

 A large, stylized graphic of the Aptitude Health logo, composed of several curved, overlapping lines in shades of blue, green, orange, and grey, arranged in a circular pattern.

EPICS

Conference Coverage: EHA 2022 – Focus on Leukemia and MDS

Full Report

11 June 2022

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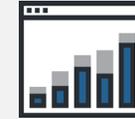
VIRTUAL CLOSED-DOOR ROUNDTABLE



DATE:
11 June 2022



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



INSIGHTS REPORT
including postmeeting
analyses and actionable
recommendations



PANEL: Key experts in
leukemia
> 7 from the US



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

Panel Consisting of 7 US Leukemia Experts



Meeting Agenda

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Time (CET)	Topic	Speaker/Moderator
18.00 – 18.05	Welcome and Introductions	Elias Jabbour, MD
18.05 – 18.15	Advances in AML: Newly Diagnosed – AML With Mutations	Naval Daver, MD
18.15 – 18.20	Advances in AML: Newly Diagnosed – AML in Older and/or Unfit Patients	Harry P. Erba, MD, PhD
18.20 – 18.25	Advances in AML: Newly Diagnosed – Other	Alexander E. Perl, MD
18.25 – 19.20	Discussion and Key Takeaways	All
19.20 – 19.25	Advances in AML: Relapsed/Refractory	Eytan M. Stein, MD
19.25 – 19.55	Discussion and Key Takeaways	All
19.55 – 20.00	<i>Break</i>	
20.00 – 20.10	New Developments in MDS	Guillermo Garcia-Manero, MD
20.10 – 20.55	Discussion and Key Takeaways	All
20.55 – 21.00	Summary and Closing Remarks	Elias Jabbour, MD



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Conference Highlights

Updates on Newly Diagnosed AML

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

Harry Erba, et al. #S100

Primary Endpoint: Overall Survival Newly Diagnosed FLT3-ITD+ AML, Ph3 Quizartinib + Chemotherapy

STUDY POPULATION

1000 newly diagnosed FLT3-ITD+ AML patients aged 18-75 years, randomized to either quizartinib (n=500) or placebo (n=500) plus intensive induction and consolidation therapy followed by single-agent continuation. The primary endpoint is overall survival. Secondary endpoints include time to relapse, time to death, and time to treatment failure.

RESULTS

Overall survival was significantly longer in the quizartinib group compared to the placebo group (p < 0.001). The median overall survival was 12.1 months in the quizartinib group and 8.5 months in the placebo group.

KEY CONCLUSIONS

Quizartinib significantly improved overall survival in newly diagnosed FLT3-ITD+ AML patients compared to placebo plus intensive induction and consolidation therapy followed by single-agent continuation.

OS: TIME TO DEATH FROM ANY CAUSE IN THE INTENT-TO-TREAT POPULATION



RESPONSE: NEWLY DIAGNOSED FLT3-ITD+ AML: TIME TO TREATMENT FAILURE



V-FAST MASTER TRIAL*: PRELIMINARY RESULTS OF TREATMENT WITH CPX-351 PLUS MIDOSTAURIN IN ADULTS WITH NEWLY DIAGNOSED FLT3-MUTATED ACUTE MYELOID LEUKEMIA

STUDY POPULATION

1. 100% of 100 newly diagnosed AML patients with FLT3-mutated AML, 50% with FLT3-ITD and 50% with FLT3-TKD, were treated with CPX-351 plus midostaurin. The median age was 68 years, 50% were male, and 50% were female. The median time from diagnosis to treatment was 10 days. The median time to start treatment was 10 days. The median time to start treatment was 10 days. The median time to start treatment was 10 days.

RESULTS

2. 100% of 100 patients achieved CR. 100% of 100 patients achieved CR.

KEY CONCLUSIONS

Continuing investigational treatment beyond week 20 provides clinical benefit to all patients and decreases the transplant need in patients.

Figure 2. Remission and MPO negativity

REMEDIATION OF MPO POSITIVITY IN THE CPX-351 PLUS MIDOSTAURIN GROUP



RESPONSE, NEUTROPENIA, AND OTHER ANALYSES FROM WEEK 10



HEMATOLOGIC IMPROVEMENTS WITH IVOSIDENIB + AZACITIDINE COMPARED WITH PLACEBO + AZACITIDINE IN PATIENTS WITH NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA

Hartmut Döhner, et al. #P557

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STUDY POPULATION

> This was conducted to report blood count recovery results from the phase III AGILE trial

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TOLERABILITY AND EFFICACY OF THE FIRST-IN-CLASS ANTI-CD47 ANTIBODY MAGROLIMAB COMBINED WITH AZACITIDINE IN FRONTLINE PATIENTS WITH TP53-MUTATED ACUTE MYELOID LEUKEMIA: PHASE 1B RESULTS

