



EPICS

Congress Coverage: ASH 2021 – Focus on Leukemia and MDS

Full Report

December 15, 2021

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Virtual Closed-Door Roundtable



DATE:
December 15, 2021



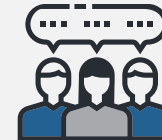
**DISEASE STATE AND
DATA PRESENTATIONS**
by key experts



INSIGHTS REPORT
including postmeeting
analyses and actionable
recommendations



PANEL: Key experts in
leukemia
> 5 from US
> 4 from EU



**LEUKEMIA-SPECIFIC
DISCUSSIONS** on
therapeutic advances and
their application in clinical
decision-making

Panel Consisting of 5 US and 4 European Leukemia Experts

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Jae Park, MD
Memorial Sloan Kettering
Cancer Center



CHAIR:
Elias Jabbour, MD
MD Anderson Cancer Center



Naval Daver, MD
MD Anderson Cancer Center



Guillermo Garcia-Manero, MD
MD Anderson Cancer Center



Amir Fathi, MD
Massachusetts General
Hospital



**Charles Craddock, CBE, FRCP
(UK), FRCPath, DPhil, FMedSci**
Queen Elizabeth Hospital



CO-CHAIR:
Nicola Gökbuget, MD
Goethe University Hospital



Valeria Santini, MD
University of Florence



Josep-Maria Ribera, MD, PhD
Hospital Germans Trias i Pujol



Meeting Agenda

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Time (CST)	Topic	Speaker/Moderator
1.00 PM – 1.05 PM	Welcome and Introductions	Elias Jabbour, MD, and Nicola Gökbüget, MD
1.05 PM – 1.15 PM	New Developments in MDS	Guillermo Garcia-Manero, MD, and Valeria Santini, MD
1.15 PM – 1.45 PM	<i>Discussion and Key Takeaways</i>	<i>All</i> <i>Moderator: Elias Jabbour, MD</i>
1.45 PM – 2.00 PM	Advances in AML: Newly Diagnosed	Amir Fathi, MD, and Charles Craddock, CBE, FRCP (UK), FRCPPath, DPhil, FMedSci
2.00 PM – 2.25 PM	<i>Discussion and Key Takeaways</i>	<i>All</i> <i>Moderator: Elias Jabbour, MD</i>
2.25 PM – 2.35 PM	Advances in AML: Relapsed/Refractory	Naval Daver, MD
2.35 PM – 3.00 PM	<i>Discussion and Key Takeaways</i>	<i>All</i> <i>Moderator: Elias Jabbour, MD</i>
3.00 PM – 3.05 PM	Break	
3.05 PM – 3.15 PM	Advances in ALL: Newly Diagnosed	Josep-Maria Ribera, MD, PhD
3.15 PM – 3.35 PM	<i>Discussion and Key Takeaways</i>	<i>All</i> <i>Moderator: Nicola Gökbüget, MD</i>
3.35 PM – 3.45 PM	Advances in ALL: Relapsed/Refractory	Jae Park, MD
3.45 PM – 4.10 PM	<i>Discussion and Key Takeaways</i>	<i>All</i> <i>Moderator: Nicola Gökbüget, MD</i>
4.10 PM – 4.15 PM	Summary and Closing Remarks	Elias Jabbour, MD, and Nicola Gökbüget, MD



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Congress Highlights

Updates on MDS

Long Term Follow-up and Combined Phase 2 Results of Eprenetapopt (APR-246) and Azacitidine (AZA) in Patients with *TP53* mutant Myelodysplastic Syndromes (MDS) and Oligoblastic Acute Myeloid Leukemia (AML)

David A. Sallman, et al, #246

STUDY POPULATION

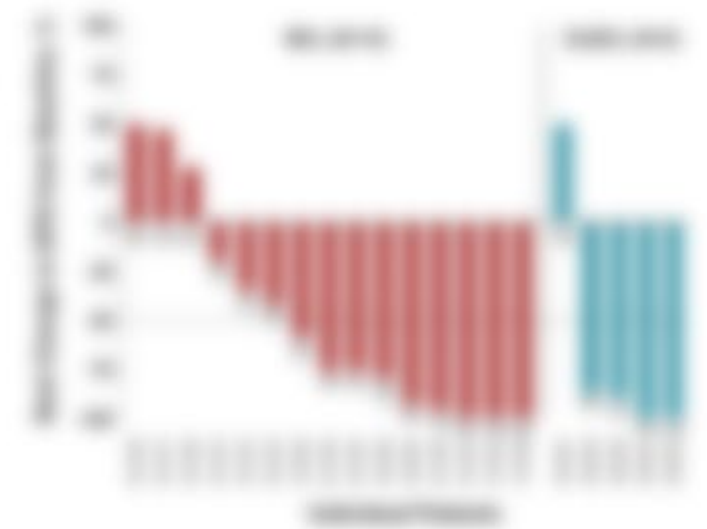
Background

- Phase 1 dose-escalation study of U.S. 101, a *TP53*-targeting APO2, in patients with newly diagnosed MDS and AML
- Primary objective was to define subgroups of MDS and AML that may respond

Results

- 21 patients were enrolled, including 10 patients with MDS
- 20.5% were CR responders and 100% durable
- CR responders occurred in 20% of patients, 100% durably sustained
- CR responders 100% durably sustained in 20% of patients, no CR durably sustained
- CRR was 47% (2 CR, 4 PR) for MDS cohort and 50% (2 CR, 2 PR) for AML cohort
- 8 responding patients have ongoing responses ranging from 20 weeks to 58 weeks

Combined Cohorts (n=100)



Key takeaway: U.S. 101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MDS and AML. Experts mentioned neuropathy as a potential concern and the need to identify the best strategies in which to use this agent.

