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

Acute Myeloid Leukemia and Myelodysplastic Syndromes

Tuesday, April 4, 2023
5:00 PM – 6:00 PM ET

Faculty

Uma Borate, MD, MS

Andrew H Wei, MBBS, PhD

Moderator

Neil Love, MD

RTP Year in Review 2023

Faculty

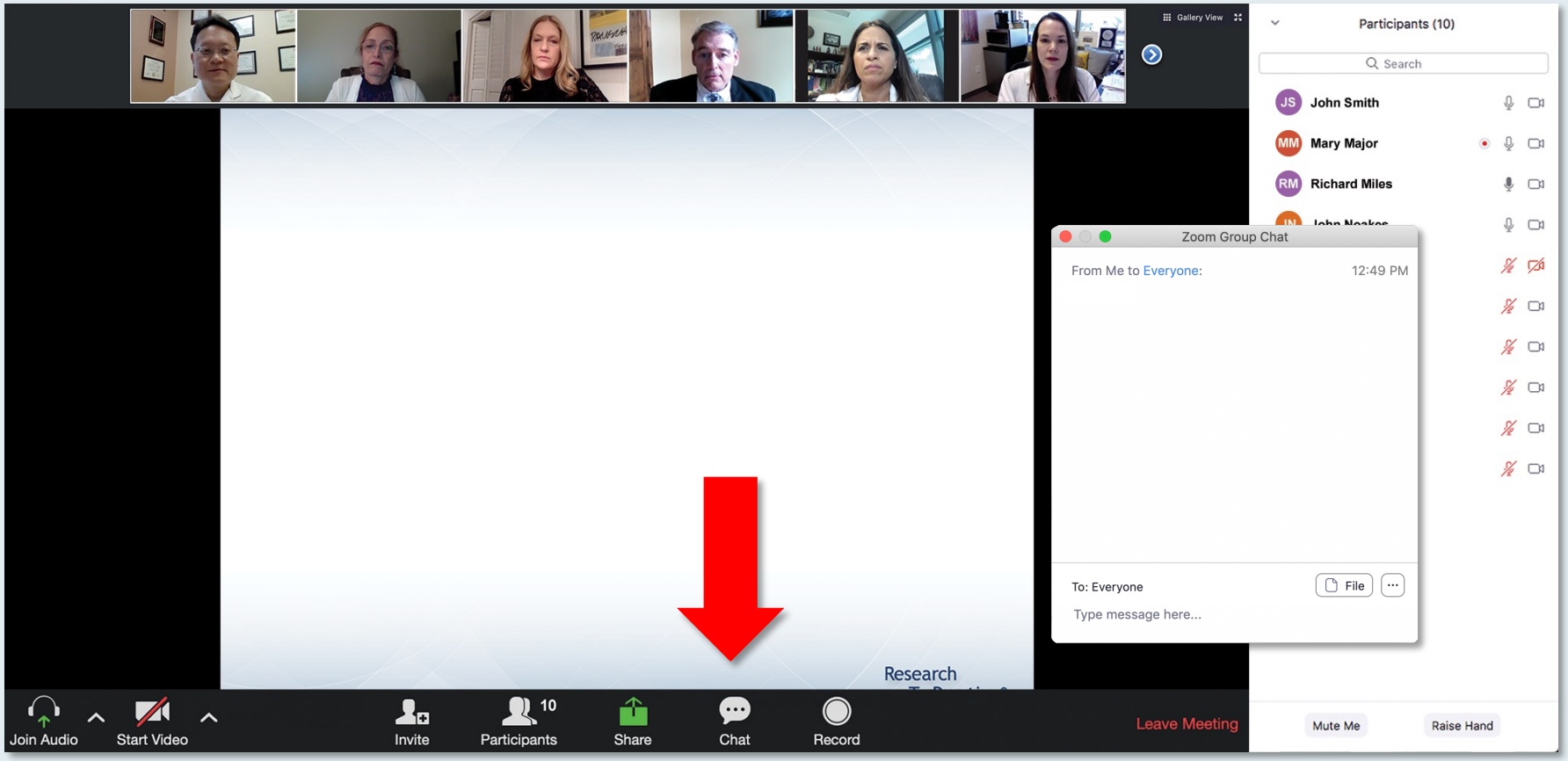
Uma Borate, MD, MS
Associate Professor of Internal Medicine
Division of Hematology
The Ohio State University
The James Cancer Center
Columbus, Ohio

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

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

RTP Year in Review 2023

We Encourage Clinicians in Practice to Submit Questions



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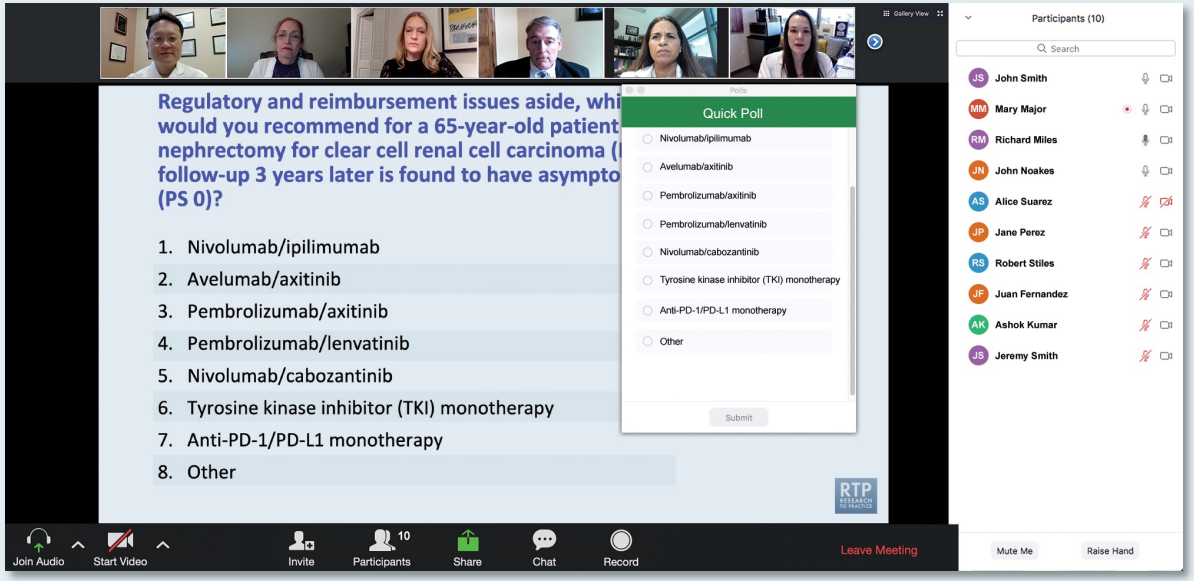

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ONCOLOGY TODAY

WITH DR NEIL LOVE

Key Presentations in Acute Myeloid Leukemia and Myelodysplastic Syndromes from the 2022 ASH Annual Meeting

DR RICHARD STONE

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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 US Inc, Gilead Sciences Inc, Grail Inc, GSK, 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, Stemline 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.

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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 Borate — Disclosures

Consulting Agreements	AbbVie Inc, Bristol-Myers Squibb Company, Daiichi Sankyo Inc, Gilead Sciences Inc, Incyte Corporation, Jazz Pharmaceuticals Inc, Novartis, Servier Pharmaceuticals LLC, Sumitomo Dainippon Pharma Oncology Inc
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Prof Wei — Disclosures

Advisory Committee	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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MODULE 2: AML and the General Medical Oncologist

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MODULE 4: MDS and the General Medical Oncologist

MODULE 5: Appendix

Thank you for joining us!

