of 6% to 7%
  - Prolonged neutropenia compared with AZA alone
  - Early bone marrow assessment (EOC1) with VEN interruption and shortened VEN duration for count recovery is recommended
- Responses are quick, with a median time to response of 1 month
  - Therapy is indefinite
  - Flow MRD negative status predicts for improved DOR and OS

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## **MODULE 1: Case Presentations – Part 1**

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## **MODULE 3: Case Presentations – Part 2**

- Dr Keruakous: 50-year-old man with therapy-related AML with an MLL mutation treated with CPX-351
- Dr Rudolph: 72-year-old man with secondary IDH-mutant AML
- Dr Sinha: 81-year-old woman with IDH2-mutant AML
- Dr Halpern: 70-year-old man with recurrent IDH2-mutant AML receives enasidenib and develops differentiation syndrome/disease progression
- Dr Olin: 44-year-old woman with NPM1, FLT3-TKD-mutant AML

## **MODULE 4: Treatment of AML with Targetable Mutations**



**Dr Amany Keruakous**  
**(Augusta, Georgia)**

**Case Presentation: 50-year-old man with therapy-related AML with an MLL mutation treated with CPX-351**



**Dr Priya Rudolph**  
**(Athens, Georgia)**

**Case Presentation: 72-year-old man with secondary IDH-mutant AML**



# Case Presentation: 81-year-old woman with IDH2-mutant AML



**Dr Rajni Sinha (Atlanta, Georgia)**



## Case Presentation: 70-year-old man with recurrent IDH2-mutant AML receives enasidenib and develops differentiation syndrome/disease progression



**Dr Anna Halpern (Seattle, Washington)**

# Questions and Comments: Selection and sequencing of targeted therapies



**Prof Andrew Wei (Melbourne, Australia)**

## Case Presentation: 44-year-old woman with NPM1, FLT3-TKD-mutant AML



**Dr Rebecca Olin (San Francisco, California)**

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# Treatment of AML with Targetable Mutations



Andrew Wei  
Peter MacCallum Cancer Centre  
Royal Melbourne Hospital  
Melbourne, Australia