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Discussion Summary

Updates on MDS

MDS with mutations

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Congress Highlights

Updates on Newly Diagnosed AML

Phase 3, Open-Label, Randomized Study of Gilteritinib and Azacitidine Vs Azacitidine for Newly Diagnosed *FLT3*-Mutated Acute Myeloid Leukemia in Patients Ineligible for Intensive Induction Chemotherapy

Eunice S. Wang, et al, #700

STUDY POPULATION

Background

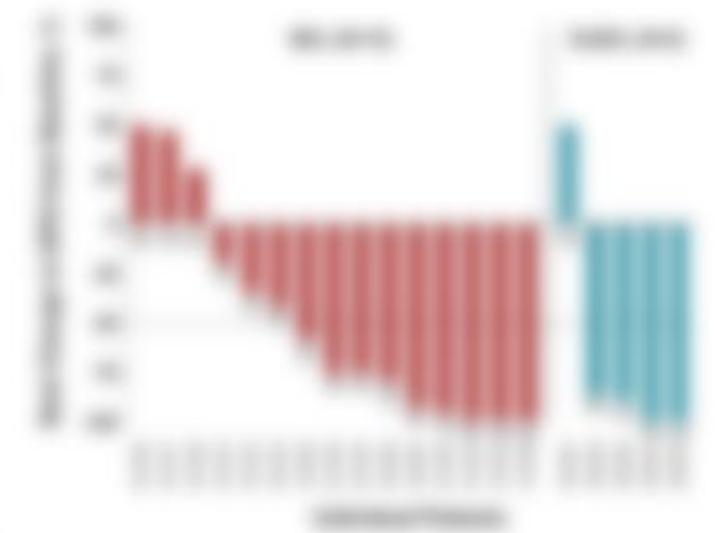
- Phase 3, open-label, randomized study of U.S. 101, a *FLT3*-inhibiting AML, in patients with newly diagnosed AML and t(8;21).
- Primary objective was to define outcomes of *FLT3* and recommended dosing regimen.

Results

- 22 patients were enrolled, including 10 patients with *FLT3*.
- 16.7% were t(8;21) and 100% were *FLT3*.
- 100% neutropenia occurred in 20% of patients, 100% successfully resolved.
- On study, overall 100% neutropenia occurred in 0% of patients, no 100% neutropenia occurred.
- 100% was 17% (2/12), 4.7% (1/21) for *FLT3* cohort and 0% (0/10), 2.7% (1/37) for t(8;21) cohort.
- 8 responding patients have ongoing responses ranging from 20 weeks to 58 weeks.

LACEWING – Overall Survival

Median Overall Survival: 17.0 months for GIL + AZA vs 17.07 months for AZA



Key takeaway: U.S. 101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced *FLT3* and t(8;21). Experts mentioned neutropenia as a potential concern and the need to identify the best strategies in which to use this agent.

AGILE: A Global, Randomized, Double-Blind, Phase 3 Study of Ivosidenib + Azacitidine Versus Placebo + Azacitidine in Patients with Newly Diagnosed Acute Myeloid Leukemia with an *IDH1* Mutation

Pau Montesinos, et al, #697

EFS in the intent-to-treat population

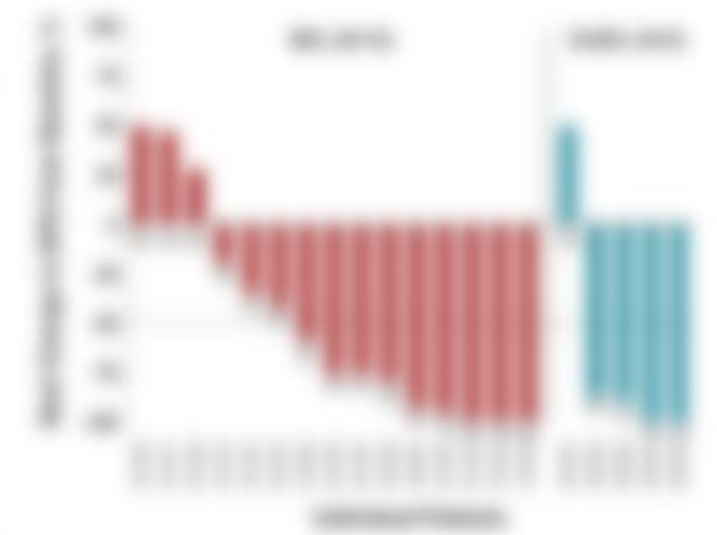
STUDY POPULATION

Background

- Phase 3, double-blind, randomized study of ivosidenib + azacitidine (I+AZ) vs placebo + azacitidine (P+AZ) in patients with newly diagnosed AML and t(8;21).
- Primary objective was to assess outcomes of EFS and overall survival during regimen.

Results

- 22 patients were enrolled, including 10 patients with t(8;21).
- 22.7% were t(8;21) and 77.3% were non-t(8;21).
- 22 patients received I+AZ, 22.7% successfully completed regimen.
- 22 patients received P+AZ, 22.7% successfully completed regimen.
- CR was 47% (21/44), 47% for t(8;21) subset and 47% (21/44) for non-t(8;21) subset.
- 8 responding patients have ongoing responses ranging from 23 weeks to 58 weeks.



Key takeaway: I+AZ demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced AML and t(8;21). Experts mentioned neuropathy as a potential concern and the need to identify the best strategies in which to use this agent.