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

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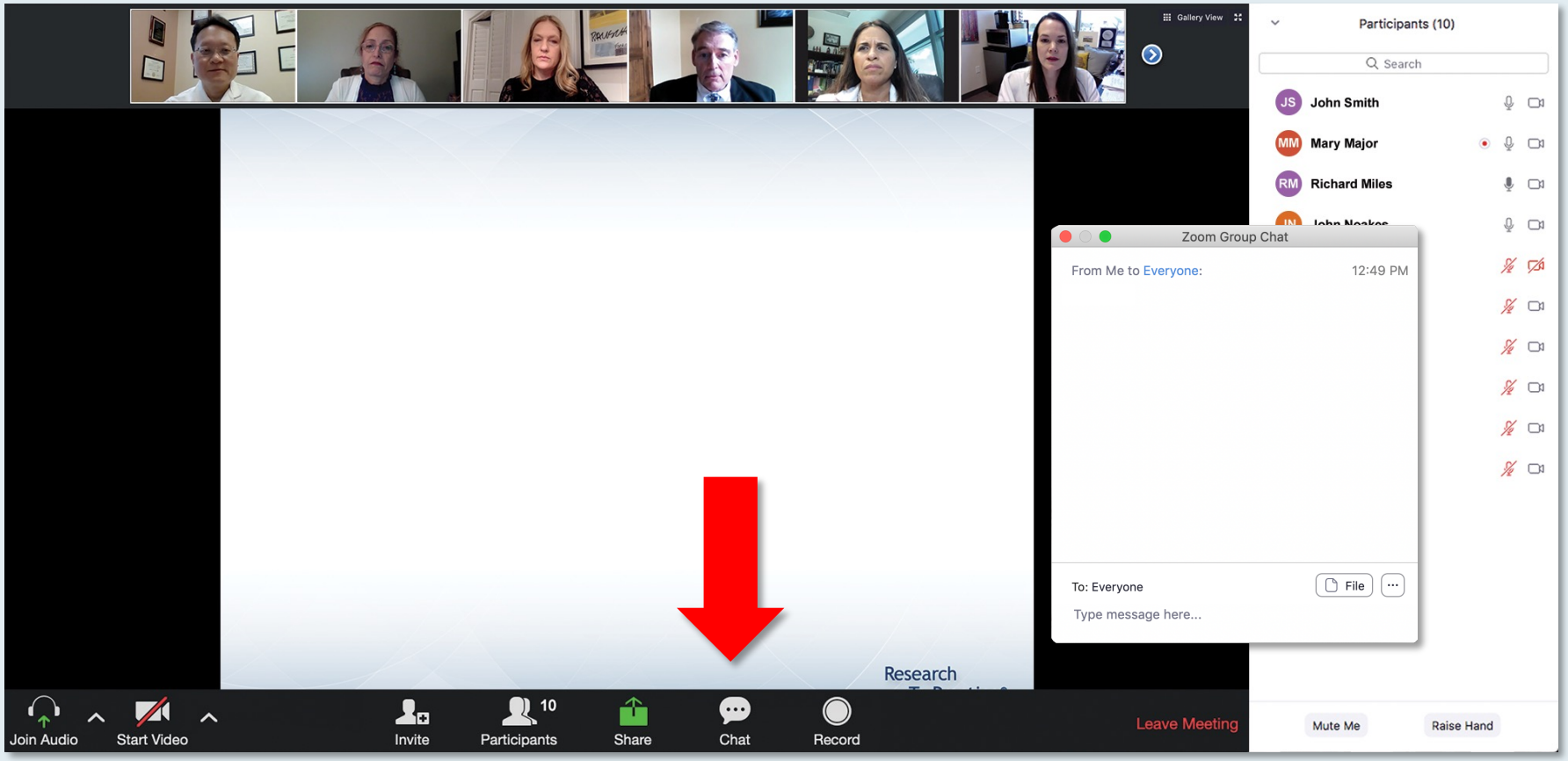

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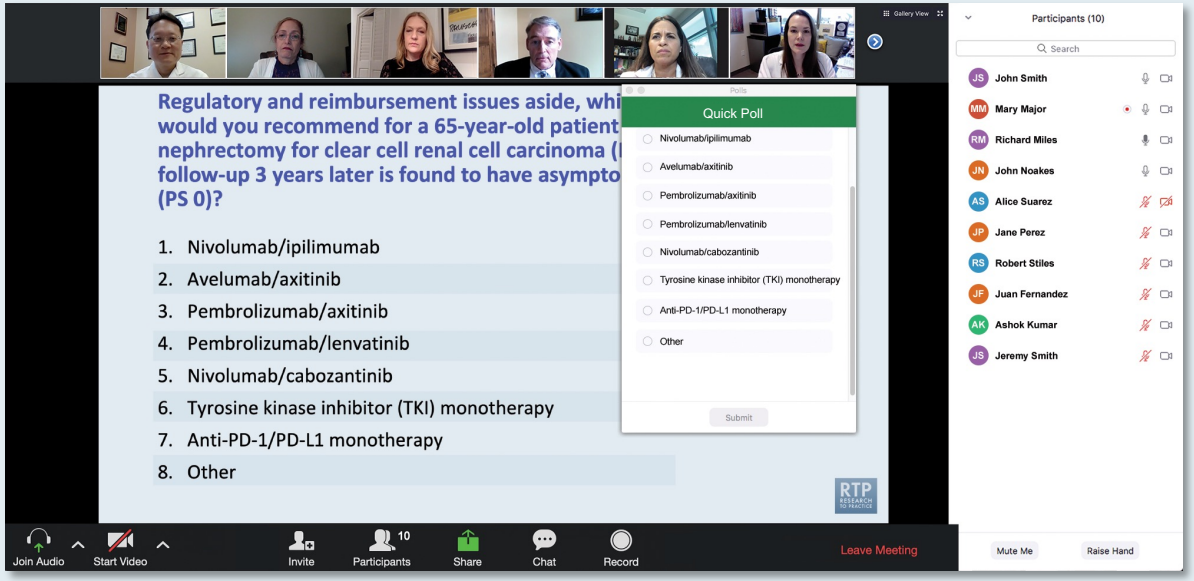

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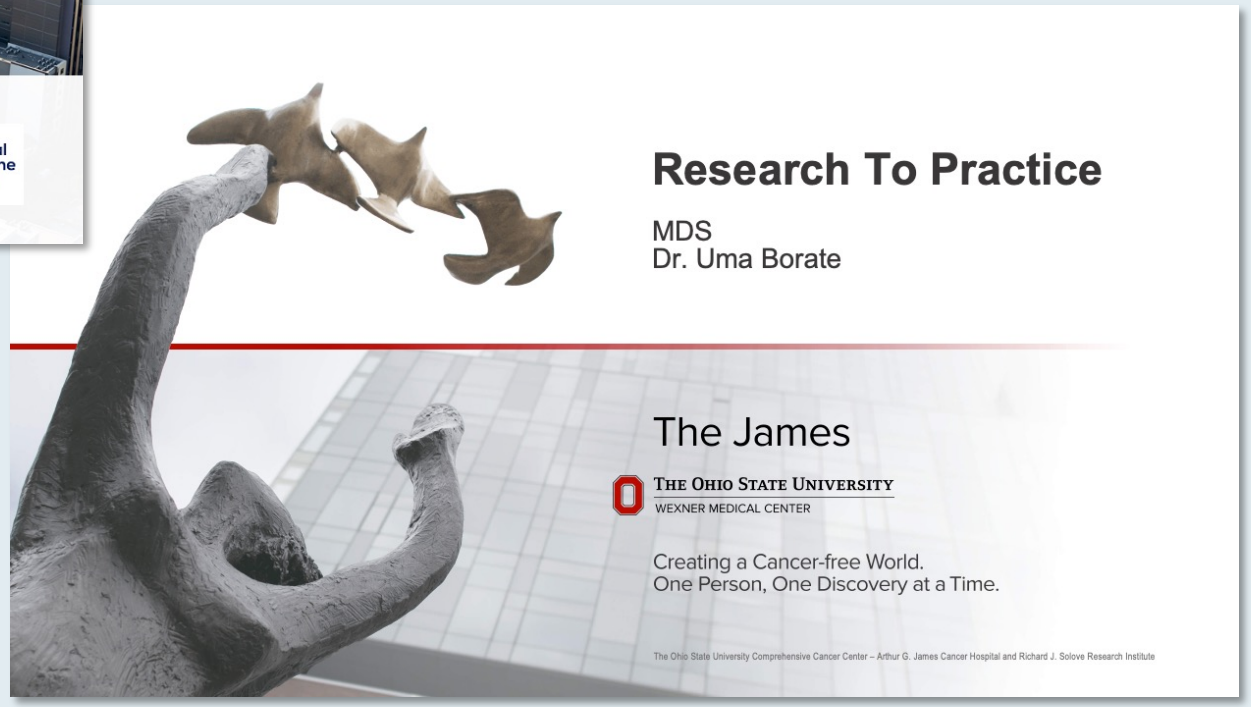

RTP Year in Review 2023

Key Data Sets

Andrew H Wei, MBBS, PhD (AML)

- Pratz KW et al. **Long-term follow-up** of the **phase 3 VIALE-A** clinical trial of **venetoclax plus azacitidine** for patients with untreated acute myeloid leukemia ineligible for intensive chemotherapy. ASH 2022;Abstract 219.
- Wei AH et al. **Long-term follow-up of VIALE-C** in patients with untreated AML ineligible for intensive chemotherapy. *Blood* 2022;140(25):2754-6.
- DiNardo CD et al. **Venetoclax** combined with **FLAG-IDA induction and consolidation** in newly diagnosed acute myeloid leukemia. *Am J Hematol* 2022;97(8):1035-43.
- Geissler K et al. Pharmacokinetic exposure equivalence and preliminary efficacy and safety from a randomized crossover phase 3 study of an **oral hypomethylating agent DEC-C,** compared to IV decitabine in AML patients. EHA 2022;Abstract P573.
- Perl AE et al. Follow-up of patients with R/R FLT3-mutation-positive AML treated with **gilteritinib** in the **phase 3 ADMIRAL** trial. *Blood* 2022;139(23):3366-75.

Key Data Sets

Andrew H Wei, MBBS, PhD (AML – continued)

- Short N et al. 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. ASH 2022;Abstract 831.
- Erba H et al. **Quizartinib** prolonged survival vs placebo plus intensive induction and consolidation therapy followed by single-agent continuation in **patients aged 18-75 years** with newly diagnosed FLT3-ITD+ AML. EHA 2022;Abstract S100.
- Levis MJ et al. **QuANTUM-First** trial: ***FLT3*-ITD-specific MRD clearance** is associated with improved overall survival. ASH 2022;Abstract 225.
- Montesinos P et al. **Ivosidenib and azacitidine** in *IDH1*-mutated acute myeloid leukemia. *N Engl J Med* 2022;386(16):1519-31.
- Cortes J et al. **Olutasidenib (FT-2102)** induces durable complete remissions in patients with relapsed/refractory mIDH1 acute myeloid leukemia. Results from a planned interim analysis of a phase 2 pivotal clinical trial. ASH 2022;Abstract 2757.