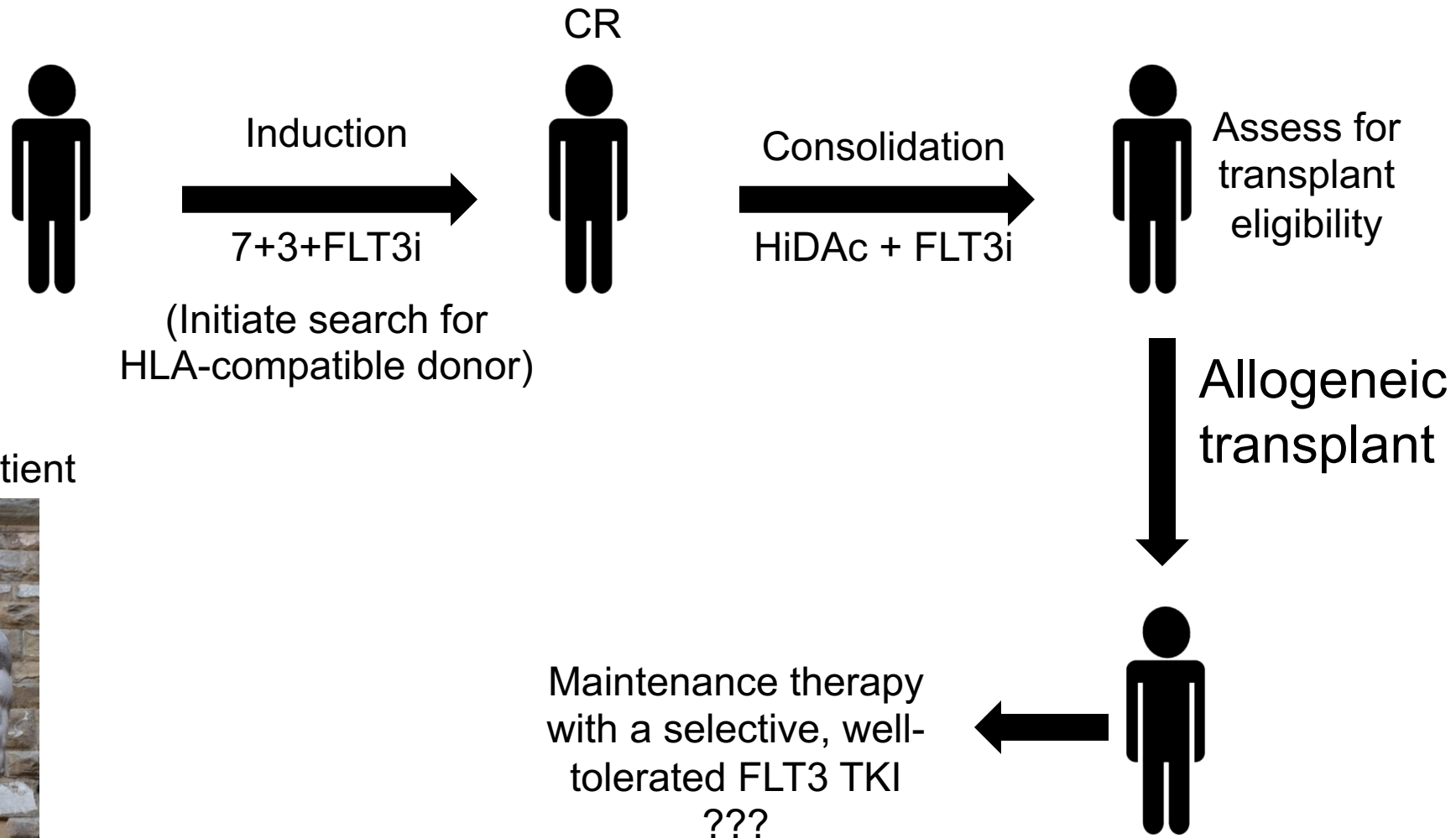
# Current landscape in AML

First line				Salvage	
Fit for intensive chemo	<b>FLT3<sup>MUT</sup></b>	<i>7+3 + Midostaurin</i>	<i>Post-remission therapy</i>  <i>HCT</i> <i>IDAC</i> <i>oral AZA</i>	<b>FLT3 mut</b>	<i>Gilteritinib</i>
	<b>FLT3-ITD</b>	<i>7+3 + Quizartinib</i>		Non-targeted	<i>IDAC +/- anthracycline</i>
	AML MRC, tAML	<i>CPX-351</i>			<i>FLAG-IDA</i>
	Non-adverse CG	<i>7+3 + GO</i>			<i>MEC</i>
	Adverse CG	<i>7+3</i>			<i>CLAG-M</i>
Unfit for chemo	<b>IDH1 mut</b>	<i>IVO + AZA</i>	Unfit for chemo	<b>IDH1 mut</b>	<i>Ivosidenib</i>
	Other	<i>VEN + AZA</i> <i>VEN + LDAC</i>		<b>IDH2 mut</b>	<i>Enasidenib</i>
				<b>FLT3 mut</b>	<i>Gilteritinib</i>