Phase I and Expansion Study of Eprenetapopt (APR-246) in Combination with Venetoclax (VEN) and Azacitidine (AZA) in TP53-Mutant Acute Myeloid Leukemia (AML)

Guillermo Garcia-Manero, et al, #3409

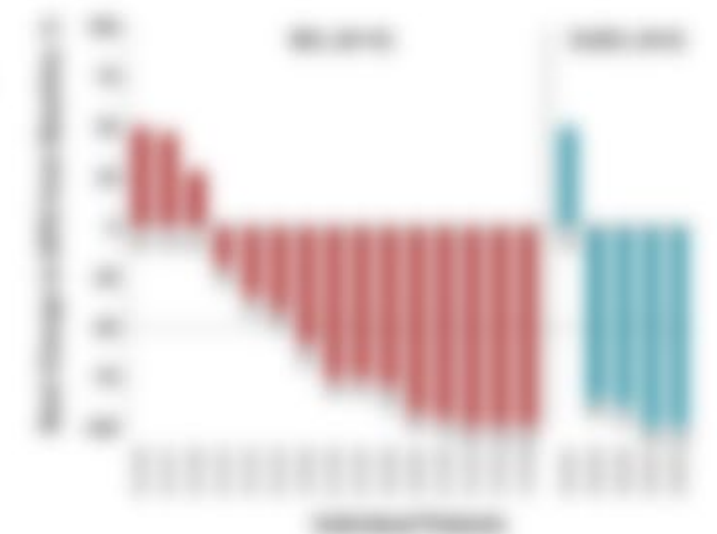
STUDY POPULATION

Background

- Phase I dose-escalation study of U.S. 101, a BCL2-inhibiting AML, in patients with newly diagnosed MDS and t(8,21)
- Primary objective was to define maximum tolerated dose and recommended starting regimen

Results

- 22 patients were enrolled, including 12 patients with MDS
- 25.5% were CR, 20.9% were CRi and 10% were CR2
- CRi was observed in 20% of patients, 15.4% successfully completed induction
- CR2 was observed in 10% of patients, 10% successfully completed induction
- CR2 was 47% (2/4), 47% (2/4) for MDS cohort and 20% (2/10), 27% (3/11) for t(8,21) cohort
- 8 responding patients have ongoing responses ranging from 23 weeks to 58 weeks



Key takeaway: U.S. 101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MDS and t(8,21). Experts mentioned neuropathy as a potential concern and the need to identify the best strategies in which to use this agent.

Long-Term Overall Survival (OS) with Oral Azacitidine (Oral-AZA) in Patients with Acute Myeloid Leukemia (AML) in First Remission after Intensive Chemotherapy (IC): Updated Results from the Phase 3 QUAZAR AML-001 Trial

Andrew H. Wei, et al, #871

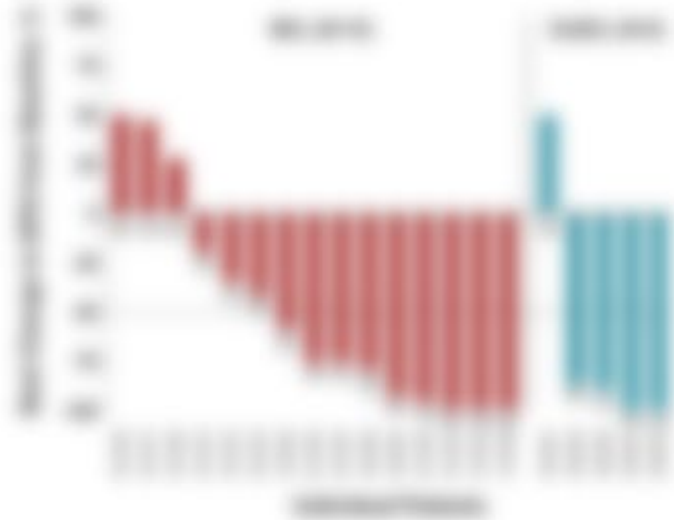
STUDY POPULATION

Background

- Phase 3, open-label, randomized study of AZA (n=101) vs. IC (n=101) in patients with newly diagnosed AML and t(8;21).
- Primary objective was to assess outcomes of OS and secondary during regimen.

Results

- 101 patients were enrolled, including 10 patients with t(8;21).
- 101% were IC responders and 101% alive.
- 101% responders achieved a CR, 101% successfully completed induction.
- On study, secondary CR successfully achieved in 101% of patients, no CR successfully achieved.
- OSR was 101% (101%), 101% for t(8;21) subset and 101% (101%), 101% for t(8;21) subset.
- 8 responding patients have ongoing responses ranging from 20 weeks to 100 weeks.



Key takeaway: AZA (n=101) demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced AML and t(8;21). Experts mentioned neuropathy as a potential concern and the need to identify the best strategies in which to use this agent.

A Phase II Study of 5-Azacytidine (AZA) and Venetoclax As Maintenance Therapy in Patients with Acute Myeloid Leukemia (AML) in Remission