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- de Botton S et al. **Enasidenib** vs conventional care **in older patients with late-stage** mutant-IDH2 relapsed/refractory AML: A randomized phase 3 trial. *Blood* 2023;141(2):156-67.
- Cortes JE et al. Efficacy and safety of **CPX-351 versus 7 + 3** chemotherapy by European LeukemiaNet 2017 risk subgroups in older adults with newly diagnosed, **high-risk/secondary AML**: Post hoc analysis of a randomized, phase 3 trial. *J Hematol Oncol* 2022;15(1):155.
- Uy GL et al. **Lower-intensity CPX-351** + venetoclax for patients with newly diagnosed AML who are **unfit for intensive chemotherapy**. ASCO 2022;Abstract 7031.
- Erba HP et al. 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. ASH 2022;Abstract 64.

Key Data Sets

Andrew H Wei, MBBS, PhD (AML – continued)

- Issa GC et al. 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. ASH 2022;Abstract 63.
- Ravandi F et al. **COVALENT-101**: A phase 1 study of **BMF-219, a novel oral irreversible menin inhibitor**, in patients with relapsed/refractory (R/R) acute leukemia (AL), diffuse large B-cell lymphoma (DLBCL), and multiple myeloma (MM). ASCO 2022;Abstract TPS7064.
- Carvajal LA et al. **SYK inhibitors, entospletinib and lanraplenib,** show potent anti-leukemic activity in combination with targeted agents. ASH 2022;Abstract 2639.

Key Data Sets

Uma Borate, MD, MS (MDS)

- Bernard E et al. Molecular International Prognostic Scoring System for myelodysplastic syndromes. *NEJM Evid* 2022;1(7).
- Garelius H et al. Erythropoietin stimulation agents significantly improve outcome in lower risk MDS. EHA 2022;Abstract S168.
- Fenaux P et al. Long-term utilization and benefit of **luspatercept** in patients (pts) with **lower-risk** myelodysplastic syndromes (LR-MDS) from the **MEDALIST** trial. ASCO 2022;Abstract 7056.
- Cadenas FL et al. Evaluation of **lenalidomide** (LEN) vs placebo in **non-transfusion dependent low risk del(5q)** MDS patients. Final results of **Sintra-REV phase III** international multicenter clinical trial. ASH 2022;Abstract 460.
- Savona MR et al. Prolonged survival in **bi-allelic *TP53*-mutated** (*TP53*mut) MDS subjects treated with **oral decitabine/cedazuridine** in the **ASCERTAIN** trial (ASTX727-02). ASH 2022;Abstract 854.

Key Data Sets

Uma Borate, MD, MS (MDS – continued)

- Garcia-Manero G et al. **ASTX727-03**: Phase 1 study evaluating **oral decitabine/cedazuridine (ASTX727) low-dose** (LD) in **lower-risk** myelodysplastic syndromes (LR-MDS) patients. ASH 2022;Abstract 461.
- Bazinet A et al. **Azacitidine plus venetoclax** in patients with **high-risk** myelodysplastic syndromes or chronic myelomonocytic leukaemia: Phase 1 results of a single-centre, dose-escalation, dose-expansion, phase 1-2 study. *Lancet Haematol* 2022;9(10):e756-65.
- Zeidan AM et al. A phase 1b study of **venetoclax and azacitidine** combination in patients with relapsed or refractory myelodysplastic syndromes. *Am J Hematol* 2023;98(2):272-81.
- Venugopal S et al. A phase I/II study of **venetoclax** in combination with **ASTX727 (decitabine/cedazuridine)** in **treatment-naïve high-risk** myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML). EHA 2022;Abstract P784.
- Sallman D et al. **Magrolimab** in combination with **azacitidine** for **untreated higher-risk** myelodysplastic syndromes (HR-MDS): 5F9005 phase 1b study results. ASCO 2022;Abstract 7017.

Key Data Sets

Uma Borate, MD, MS (MDS – continued)

- Zeidan AM et al. Primary results of **Stimulus-MDS1**: A randomized, double-blind, placebo-controlled Phase II study of **TIM-3 inhibition** with **sabatolimab** added to hypomethylating agents (HMAs) in adult patients with higher-risk myelodysplastic syndromes (MDS). ASH 2022;Abstract 853.
- Santini V et al. Disease characteristics and International Prognostic Scoring Systems (IPSS, IPSS-R, IPSS-M) in adult patients with **higher-risk** myelodysplastic syndromes (MDS) participating in two randomized, double-blind, placebo-controlled studies with intravenous **sabatolimab** added to hypomethylating agents (HMA) (**STIMULUS-MDS1 and MDS2**). ASH 2022;Abstract 559.
- Adès L et al. **Pevonedistat plus azacitidine** vs azacitidine alone in **higher-risk** MDS/chronic myelomonocytic leukemia or low-blast-percentage AML. *Blood Adv* 2022;6(17):5132-45.

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MODULE 2: AML and the General Medical Oncologist

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MODULE 4: MDS and the General Medical Oncologist

MODULE 5: Appendix

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- Venetoclax combinations
- Decitabine/cedazuridine: Oral decitabine
- FLT3: QuANTUM-First trial and more
- IDH-mutant disease
- More on CPX-351: New subsets?
- Menin inhibitors!

MODULE 2: AML and the General Medical Oncologist

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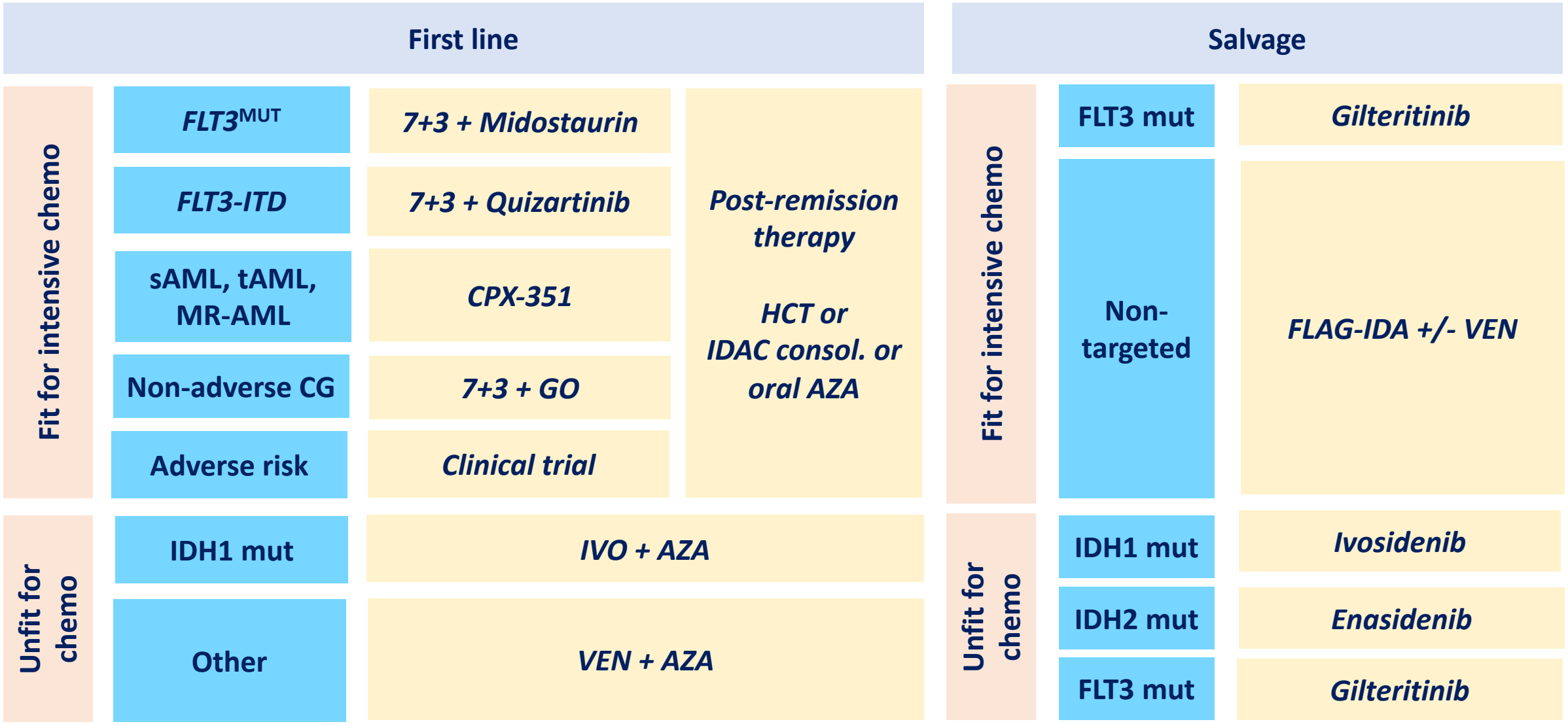
MODULE 5: Appendix

AML update

Andrew Wei

Peter MacCallum Cancer Centre
Royal Melbourne Hospital
Melbourne, Australia

Current landscape in AML



Courtesy of Andrew H Wei, MBBS, PhD

Venetoclax Combinations

- Pratz KW et al. **Long-term follow-up** of the **phase 3 VIALE-A** clinical trial of **venetoclax plus azacitidine** for patients with untreated acute myeloid leukemia ineligible for intensive chemotherapy. ASH 2022;Abstract 219.
- Wei AH et al. **Long-term follow-up of VIALE-C** in patients with untreated AML ineligible for intensive chemotherapy. *Blood* 2022;140(25):2754-6.
- DiNardo CD et al. **Venetoclax** combined with **FLAG-IDA induction and consolidation** in newly diagnosed acute myeloid leukemia. *Am J Hematol* 2022;97(8):1035-43.