# FLT3-ITD AML



# Current treatment scheme for the “fit” patient with newly-diagnosed FLT3/ITD AML



The fit AML patient



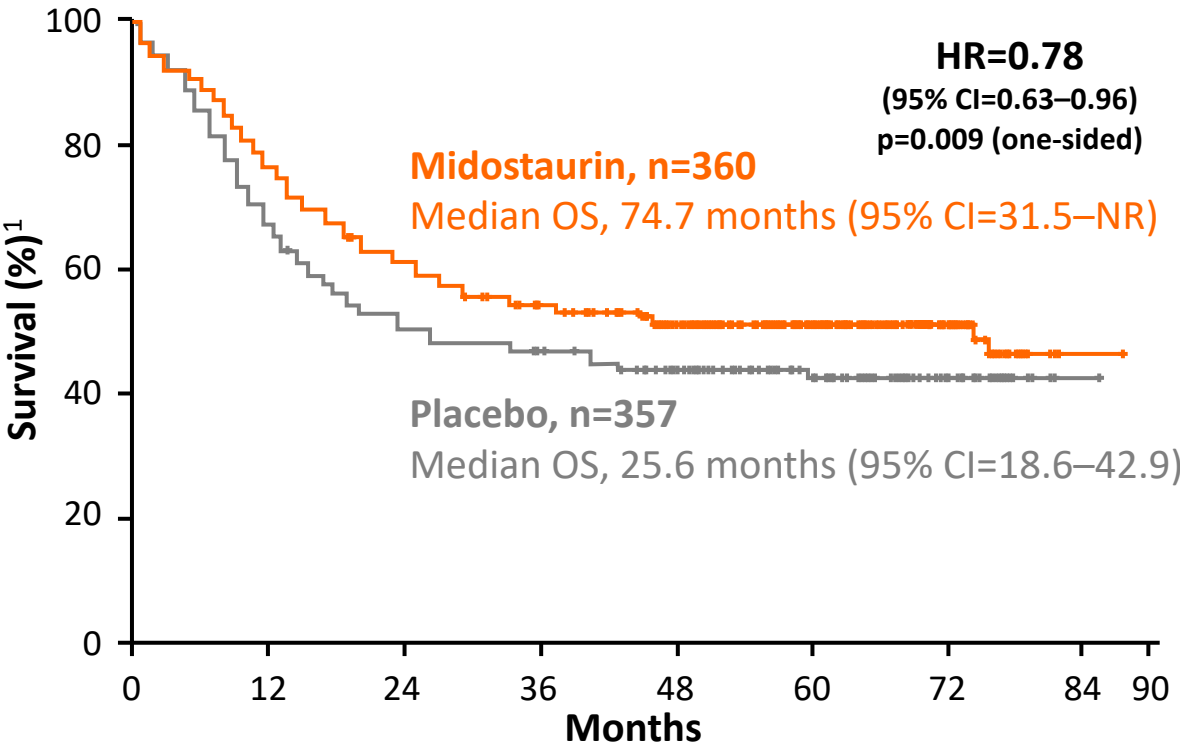


# Controversies

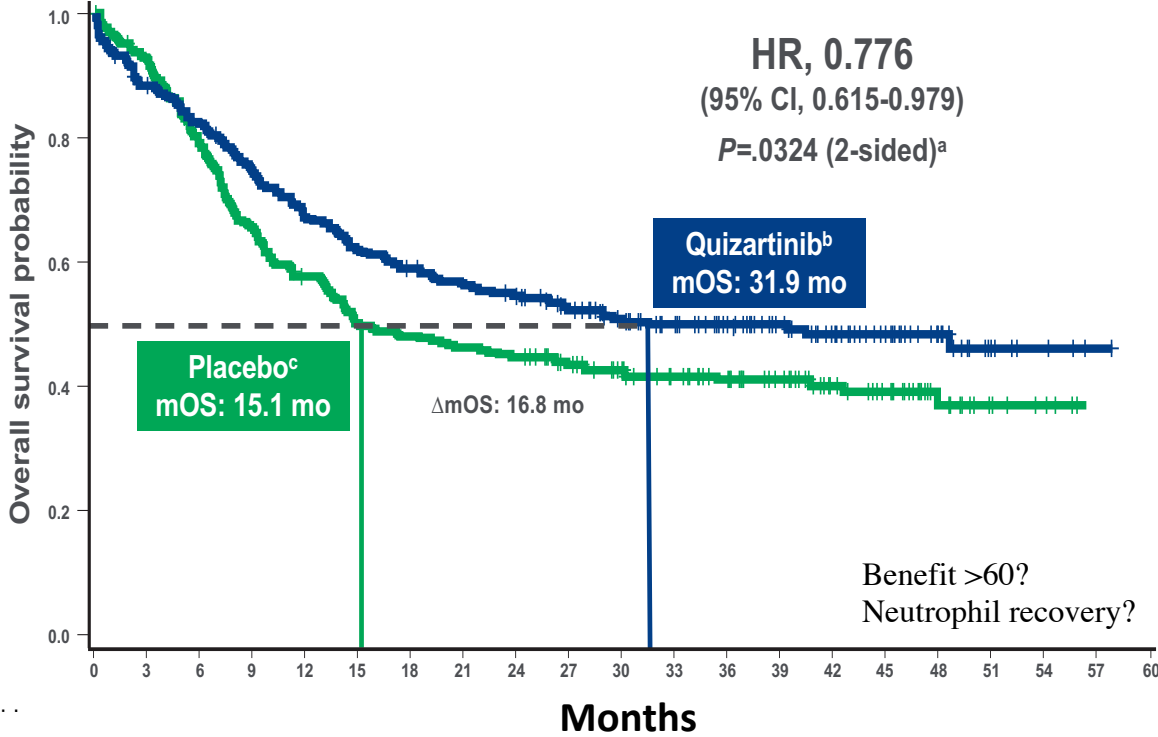
- Which FLT3 inhibitor for 1L therapy?
- FLT3 TKI or oral AZA as maintenance for patients with *FLT3* mutation?
- IVO-AZA or VEN-AZA for IDH1 mut AML?
- When to use gilteritinib in relapsed/refractory AML?
- 7+3 or VEN-AZA for adverse CG risk AML?