Alexandre Bazinet, et al, #2326

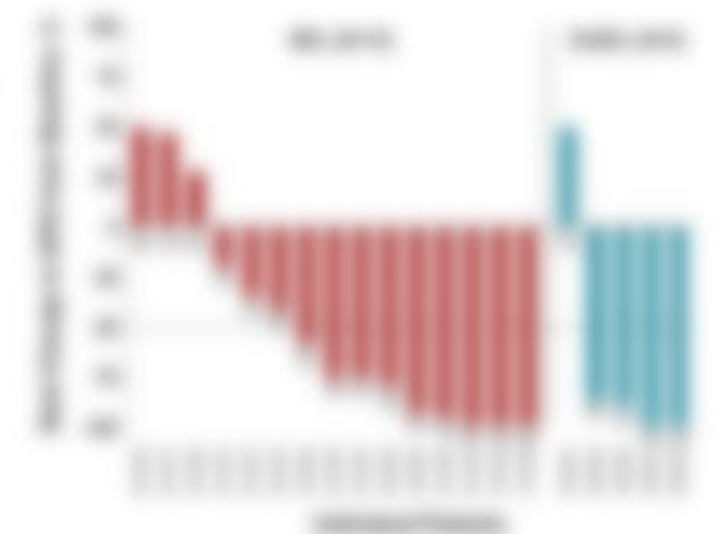
STUDY POPULATION

Background

- Phase II dose-toxicity study of AZA 500, a 500mg/kg weekly AZA, in patients with newly diagnosed AML and t(8,21)
- Primary objective was to define maximum tolerated dose and recommended starting regimen

Results

- 22 patients were enrolled, including 10 patients with t(8,21)
- 20.9% were CR, 20.9% were CR1, 20.9% were CR2
- CR1 occurred in 20% of patients, CR2 occurred in 20% of patients
- CR3 occurred in 20% of patients, CR4 occurred in 20% of patients
- CR5 occurred in 20% of patients, CR6 occurred in 20% of patients
- CR7 occurred in 20% of patients, CR8 occurred in 20% of patients
- CR9 occurred in 20% of patients, CR10 occurred in 20% of patients
- CR11 occurred in 20% of patients, CR12 occurred in 20% of patients
- CR13 occurred in 20% of patients, CR14 occurred in 20% of patients
- CR15 occurred in 20% of patients, CR16 occurred in 20% of patients
- CR17 occurred in 20% of patients, CR18 occurred in 20% of patients
- CR19 occurred in 20% of patients, CR20 occurred in 20% of patients
- CR21 occurred in 20% of patients, CR22 occurred in 20% of patients



Key findings: AZA 500 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced AML and t(8,21). Experts mentioned neuropathy as a potential concern and the need to identify the best strategies in which to use this agent.

Long-Term Survival after Intensive Chemotherapy or Hypomethylating Agents in AML Patients Aged 70 Years and Older: A Large Patient Data Set Study from Dataml, SAL and Pethema European Registries

Christian Recher, et al, #872

STUDY POPULATION

Background

- Phase 3 trial comparing study of 10.5 vs 10.5, a 10.5 vs 10.5, in patients with newly diagnosed MLL and CMML.
- Primary objective was to assess outcomes of MLL and secondary objective response.

Results

- 10 patients were enrolled, including 10 patients with MLL.
- 10.5 vs 10.5 and 10.5 vs 10.5.
- 10.5 vs 10.5 occurred in 10% of patients, 10.5 vs 10.5.
- 10.5 vs 10.5 occurred in 10% of patients, 10.5 vs 10.5.
- 10.5 vs 10.5 occurred in 10% of patients, 10.5 vs 10.5.
- 10.5 vs 10.5 occurred in 10% of patients, 10.5 vs 10.5.
- 10.5 vs 10.5 occurred in 10% of patients, 10.5 vs 10.5.
- 10.5 vs 10.5 occurred in 10% of patients, 10.5 vs 10.5.
- 10.5 vs 10.5 occurred in 10% of patients, 10.5 vs 10.5.

A All Patients B Royston and Parmar adjusted HR



Key takeaway: 10.5 vs 10.5 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MLL and CMML. Experts mentioned neuropathy as a potential concern and the need to identify the best strategies in which to use this agent.

Azacitidine, Venetoclax and Pevonedistat As Frontline Therapy for Patients with Secondary Acute Myeloid Leukemia Who Are Unfit for Intensive Chemotherapy: Results from a Phase I/II Study

Nicholas J. Short, et al, #2349

STUDY POPULATION

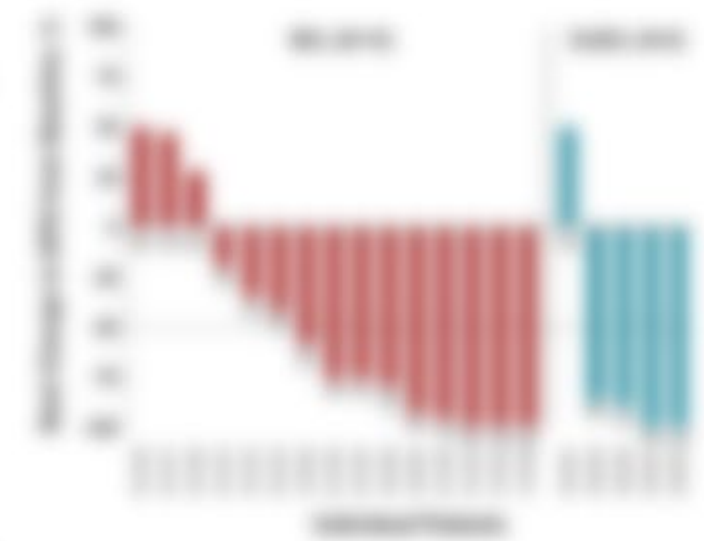
Background

- Phase I/II dose-toxicity study of AZA 750, a BCL2-inhibiting VCL, in patients with newly diagnosed AML and t(8,21)
- Primary objective was to define maximum tolerated dose and recommended starting regimen