Decitabine/Cedazuridine: Oral Decitabine

- Geissler K et al. Pharmacokinetic exposure equivalence and preliminary efficacy and safety from a randomized crossover phase 3 study of an **oral hypomethylating agent DEC-C,** compared to IV decitabine in AML patients. EHA 2022;Abstract P573.

FLT3: QuANTUM-First and More

- Levis MJ et al. **QuANTUM-First** trial: ***FLT3*-ITD-specific MRD clearance** is associated with improved overall survival. ASH 2022;Abstract 225.
- Perl AE et al. Follow-up of patients with R/R FLT3-mutation-positive AML treated with **gilteritinib** in the **phase 3 ADMIRAL** trial. *Blood* 2022;139(23):3366-75.
- Short N et al. 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. ASH 2022;Abstract 831.
- Erba H et al. **Quizartinib** prolonged survival vs placebo plus intensive induction and consolidation therapy followed by single-agent continuation in **patients aged 18-75 years** with newly diagnosed FLT3-ITD+ AML. EHA 2022;Abstract S100.

IDH-Mutant Disease

- Montesinos P et al. **Ivosidenib and azacitidine** in *IDH1*-mutated acute myeloid leukemia. *N Engl J Med* 2022;386(16):1519-31.
- Cortes JE et al. **Olutasidenib (FT-2102)** induces durable complete remissions in patients with relapsed/refractory mIDH1 acute myeloid leukemia. Results from a planned interim analysis of a phase 2 pivotal clinical trial. ASH 2022;Abstract 2757.
- de Botton S et al. **Enasidenib** vs conventional care **in older patients with late-stage** mutant-IDH2 relapsed/refractory AML: A randomized phase 3 trial. *Blood* 2023;141(2):156-67.

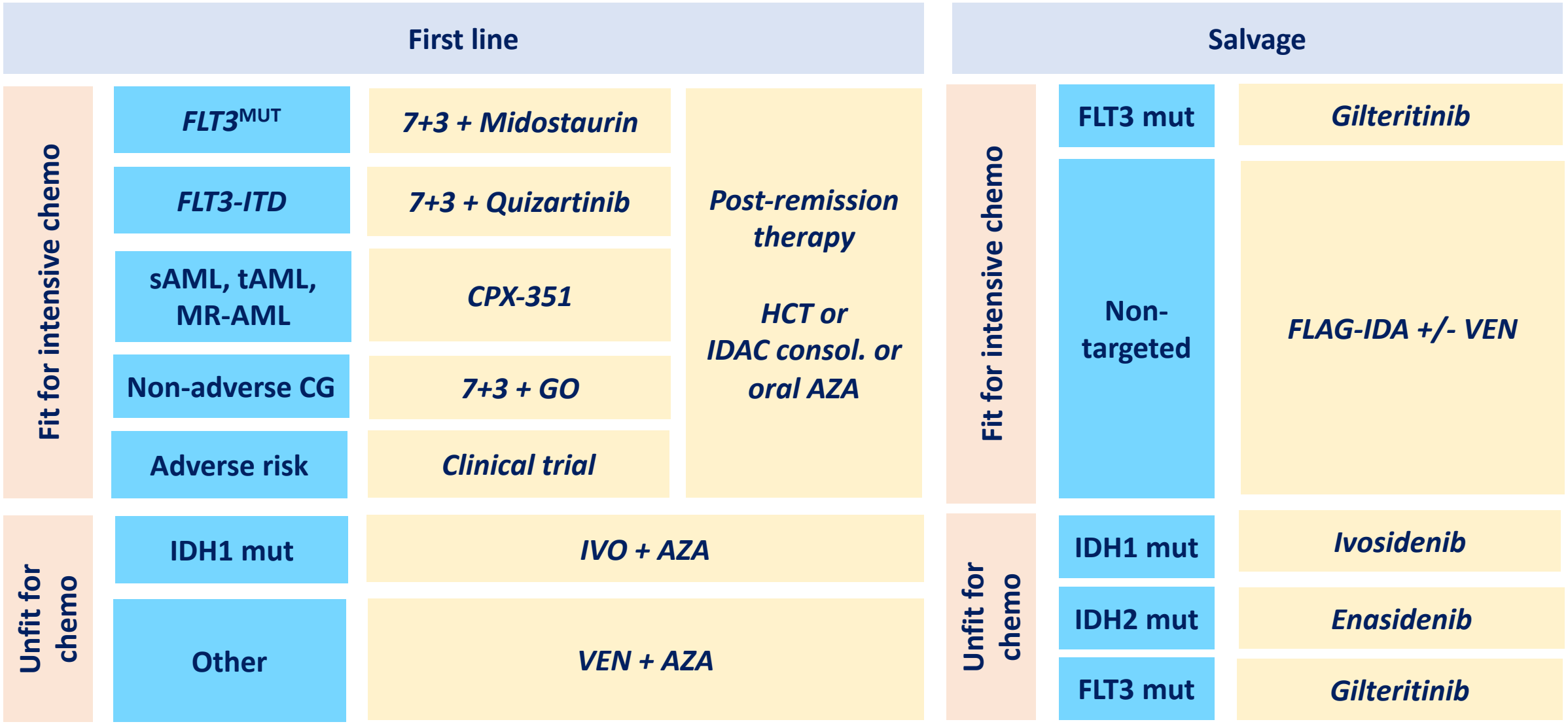
More on CPX-351: New Subsets?

- Cortes JE et al. Efficacy and safety of **CPX-351 versus 7 + 3** chemotherapy by European LeukemiaNet 2017 risk subgroups in older adults with newly diagnosed, **high-risk/secondary AML**: Post hoc analysis of a randomized, phase 3 trial. *J Hematol Oncol* 2022;15(1):155.
- Uy GL et al. **Lower-intensity CPX-351** + venetoclax for patients with newly diagnosed AML who are **unfit for intensive chemotherapy**. ASCO 2022;Abstract 7031.

Menin Inhibitors!

- Erba HP et al. 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. ASH 2022;Abstract 64.
- Issa GC et al. 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. ASH 2022;Abstract 63.
- Ravandi F et al. **COVALENT-101**: A phase 1 study of **BMF-219, a novel oral irreversible menin inhibitor**, in patients with relapsed/refractory (R/R) acute leukemia (AL), diffuse large B-cell lymphoma (DLBCL), and multiple myeloma (MM). ASCO 2022;Abstract TPS7064.

Current landscape in AML



Courtesy of Andrew H Wei, MBBS, PhD

Agenda

MODULE 1: Acute Myeloid Leukemia (AML): Key Papers and Presentations

MODULE 2: AML and the General Medical Oncologist

MODULE 3: Myelodysplastic Syndromes (MDS): Key Papers and Presentations

MODULE 4: MDS and the General Medical Oncologist

MODULE 5: Appendix

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Key Discussion Question

From the global, macro perspective of a general medical oncologist in community-based practice, what do you consider to be some of the most important recent developments in AML?

Key Discussion Question

What are some ongoing clinical trials in AML from which we might see data this year that may have an important impact on clinical practice?

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MODULE 1: Acute Myeloid Leukemia (AML): Key Papers and Presentations

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MODULE 3: Myelodysplastic Syndromes (MDS): Key Papers and Presentations

- Defining low- and high-risk MDS
- Management of low-risk MDS: When to treat and with what?
- Decitabine/cedazuridine: Oral decitabine for MDS
- Hypomethylating agents (HMAs)/venetoclax for high-risk MDS
- Novel antibodies: Magrolimab and sabatolimab
- Better use of HMAs for MDS

MODULE 4: MDS and the General Medical Oncologist

MODULE 5: Appendix

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Research To Practice

MDS
Dr. Uma Borate

The James

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Creating a Cancer-free World.
One Person, One Discovery at a Time.

Defining Low- and High-Risk MDS

- Bernard E et al. Molecular International Prognostic Scoring System for myelodysplastic syndromes. *NEJM Evid* 2022;1(7).

Management of Low-Risk MDS: When to Treat and with What?