# Targeted options for 1L therapy of *FLT3*-ITD AML

	RATIFY	QuANTUM-First	
	Median Age	47	56
	≥ 60 y	0%	40%
	FLT3-ITD	78%	100%
	CR	59%	55%
Maint 12 m	Duration of CR	27m	39m
Gr 3+ Rash 14%	30-day death (vs PBO)	4.5% (3.1%)	5.7% (3.4%)



Stone RM, et al. *N Engl J Med* 2017; **377**:454–464

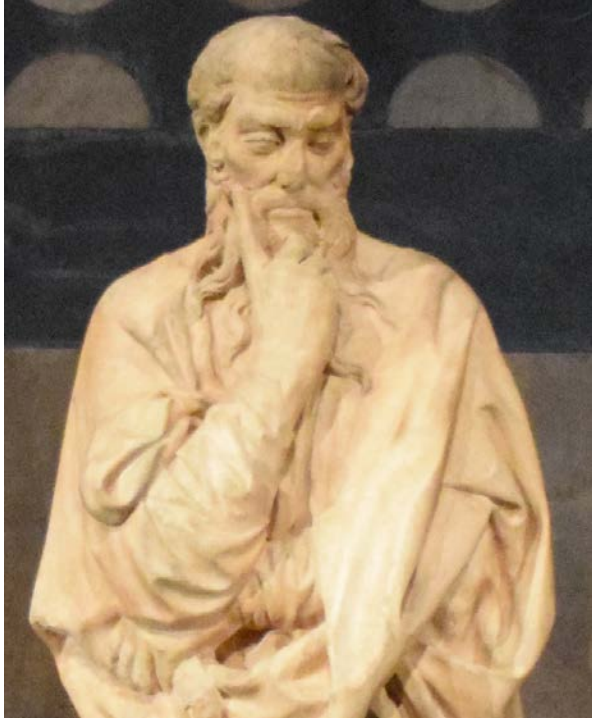


Courtesy of Andrew Wei, MBBS, PhD

Harry Erba, EHA 2022


# Controversies

- Which FLT3 inhibitor for 1L therapy?
- FLT3 TKI or oral AZA as maintenance for patients with *FLT3* mutation?
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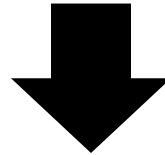


What would happen if we combined venetoclax and gilteritinib...or even used a triplet of aza/ven/gilt?

# FLT3 tyrosine kinase inhibitors synergize with BCL-2 inhibition to eliminate FLT3/ITD acute leukemia cells through BIM activation

Ruiqi Zhu<sup>1,2</sup>, Li Li<sup>1</sup>, Bao Nguyen<sup>1</sup>, Jaesung Seo<sup>1</sup>, Min Wu<sup>1</sup>, Tessa Seale<sup>1</sup>, Mark Levis<sup>1</sup>, Amy Duffield<sup>1,3</sup>, Yu Hu <sup>2</sup> and Donald Small<sup>1,4</sup>