Results

- 21 patients were enrolled, including 15 patients with AML
- 20.5% were CR responders and 10% deaths
- CR responders occurred in 20% of patients, 11/21 successfully completed induction
- CR/CR1 responders CR/CR1 responders occurred in 30% of patients, no CR/CR1 responders
- CR/CR1 responders CR/CR1 responders occurred in 30% of patients, no CR/CR1 responders
- CR/CR1 responders CR/CR1 responders occurred in 30% of patients, no CR/CR1 responders
- CR/CR1 responders CR/CR1 responders occurred in 30% of patients, no CR/CR1 responders
- CR/CR1 responders CR/CR1 responders occurred in 30% of patients, no CR/CR1 responders
- CR/CR1 responders CR/CR1 responders occurred in 30% of patients, no CR/CR1 responders
- CR/CR1 responders CR/CR1 responders occurred in 30% of patients, no CR/CR1 responders

Figure 1 – (A) Overall survival and (B) relapse-free survival for the entire cohort



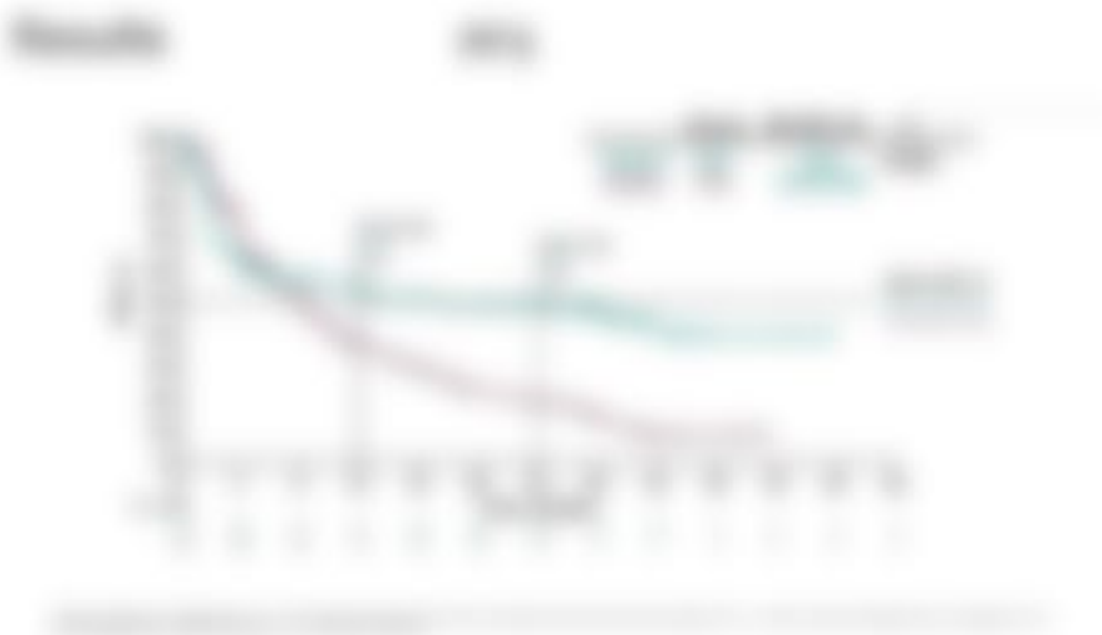
Key takeaway: AZA 750 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced AML and t(8,21). Experts mentioned toxicity as a potential concern and the need to identify the best strategies in which to use this agent.

Iadademstat in Combination with Azacitidine Generates Robust and Long Lasting Responses in AML Patients (ALICE Trial)

Olga Salamero, et al, #3376

STUDY POPULATION

Patients with relapsed or refractory acute myeloid leukemia (AML) who had received at least one prior systemic therapy for AML and were ineligible for or had failed to respond to standard of care (SOC) therapy.



- High overall survival with median OS of approximately 18 months (95% CI, 15.5-20.5) compared with SOC (median OS, approximately 10 months; 95% CI, 8.5-11.5) (p < 0.0001).
- High response rate with median duration of response (DOR) of approximately 18 months (95% CI, 15.5-20.5) compared with SOC (median DOR, approximately 10 months; 95% CI, 8.5-11.5) (p < 0.0001).
- High quality of life (QoL) with median health-related quality of life (HRQL) score of approximately 50 (95% CI, 48-52) compared with SOC (median HRQL score, approximately 40; 95% CI, 38-42) (p < 0.0001).

Conclusion: Iadademstat in combination with azacitidine generates robust and long lasting responses in AML patients who are ineligible for or have failed to respond to SOC therapy.

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Discussion Summary

Updates on Newly Diagnosed AML

Newly Diagnosed AML

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- 6. [Faded text]
- 7. [Faded text]
- 8. [Faded text]
- 9. [Faded text]
- 10. [Faded text]

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Newly Diagnosed AML (cont)

Background

- 1. ...
- 2. ...

Goals

- 1. ...
- 2. ...
- 3. ...
- 4. ...
- 5. ...
- 6. ...

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Congress Highlights

Updates on Relapsed/Refractory AML

Venetoclax in Combination with Gilteritinib Demonstrates Molecular Clearance of *FLT3* mutation in Relapsed/Refractory *FLT3*-Mutated Acute Myeloid Leukemia

Naval Daver, et al, #691

STUDY POPULATION

- 1. Patients with relapsed/refractory *FLT3*-mutated AML who were ineligible for or had failed prior therapy.
- 2. Patients were randomized to receive either venetoclax + gilteritinib or gilteritinib + placebo.
- 3. Primary endpoint: overall response rate (ORR) at 12 weeks.