- Garelius H et al. Erythropoietin stimulation agents significantly improve outcome in lower risk MDS. EHA 2022;Abstract S168.
- Fenaux P et al. Long-term utilization and benefit of **luspatercept** in patients (pts) with **lower-risk** myelodysplastic syndromes (LR-MDS) from the **MEDALIST** trial. ASCO 2022;Abstract 7056.
- Cadenas FL et al. Evaluation of **lenalidomide** (LEN) vs placebo in **non-transfusion dependent low risk del(5q)** MDS patients. Final results of **Sintra-REV phase III** international multicenter clinical trial. ASH 2022;Abstract 460.

Decitabine/Cedazuridine: Oral Decitabine for MDS

- Savona MR et al. Prolonged survival in **bi-allelic *TP53*-mutated** (*TP53*mut) MDS subjects treated with **oral decitabine/cedazuridine** in the **ASCERTAIN** trial (ASTX727-02). ASH 2022;Abstract 854.
- Garcia-Manero G et al. **ASTX727-03**: Phase 1 study evaluating **oral decitabine/cedazuridine (ASTX727) low-dose** (LD) in **lower-risk** myelodysplastic syndromes (LR-MDS) patients. ASH 2022;Abstract 461.

HMAs/Venetoclax for High-Risk MDS

- Bazinet A et al. **Azacitidine plus venetoclax** in patients with **high-risk** myelodysplastic syndromes or chronic myelomonocytic leukaemia: Phase 1 results of a single-centre, dose-escalation, dose-expansion, phase 1-2 study. *Lancet Haematol* 2022;9(10):e756-65.
- Zeidan AM et al. A phase 1b study of **venetoclax and azacitidine** combination in patients with relapsed or refractory myelodysplastic syndromes. *Am J Hematol* 2023;98(2):272-81.
- Venugopal S et al. A phase I/II study of **venetoclax** in combination with **ASTX727 (decitabine/cedazuridine)** in **treatment-naïve high-risk** myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML). EHA 2022;Abstract P784.

Novel Antibodies: Magrolimab and Sabatolimab

- Sallman DA et al. **Magrolimab** in combination with **azacitidine** for **untreated higher-risk** myelodysplastic syndromes (HR-MDS): 5F9005 phase 1b study results. ASCO 2022;Abstract 7017.
- Zeidan AM et al. Primary results of **Stimulus-MDS1**: A randomized, double-blind, placebo-controlled Phase II study of **TIM-3 inhibition** with **sabatolimab** added to hypomethylating agents (HMAs) in adult patients with higher-risk myelodysplastic syndromes (MDS). ASH 2022;Abstract 853.
- Santini V et al. Disease characteristics and International Prognostic Scoring Systems (IPSS, IPSS-R, IPSS-M) in adult patients with **higher-risk** myelodysplastic syndromes (MDS) participating in two randomized, double-blind, placebo-controlled studies with intravenous **sabatolimab** added to hypomethylating agents (HMA) (**STIMULUS-MDS1 and MDS2**). ASH 2022;Abstract 559.

Better Use of HMAs for MDS

- Adès L et al. **Pevonedistat plus azacitidine** vs azacitidine alone in **higher-risk** MDS/chronic myelomonocytic leukemia or low-blast-percentage AML. *Blood Adv* 2022;6(17):5132-45.

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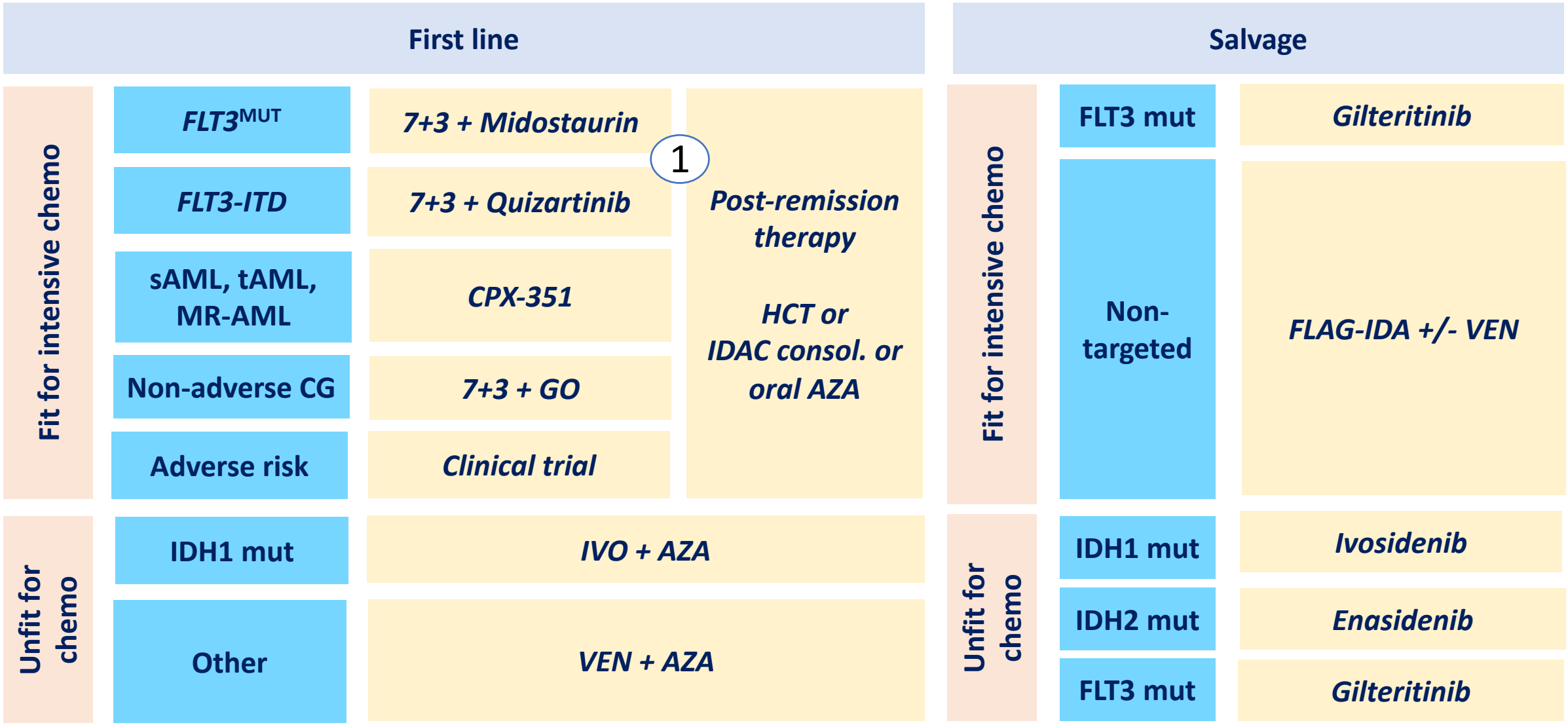
Acute Myeloid Leukemia

Current landscape in AML



Courtesy of Andrew H Wei, MBBS, PhD

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

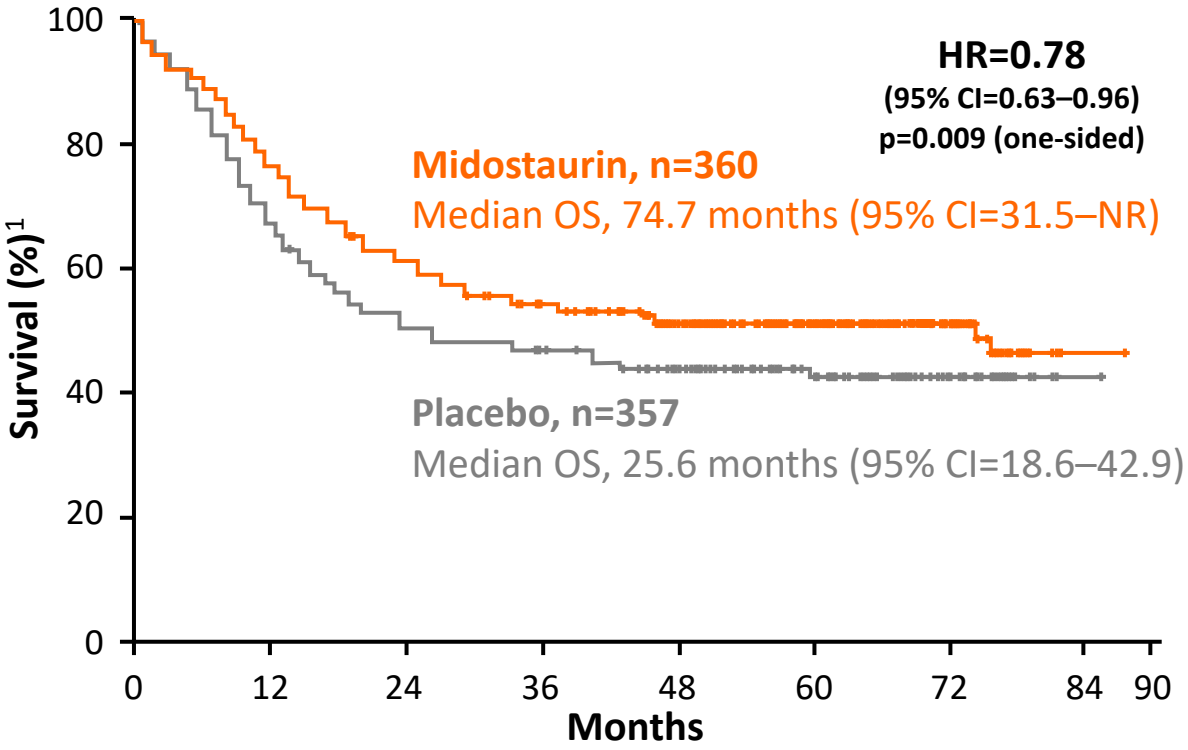
	RATIFY	QuANTUM-First
Median Age	47	56
≥ 60 y	0%	40%
FLT3-ITD	78%	100%
CR	59%	55%
Duration of CR	27m	39m
30-day death (vs PBO)	4.5% (3.1%)	5.7% (3.4%)