*Signal Transduction and Targeted Therapy* (2021)6:186



In vitro rationale for combining venetoclax and gilteritinib

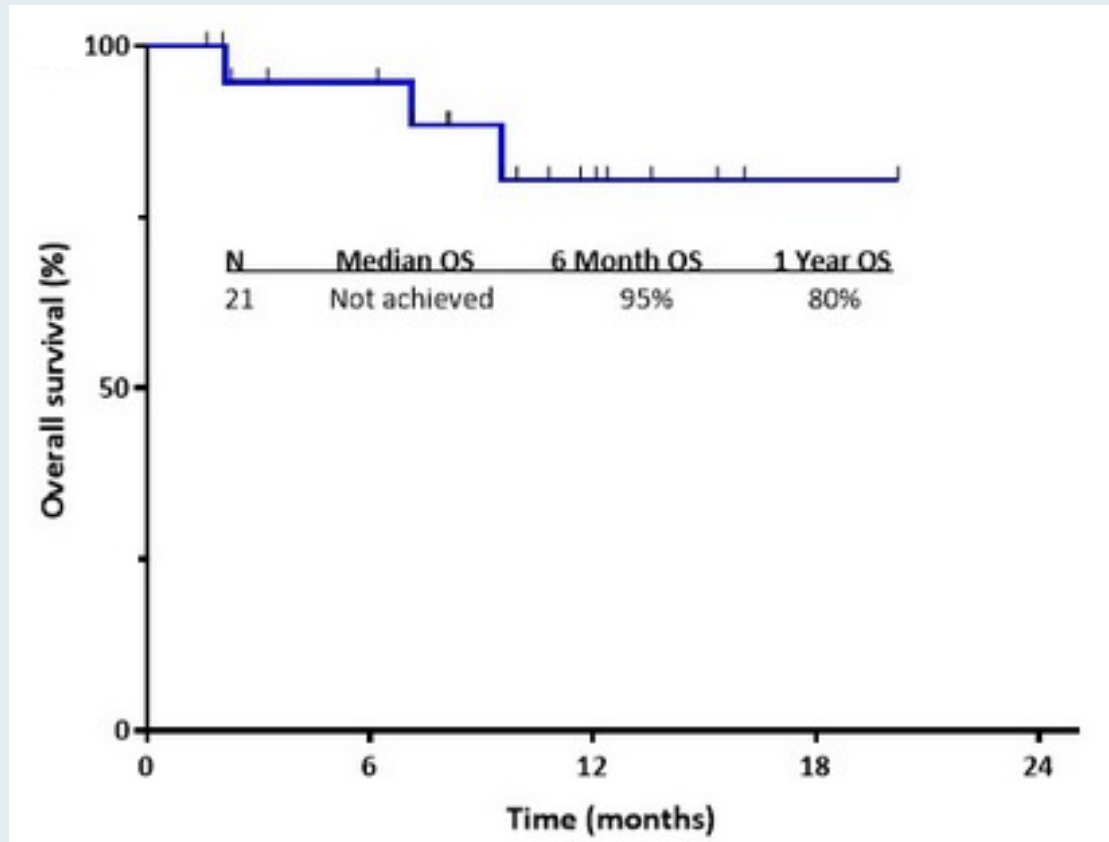
# Updated Results from a Phase I/II Study of the Triplet Combination of Azacitidine, Venetoclax and Gilteritinib for Patients with FLT3-Mutated Acute Myeloid Leukemia

Short N et al.

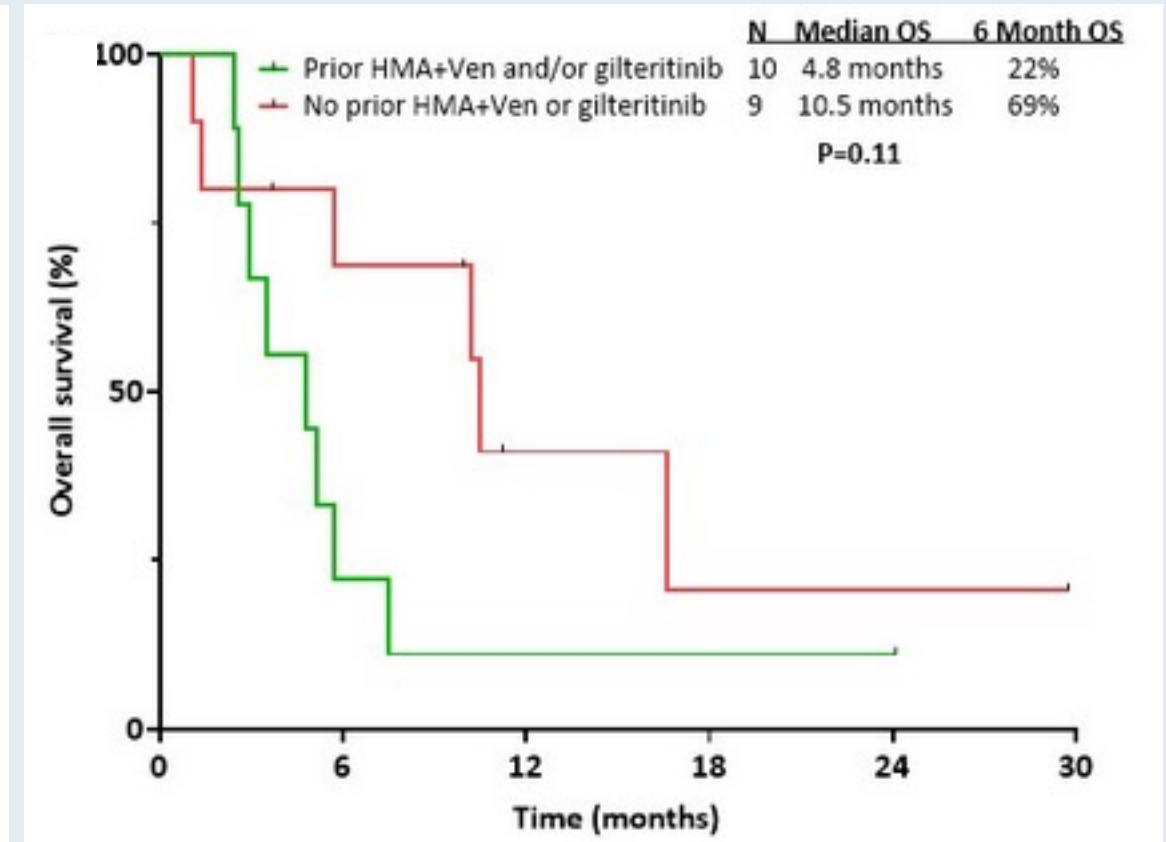
ASH 2022;Abstract 831.