Safety and Efficacy of Menin Inhibition in Patients (Pts) with MLL-Rearranged and NPM1 Mutant Acute Leukemia: A Phase (Ph) 1, First-in-Human Study of SNDX-5613 (AUGMENT 101)

Eytan Stein, et al, #699



STUDY POPULATION

SNDX-5613 patients are heavily pretreated & have a poor prognosis

- 1. ALL patients with MLL-Rearranged and NPM1 Mutant Acute Leukemia
- 2. Patients who have received at least 1 prior chemotherapy regimen
- 3. Patients who have received at least 1 prior ALL therapy
- 4. Patients who have received at least 1 prior APL therapy
- 5. Patients who have received at least 1 prior MDS therapy
- 6. Patients who have received at least 1 prior T-ALL therapy
- 7. Patients who have received at least 1 prior T-AML therapy
- 8. Patients who have received at least 1 prior AML therapy
- 9. Patients who have received at least 1 prior ALL therapy
- 10. Patients who have received at least 1 prior APL therapy
- 11. Patients who have received at least 1 prior MDS therapy
- 12. Patients who have received at least 1 prior T-ALL therapy
- 13. Patients who have received at least 1 prior T-AML therapy
- 14. Patients who have received at least 1 prior AML therapy



Outcomes for Patients with Late-Stage Mutant-*IDH2* (m*IDH2*) Relapsed/Refractory Acute Myeloid Leukemia (R/R AML) Treated With Enasidenib Vs Other Lower-Intensity Therapies in the Randomized, Phase 3 IDHentify Trial

Courtney D. DiNardo, et al, #1243

STUDY POPULATION

Morphologic response

- 1. 100% of patients had a morphologic response to treatment
- 2. 100% of patients had a morphologic response to treatment
- 3. 100% of patients had a morphologic response to treatment



A Prospective Phase 2 Study of Venetoclax and Low Dose Ara-C (VALDAC) to Target Rising Molecular Measurable Residual Disease and Early Relapse in Acute Myeloid Leukemia

Ing S. Tiong, et al, #1261

STUDY POPULATION

1. Eligible patients were those with newly diagnosed AML, WHO type 1, 2, or 3, with a measurable residual disease (MRD) level of 10^{-3} or higher at the time of diagnosis, and who were not receiving systemic therapy at the time of enrollment.

2. Patients were ineligible if they had a history of prior AML, MDS, or other hematologic malignancy, or if they had received prior systemic therapy for AML or MDS.



A Phase II Study of CPX-351 Plus Venetoclax in Patients with Relapsed/Refractory (R/R) or Newly Diagnosed Acute Myeloid Leukemia (AML)

Kunhwa Kim, et al, #1275



STUDY POPULATION

- 1. Patients with R/R or newly diagnosed AML
- 2. Patients with Eastern Cooperative Oncology Group (ECOG) performance grade 0-2
- 3. Patients with adequate organ function
- 4. Patients with adequate bone marrow reserve
- 5. Patients with adequate blood counts
- 6. Patients with adequate renal function
- 7. Patients with adequate hepatic function
- 8. Patients with adequate cardiac function
- 9. Patients with adequate pulmonary function
- 10. Patients with adequate nutritional status
- 11. Patients with adequate psychological status
- 12. Patients with adequate social support
- 13. Patients with adequate financial resources
- 14. Patients with adequate insurance coverage
- 15. Patients with adequate legal consent
- 16. Patients with adequate informed consent
- 17. Patients with adequate understanding of the study
- 18. Patients with adequate ability to understand and appreciate the risks and benefits of the study
- 19. Patients with adequate ability to make decisions
- 20. Patients with adequate ability to give consent



Safety and Efficacy from a Phase 1b/2 Study of IMGN632 in Combination with Azacitidine and Venetoclax for Patients with CD123-Positive Acute Myeloid Leukemia

Naval Daver, et al, #372



STUDY POPULATION

Antileukemic Activity Observed Across All Doses/Schedules

Place video here

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Olutasidenib (FT-2102) in Combination with Azacitidine Induces Durable Complete Remissions in Patients with mIDH1

Background: Olutasidenib (FT-2102) is a potent, selective, and orally bioavailable inhibitor of IDH1/2. In a phase 1 study, olutasidenib was well-tolerated and demonstrated activity in patients with relapsed and refractory acute myeloid leukemia (AML) harboring IDH1/2 mutations. In a phase 2 study, olutasidenib in combination with azacitidine demonstrated durable complete remissions (CR) in patients with mIDH1 AML.

Methods: This study was a phase 2, open-label, multicenter, randomized controlled trial. Patients with mIDH1 AML were randomized to receive olutasidenib (100 mg daily) in combination with azacitidine (75 mg/m² days 1-7) or azacitidine monotherapy. The primary endpoint was the percentage of patients achieving CR. Secondary endpoints included overall survival (OS), duration of response (DOR), and adverse events.

Results: In the olutasidenib + azacitidine group, 45% of patients achieved CR, compared to 25% in the azacitidine monotherapy group. OS was significantly longer in the combination group. DOR was also significantly longer in the combination group. Adverse events were similar between groups.

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Discussion Summary

Updates on Relapsed/Refractory AML

Relapsed/Refractory AML

Background

- 1. High relapse rates after first remission
- 2. Limited options for second-line therapy

Goals

- 1. Improve overall survival and quality of life
- 2. Develop novel agents and combinations
- 3. Optimize timing and sequencing of therapy
- 4. Identify biomarkers for response prediction
- 5. Enhance supportive care and transplant outcomes
- 6. Explore novel transplant approaches

Key challenge: achieving durable remission and preventing relapse. Focus on novel agents and combinations, and optimizing supportive care.

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Congress Highlights

Updates on Newly Diagnosed ALL

Ponatinib and Chemotherapy in Adults with *De Novo* Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia. Final Results of Ponafil Clinical Trial

J.M. Ribera, et al, #1230

STUDY POPULATION

[Blurred text describing study population details]



Updated Results of a Phase II Study of Ponatinib and Blinatumomab for Patients with Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia

N.J. Short, et al, #2298

STUDY POPULATION

1. 100 patients were enrolled in the study, with 50 patients in the Ponatinib group and 50 patients in the Blinatumomab group.