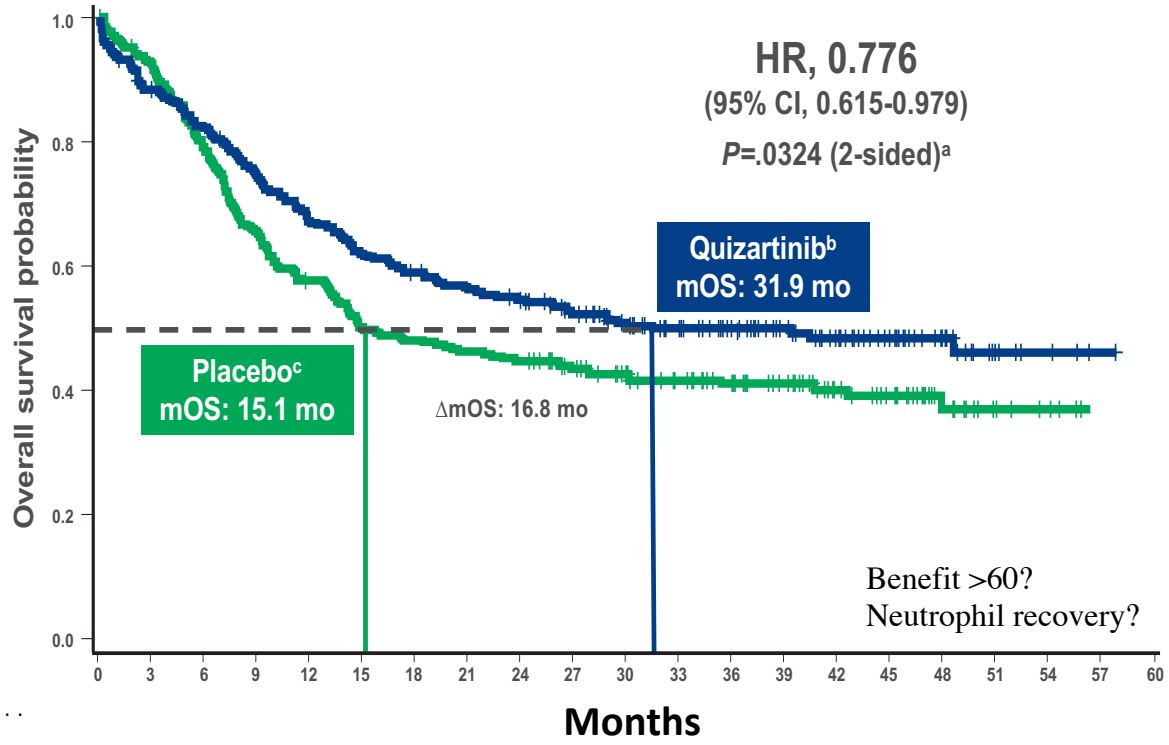
Maint 12 m

Gr 3+ Rash 14%

Maint 36 m + post HCT Quiz

Gr 3+ QTc inc 13.6%



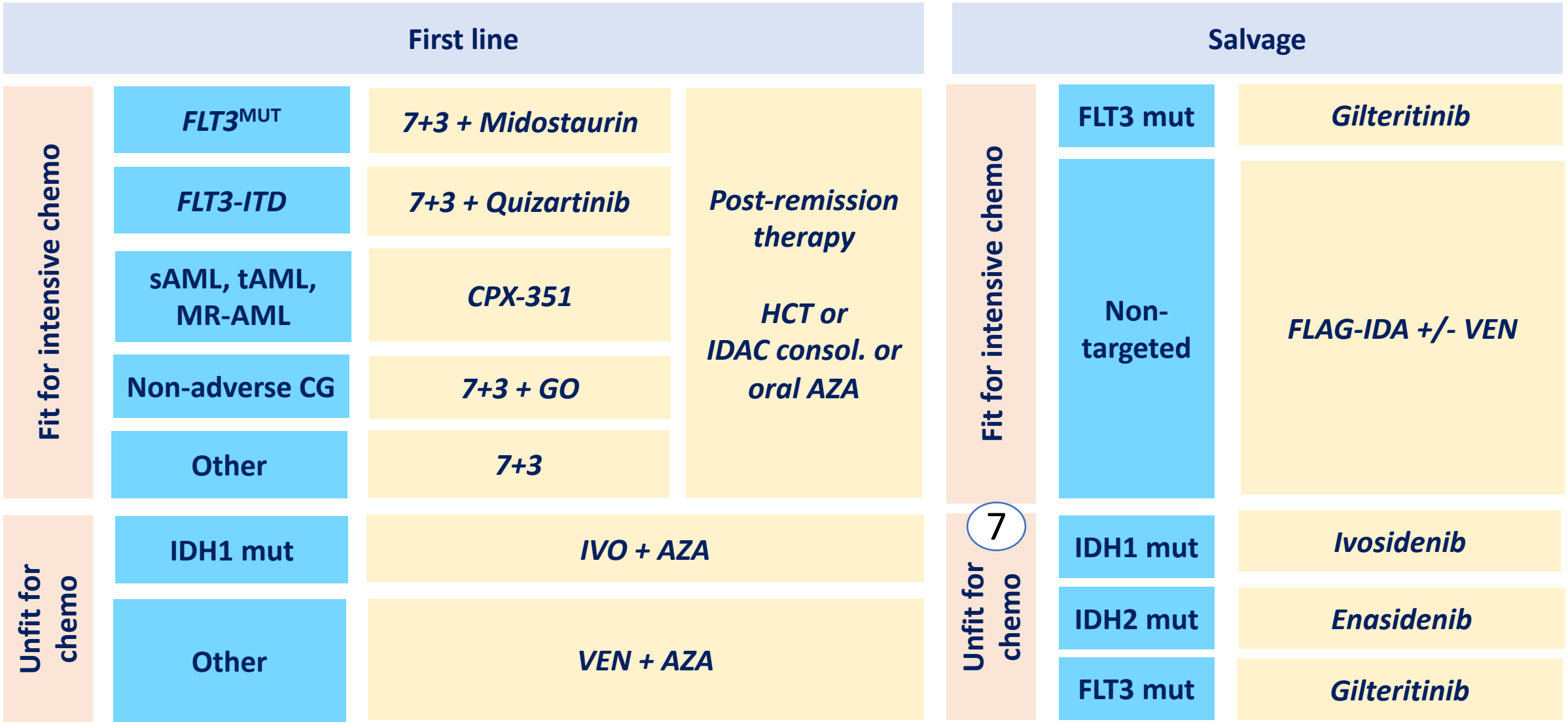


Courtesy of Andrew H Wei, MBBS, PhD

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

Harry Erba, EHA 2022; Abstract S100, Levis ASH 2022; Abstract 225

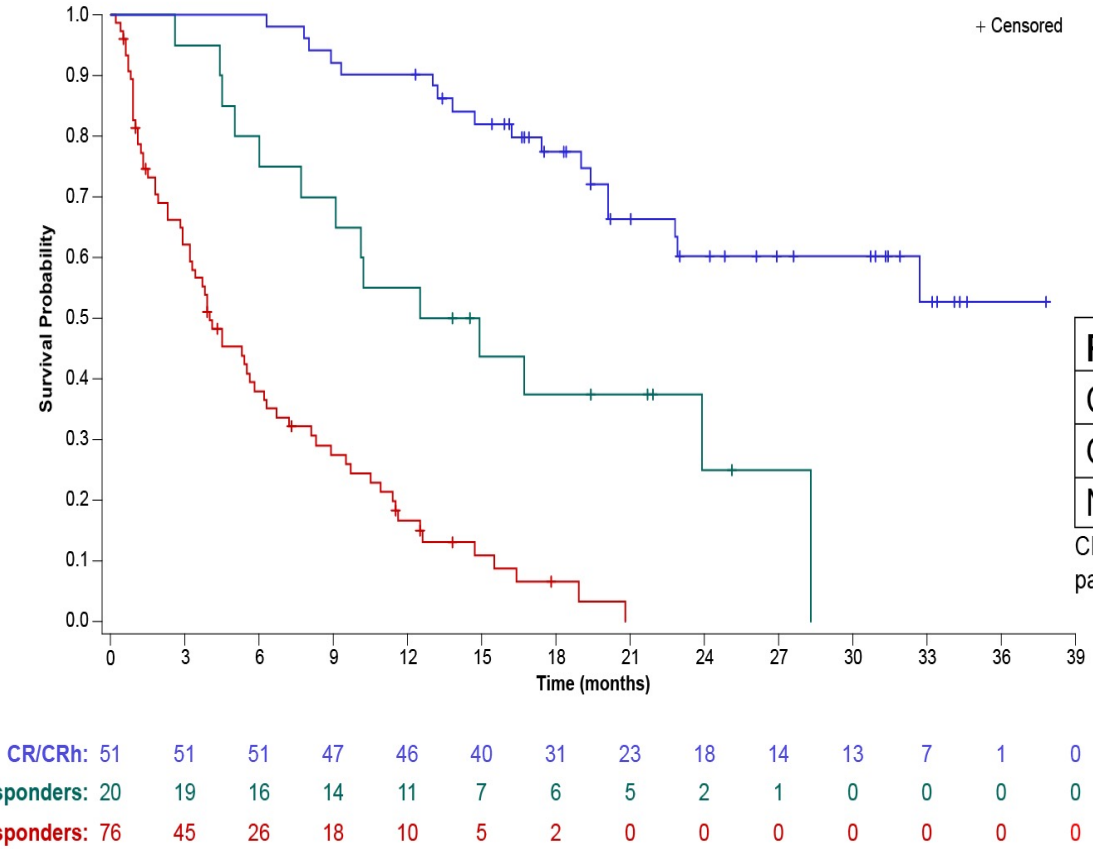
Current landscape in AML



Courtesy of Andrew H Wei, MBBS, PhD

Olutasidenib (FT-2102) in Relapsed/Refractory mIDH1 AML

Response Rates, n (%)	Efficacy Evaluable Cohort (N = 147)
ORR	71 (48)
CR	47 (32)
CRh	4 (3)
CRi	15 (10)
PR	3 (2)
MLFS	2 (1)



Response Category	Median OS (95% CI)
CR/CRh Responders	NR (22.8–NR)
Other Responders	13.7 months (6.0–NR)
Non-Responders	4.0 months (3.2–5.8)

CI=confidence interval; CR=complete remission; CRh=CR with partial hematologic recovery; NR=not reached; OS=overall survival

Courtesy of Andrew H Wei, MBBS, PhD

Cortes et al, ASH 2022

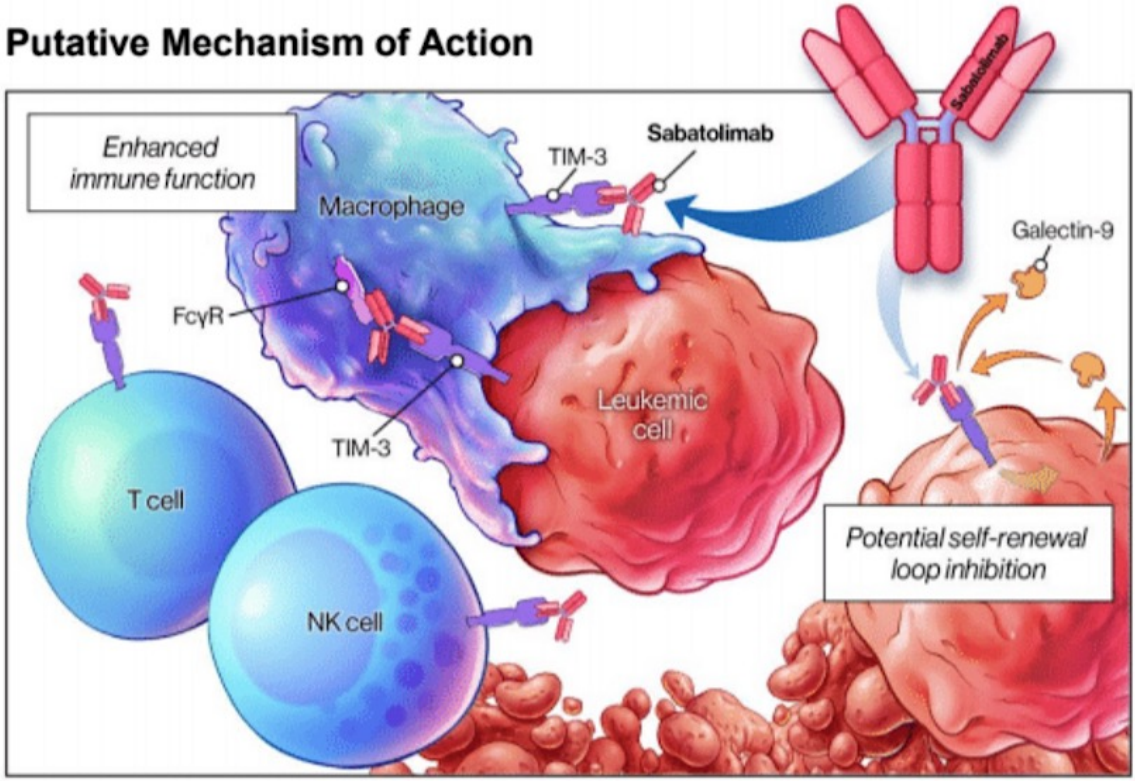
Myelodysplastic Syndromes

Primary results of Stimulus-MDS1: A randomized, double-blind, placebo-controlled Phase II study of TIM-3 inhibition with sabatolimab added to hypomethylating agents (HMAs) in HR-MDS

Sabatolimab is a novel immunotherapy targeting the immuno-myeloid regulator TIM-3

- TIM-3 is expressed on LSCs and blasts, but not on normal HSCs[1-5]