# Overall Survival with the Triplet of Azacitidine, Venetoclax and Gilteritinib in the Newly Diagnosed Cohort and in the Relapsed/Refractory Cohort Stratified by Prior Therapy

Newly Diagnosed



Relapsed/Refractory





# APPENDIX

# **ASH 2022 – Select Additional Abstracts**

# Long-Term Survival of Acute Myeloid Leukemia Responding Patients Who Stopped Azacytidine and/or Venetoclax Because of Poor Tolerance or Physician Choice: A Retrospective Multicenter Study from the French Innovative Leukemia Organization (FILO)

Garciaz S et al.

ASH 2022;Abstract 2737 (Poster).

# Phase I/II Study of Azacitidine (AZA) with Venetoclax (VEN) and Magrolimab (Magro) in Patients (Pts) with Newly Diagnosed (ND) Older/Unfit or High-Risk Acute Myeloid Leukemia (AML) and Relapsed/Refractory (R/R) AML

Daver N et al.

ASH 2022;Abstract 61 (Oral).

# Single versus Double Induction with “7 + 3” Containing 60 versus 90 mg Daunorubicin for Newly Diagnosed AML: Results from the Randomized Controlled SAL Dauno-Double Trial

Röllig C et al.

ASH 2022;Abstract 217 (Oral).

# The Menin Inhibitor SNDX-5613 (Revumenib) Leads to Durable Responses in Patients (Pts) with KMT2A-Rearranged or NPM1 Mutant AML: Updated Results of a Phase (Ph) 1 Study

Issa GC et al.

ASH 2022;Abstract 63 (Oral).

# Update on a Phase 1/2 First-in-Human Study of the Menin-KMT2A (MLL) Inhibitor Ziftomenib (KO-539) in Patients with Relapsed or Refractory Acute Myeloid Leukemia

Erba HP et al.

ASH 2022;Abstract 64 (Oral).



# **FLAG-IDA Combined with Gemtuzumab Ozogamicin (GO) Improves Event Free Survival in Younger Patients with Newly Diagnosed Acute Myeloid Leukaemia (AML) and Shows an Overall Survival Benefit in NPM1 and FLT3 Mutated Subgroups. Results from the UK NCRI AML19 Trial**

Russell NH et al.

ASH 2022;Abstract 218 (Oral).

# ***Meet The Professor***

## **Optimizing the Management of Multiple Myeloma**

**Thursday, December 15, 2022  
5:00 PM – 6:00 PM ET**

**Faculty**

**Shaji K Kumar, MD**

**Moderator**

**Neil Love, MD**

***Thank you for joining us!***

***CME and MOC credit information will be emailed  
to each participant within 5 business days.***