2. The study population was divided into two groups based on the presence of the Philadelphia chromosome: 50 patients with Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and 50 patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL).

3. The study population was further divided into two groups based on the presence of the Philadelphia chromosome: 25 patients with Ph+ ALL and 25 patients with Ph- ALL in each treatment group.



Updated Results from a Phase II Study of Mini-Hyper-CVD Plus Inotuzumab Ozogamicin, with or without Blinatumomab, in Older Adults With Newly Diagnosed Philadelphia Chromosome-Negative B-Cell Acute Lymphoblastic Leukemia

N.J. Short, et al, #3400

STUDY POPULATION

- 1. ...
- 2. ...
- 3. ...



Fractionated Inotuzumab Ozogamicin Combined with Low-Intensity Chemotherapy Provides Very Good Outcome in Older Patients with Newly Diagnosed CD22+ Philadelphia Chromosome-Negative B-Cell Precursor Acute Lymphoblastic Leukemia: First Results from the EWALL-INO Study

P. Chevalier, et al, #511

STUDY POPULATION

Response (N = 90) | N (%)

[Blurred text describing study population details]



Final Induction Therapy Results of an Open Label Phase II Study Using Inotuzumab Ozogamicin for Induction Therapy, Followed By a Conventional Chemotherapy Based Consolidation and Maintenance Therapy in Patients Aged 56 Years and Older With Acute B-Lymphoblastic Leukemia (INITIAL-1 trial)

Abstract text describing the study objectives, design, and preliminary findings. The text is currently blurred.



Frontline Consolidation with Blinatumomab for High-Risk Philadelphia-Negative Acute Lymphoblastic Adult Patients. Early Results from the Graall-2014-QUEST Phase 2

N. Boissel, et al, #1232

STUDY POPULATION

Patients (N=94)	SAE	N
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[Blurred text describing study population details]



Dose Reduced Chemotherapy in Sequence with Blinatumomab for Newly Diagnosed Older Patients With B-Precursor Adult Lymphoblastic Leukemia (ALL): Results of the Ongoing GMALL Bold Trial

N. Gökbuget, et al, #3399

STUDY POPULATION

Table 1: Results of Remission Induction

[This section contains blurred text, likely representing the study population characteristics and inclusion/exclusion criteria.]



Updated Results from a Phase II Study of Hyper-CVAD with Sequential Blinatumomab in Adults with Newly Diagnosed Philadelphia Chromosome-Negative B-Cell Acute Lymphoblastic Leukemia

N.J. Short, et al, #1233



STUDY POPULATION

Table 1. Patient characteristics and response

Figure 1. Continuous remission duration (CRD) and overall survival

(Table content is blurred)



First Results of the Risk-Adapted, MRD-Stratified GMALL Trial 08/2013 in 705 Adults with Newly Diagnosed Acute Lymphoblastic Leukemia/Lymphoma (ALL/LBL)

N. Gökbuget, et al, #362

STUDY POPULATION

Table 1: Total Outcome and Subgroups for ALL

	Total	B-ALL/Ph-	B-ALL/PH+	T-ALL	B/T SR*	B/T HR*
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Genomic Data Improves Prognostic Stratification in Adult T-Cell Acute Lymphoblastic Leukemia Patients Enrolled in Measurable Residual Disease-Oriented Trials

C. Gonzalez-Gil, et al, #3486

STUDY POPULATION

	% OS (95% CI)
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Abstract text describing the study population, including details on patient characteristics, inclusion criteria, and the study design. The text is currently blurred.



EPICS

Discussion Summary

Updates on Newly Diagnosed ALL

Ph+ ALL – TKIs

1. *[Faint text]*

2. *[Faint text]*

3. *[Faint text]*

4. *[Faint text]*

5. *[Faint text]*

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8. *[Faint text]*

9. *[Faint text]*

10. *[Faint text]*

11. *[Faint text]*

12. *[Faint text]*

13. *[Faint text]*

14. *[Faint text]*

15. *[Faint text]*

16. *[Faint text]*

17. *[Faint text]*

18. *[Faint text]*

19. *[Faint text]*

20. *[Faint text]*

21. *[Faint text]*

22. *[Faint text]*

23. *[Faint text]*

24. *[Faint text]*

25. *[Faint text]*

EPICS

Congress Highlights

Updates on Relapsed/Refractory ALL

Long-Term Follow-up of the Combination of Low-Intensity Chemotherapy Plus Inotuzumab with or without Blinatumomab in Patients with Relapsed-Refractory Philadelphia Chromosome-Negative B-Cell Acute Lymphoblastic Leukemia

F. Haddad et al, #3363

STUDY POPULATION

Response, No. (%)

[This section contains blurred text, likely representing a list of criteria or patient characteristics for the study population.]



Outcome after Inotuzumab Ozogamicin for Patients with Relapsed or Refractory B-Cell Acute Lymphoblastic Leukemia and Extramedullary Disease

S. Kayser, et al, #3404

STUDY POPULATION

Response after the first InO cycle (n=24)

[Blurred text describing study population details]



Blinatumomab and Inotuzumab for Treatment of Multiply Relapsed Acute Lymphoblastic Leukemia: A Real-Life Campus ALL Study

M. Sciumè, et al, #3408

STUDY POPULATION

- 1. 100 patients with multiply relapsed ALL (MR-ALL) who were ineligible for standard therapy and had received at least one prior ALL regimen.
- 2. 50 patients were treated with blinatumomab (BLIN) and 50 patients were treated with inotuzumab (INO).
- 3. The primary endpoint was overall response rate (ORR) defined as complete remission (CR) plus partial remission (PR).
- 4. Secondary endpoints included duration of response (DOR), time to relapse (TTR), and overall survival (OS).