- As an inhibitory receptor, TIM-3 plays a key role in regulating innate and adaptive immune responses[1,2]
- Preclinical studies show that sabatolimab has a potential dual mechanism to combat myeloid malignancies by reactivating the immune system[6]
- Sabatolimab + HMAs demonstrated clinical benefit with favorable tolerability in a Phase Ib study in patients with HR/vHR-MDS[7]

Putative Mechanism of Action



Zeidan AM et al. ASH 2022; Abstract 853

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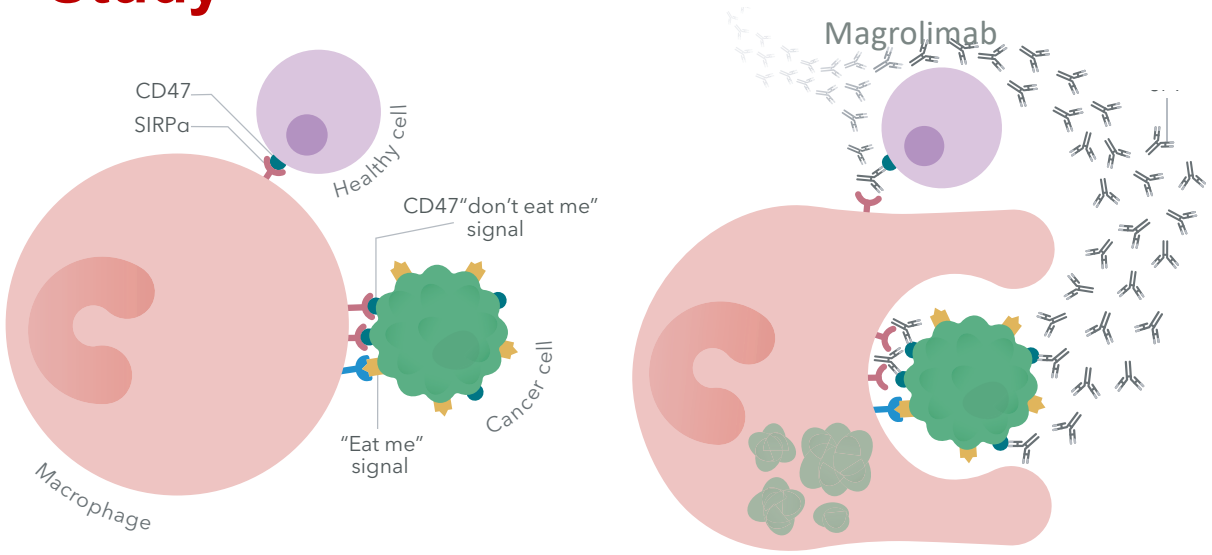
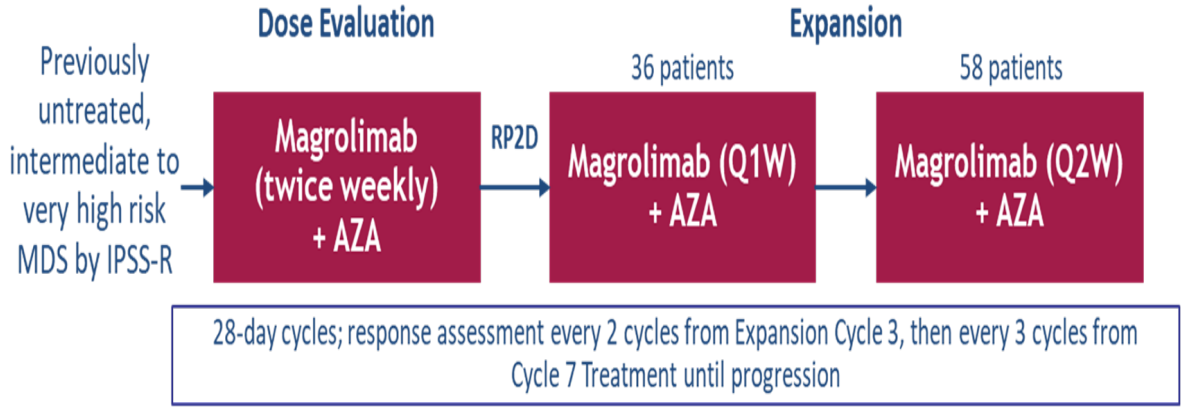
Courtesy of Uma Borate, MD, MS

Magrolimab, a First-in-Class Macrophage Immune Checkpoint Inhibitor Targeting CD47-Magrolimab in Combination With Azacitidine in Patients With Higher-Risk Myelodysplastic Syndromes: Final Results of a Phase Ib Study



- CD47 is a "don't eat me" signal that is overexpressed in multiple cancers, including MDS, leading to macrophage immune evasion.[1,2]
- Magrolimab, an IgG4 anti-CD47 monoclonal antibody, eliminates tumor cells through macrophage phagocytosis.[1]



- Patients received magrolimab IV as a 1 mg/kg priming dose on Days 1 and 4, then ramp-up to 30 mg/kg QW or Q2W maintenance; AZA dose was SC or IV 75 mg/m^2 on Days 1-7 of each cycle.