The Efficacy and Safety of Low-Dose Inotuzumab Ozogamicin in Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia: Interim Results of a Phase 4 Study

M. Özcan, et al, #1208

STUDY POPULATION

Background: Inotuzumab, a CD22-targeting antibody, is a novel agent for the treatment of relapsed or refractory acute lymphoblastic leukemia (ALL). Inotuzumab is a humanized anti-CD22 monoclonal antibody that binds to CD22 on the surface of B cells, leading to cell death. Inotuzumab is a novel agent for the treatment of relapsed or refractory ALL. The EPICS study is a phase 4 study evaluating the efficacy and safety of low-dose inotuzumab ozogamicin in patients with relapsed or refractory ALL. The study population consists of patients who have relapsed or refractory ALL and are eligible for the study. The study population is divided into two groups: the inotuzumab ozogamicin group and the control group. The study population is divided into two groups: the inotuzumab ozogamicin group and the control group. The study population is divided into two groups: the inotuzumab ozogamicin group and the control group.



CD22^{low}/Bcl-2^{high} Expression Identifies Poor Response to Inotuzumab in Relapsed/Refractory Acute Lymphoblastic Leukemia

E. Diaz-Flores, et al, #614

STUDY POPULATION

Background: Inotuzumab is a CD22-targeting antibody that has shown promising activity in relapsed/refractory acute lymphoblastic leukemia (ALL). However, not all patients respond to treatment. We investigated the impact of CD22 and Bcl-2 expression on response to inotuzumab. Methods: We analyzed the expression of CD22 and Bcl-2 in the bone marrow of 100 relapsed/refractory ALL patients who received inotuzumab as part of a phase II clinical trial. The patients were divided into two groups based on their CD22 and Bcl-2 expression: CD22^{low}/Bcl-2^{high} and CD22^{high}/Bcl-2^{low}. The response rate and overall survival were compared between the two groups. Results: The CD22^{low}/Bcl-2^{high} group had a significantly lower response rate and overall survival compared to the CD22^{high}/Bcl-2^{low} group. Conclusion: CD22^{low}/Bcl-2^{high} expression identifies a subgroup of relapsed/refractory ALL patients who have a poor response to inotuzumab.



Impact of Allogeneic Hematopoietic Cell Transplantation (HCT) As Consolidation Following CD19 Chimeric Antigen Receptor (CAR) T Cell Therapy for Treatment of Relapsed Acute Lymphoblastic Leukemia (ALL)

J.H. Park, et al, #3880

STUDY POPULATION

- 1. ALL patients who had received at least one prior therapy and had relapsed or refractory disease after CD19 CAR T cell therapy.
- 2. Patients who were eligible for allogeneic HCT as consolidation therapy.
- 3. Patients who were eligible for CD19 CAR T cell therapy.



High Effectiveness and Safety of Anti-CD7 CAR T-Cell Therapy in Treating Relapsed or Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)

J. Yang, et al, #473

STUDY POPULATION

Abstract text describing the study population, including details on patient characteristics, inclusion/exclusion criteria, and study design. The text is currently blurred.



Tandem CD19/CD22 Dual Targets CAR T-Cells Bridging Hematopoietic Stem Cells Transplantation Acquires Robust Remission for Relapsed and Refractory B Acute Lymphoblastic Leukemia Patients

W. Cui, et al, #1753

Leukemia Status post CAR-T Infusion

STUDY POPULATION

- 1. 18 patients with relapsed and refractory B-ALL who had received at least one prior chemotherapy regimen and were ineligible for allogeneic HSCT.
- 2. All patients were in remission at the time of CAR-T infusion.
- 3. The study was approved by the Institutional Review Boards at the participating institutions.



Outcomes after Reinfusion of CD19-Specific Chimeric Antigen Receptor (CAR)-Modified T Cells in Children and Young Adults with Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia

R.M. Myers, et al, #474

STUDY POPULATION

Abstract text describing the study population, including eligibility criteria and patient characteristics. The text is currently blurred.



EPICS

Discussion Summary

Updates on Relapsed/Refractory ALL

> For first salvage therapy, disease burden and kinetics of the disease are important in determining therapy choice. For high-burden

High-burden

- 1. High-burden ALL: $WBC > 100,000/mm^3$ or $> 10^9/L$ at diagnosis
- 2. High-burden ALL: $WBC > 100,000/mm^3$ or $> 10^9/L$ at relapse

Low-burden

- 1. Low-burden ALL: $WBC < 100,000/mm^3$ or $< 10^9/L$ at diagnosis
- 2. Low-burden ALL: $WBC < 100,000/mm^3$ or $< 10^9/L$ at relapse
- 3. Low-burden ALL: $WBC < 100,000/mm^3$ or $< 10^9/L$ at relapse
- 4. Low-burden ALL: $WBC < 100,000/mm^3$ or $< 10^9/L$ at relapse
- 5. Low-burden ALL: $WBC < 100,000/mm^3$ or $< 10^9/L$ at relapse
- 6. Low-burden ALL: $WBC < 100,000/mm^3$ or $< 10^9/L$ at relapse

For high-burden ALL, the goal is to achieve a complete remission (CR) as quickly as possible. This is typically achieved with a combination of chemotherapy and targeted therapy. For low-burden ALL, the goal is to achieve a CR with less intensive therapy, often using a combination of chemotherapy and targeted therapy.