Primary objectives

Safety, tolerability and efficacy (CR rate) of magrolimab + azacitidine in HR-MDS

Secondary objectives

Efficacy of magrolimab + azacitidine; PK profile; Immunogenicity; MRD negativity

Exploratory objectives

CD47 RO, Biomarkers, Efficacy in molecular subtypes of MDS

CR = complete remission; IPSS-R = Revised International Prognostic Scoring System; IV = intravenous; MRD = minimal residual disease; RO = receptor occupancy; RP2D = recommended Phase 2 dose; SC = subcutaneous; Q1W = weekly; Q2W = every two weeks.

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Courtesy of Uma Borate, MD, MS

1. Liu J, et al. *PLoS One*. 2015;10(9):e0137345. 2. Chao MP, et al. *Front Oncol*. 2020;9:1380.

Sallman ASCO 2022; Abstract 7017

Precision Medicine in MDS?

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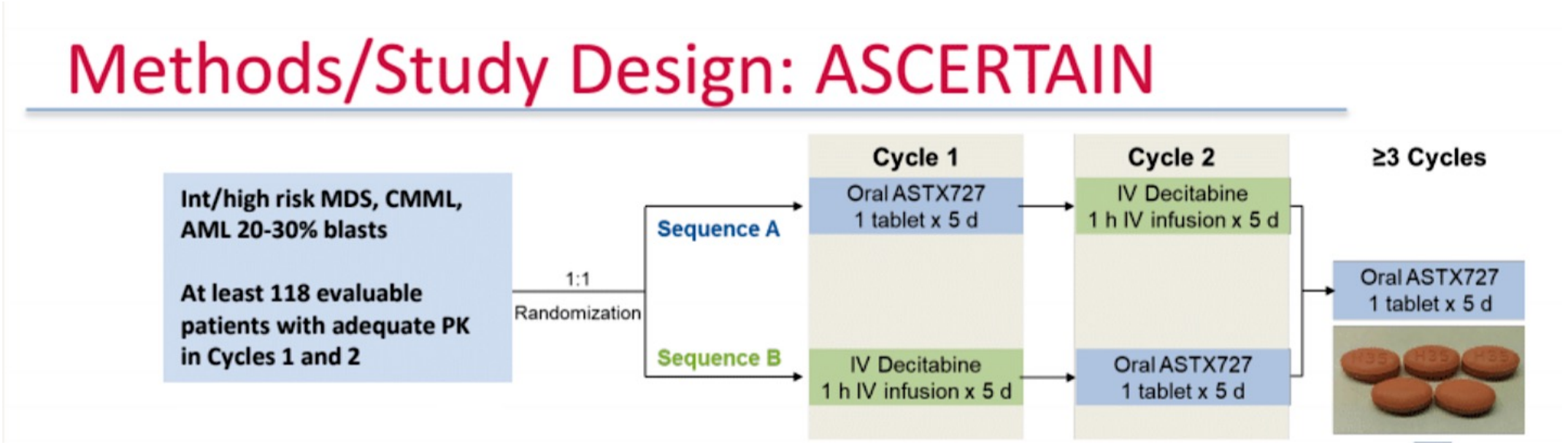
Courtesy of Uma Borate, MD, MS

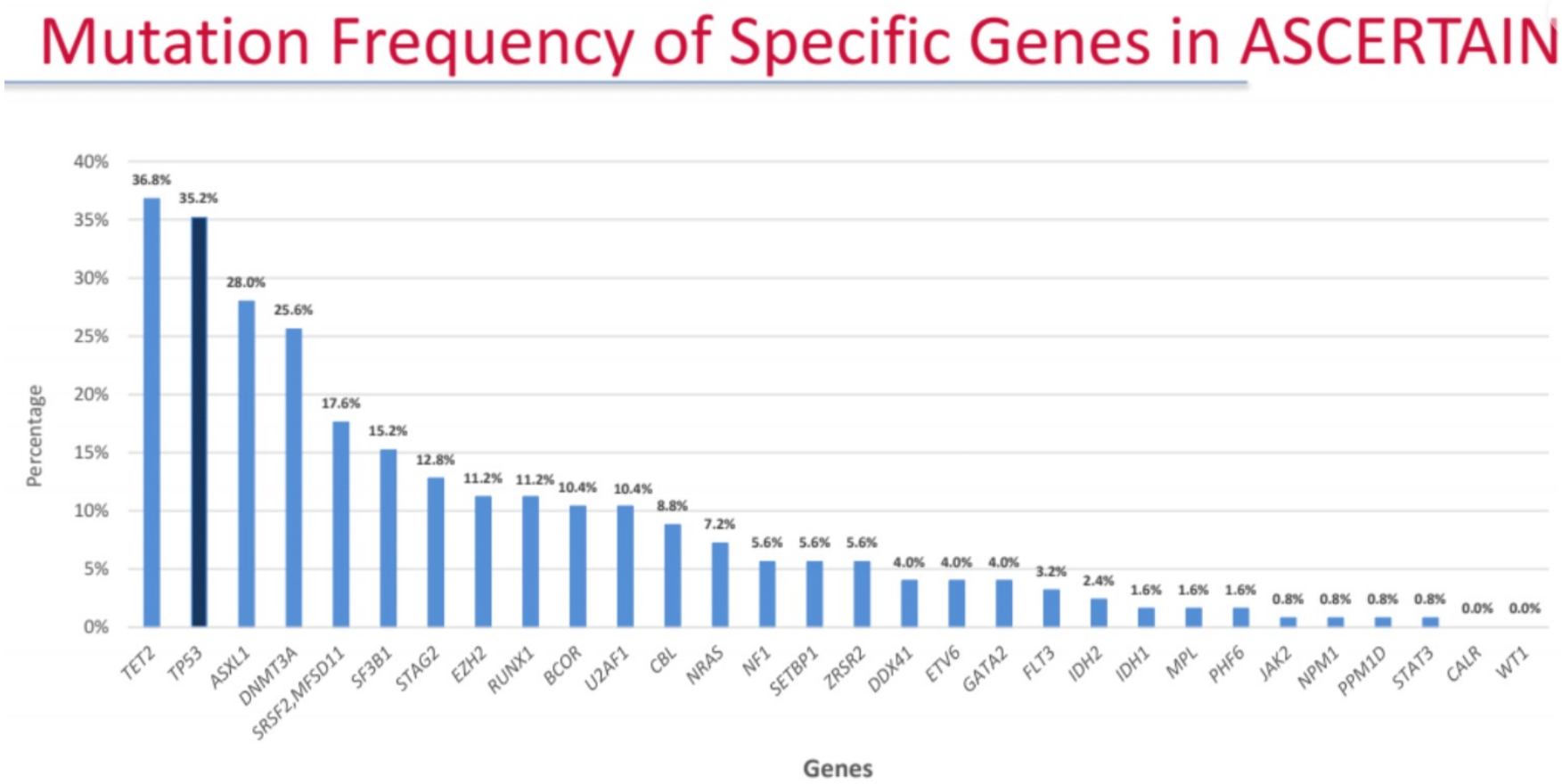
What do we do about TP53 mutated MDS?

- TP53 mutations are associated with poor overall survival despite similar response rates in MDS (9.4 vs. 20.7 months in TP53mut vs.TP53wt)



Garcia-Manero ASH 2022; Abstract 854

TP53 mutations in ASCERTAIN study



The TP53mut population was analyzed by allelic status:
Biallelic if more than one TP53 copy OR 17p deletion and at least one TP53 mutation (*LOH analyses were not conducted).
TP53mut: 30 monoallelic, 14 biallelic (by this definition)

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Garcia-Manero ASH 2022; Abstract 854

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Courtesy of Uma Borate, MD, MS

Meet The Professor

Optimizing the Management of ER-Positive and Triple-Negative Breast Cancer

Wednesday, April 12, 2023
5:00 PM – 6:00 PM ET

Faculty

Sara A Hurvitz, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open up to 5 minutes after the meeting ends.

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

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