Naval G. Daver, et al. #S132



Magrolimab in Combination with AZA Demonstrated Encouraging Response Rates in TP53-mut AML

STUDY POPULATION

100 patients with TP53-mutated AML, median age 68 years, median TP53 mutation burden 100%. All patients were TP53-mutated and received AZA 75 mg/m² daily for 7 days followed by 100 mg/m² of magrolimab weekly for 4 weeks. The primary endpoint was the percentage of patients achieving CR or CRi. The secondary endpoint was the percentage of patients achieving CR or CRi with a duration of response of ≥ 6 months. The overall response rate (ORR) was 50% (50/100) and the CR rate was 30% (30/100). The median duration of response was 12 months. The median overall survival was 12 months. The median time to next treatment was 12 months.

RESULTS

100 patients were enrolled in the study. 50 patients achieved CR or CRi. The overall response rate (ORR) was 50%. The median duration of response was 12 months. The median overall survival was 12 months. The median time to next treatment was 12 months.

KEY CONCLUSIONS

Combining magrolimab with AZA demonstrated encouraging response rates in TP53-mutated AML. The combination was well tolerated and demonstrated a favorable safety profile.

RESPONSE RATES IN TP53-MUTATED AML



RESPONSE RATES IN TP53-MUTATED AML: KEY FINDINGS



FINAL RESULTS OF THE QOLESS AZA-AMLE RANDOMIZED TRIAL TO EVALUATE THE EFFICACY OF 5-AZA FOR POST-REMISSION THERAPY OF ACUTE MYELOID LEUKEMIA IN ELDERLY PATIENTS

Esther Natalie Oliva, et al. #P564

STUDY POPULATION

> Pts aged ≥ 61 years with untreated AML, "de novo" or evolving from MDS, fit for intensive chemotherapy but ineligible for stem cell

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



LOWER-INTENSITY CPX-351 + VENETOCLAX FOR PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA WHO ARE UNFIT FOR INTENSIVE CHEMOTHERAPY

Geoffrey L. Uy, et al. #P515

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PHASE II STUDY OF LOWER-INTENSITY FRONTLINE THERAPY FOR NEWLY DIAGNOSED PATIENTS WITH AML WHO ARE UNFIT OR OTHERWISE NOT ELIGIBLE FOR FRONTLINE CLINICAL TRIALS

Sangeetha Venugopal, et al. #P581

STUDY POPULATION

100 newly diagnosed AML patients with a WHO grade 1-2, WHO type M1-M2, WHO type M4-M5, WHO type M6-M7, WHO type M9-M10, WHO type M11-M12, WHO type M13-M14, WHO type M15-M16, WHO type M17-M18, WHO type M19-M20, WHO type M21-M22, WHO type M23-M24, WHO type M25-M26, WHO type M27-M28, WHO type M29-M30, WHO type M31-M32, WHO type M33-M34, WHO type M35-M36, WHO type M37-M38, WHO type M39-M40, WHO type M41-M42, WHO type M43-M44, WHO type M45-M46, WHO type M47-M48, WHO type M49-M50, WHO type M51-M52, WHO type M53-M54, WHO type M55-M56, WHO type M57-M58, WHO type M59-M60, WHO type M61-M62, WHO type M63-M64, WHO type M65-M66, WHO type M67-M68, WHO type M69-M70, WHO type M71-M72, WHO type M73-M74, WHO type M75-M76, WHO type M77-M78, WHO type M79-M80, WHO type M81-M82, WHO type M83-M84, WHO type M85-M86, WHO type M87-M88, WHO type M89-M90, WHO type M91-M92, WHO type M93-M94, WHO type M95-M96, WHO type M97-M98, WHO type M99-M100.

RESULTS

100 patients were enrolled in the study. The overall response rate was 45%. The median overall survival was 12 months. The median time to progression was 6 months. The median time to death was 8 months.

EXPERT CONCLUSIONS

Continuing treatment beyond week 20 provides clinical benefit in terms of response and decreases the proportion of patients who die.

Response rates



RESPONSE RATE AT WEEK 20 AND AT WEEK 30



OVERALL SURVIVAL WITH INTENSIVE CHEMOTHERAPY (IC) VS NON-IC IN PATIENTS (PTS) WITH NEWLY DIAGNOSED (ND) AML FROM THE CONNECT® MYELOID DISEASE REGISTRY INELIGIBLE FOR RANDOMIZED CLINICAL TRIALS (RCT)

Harry Erba, et al. #P584

STUDY POPULATION

> In a broad cohort of real-world pts with AML from the Connect® Myeloid Disease Registry, pts were stratified into 3 groups on the basis of the



PHASE 2 STUDY OF ASTX727 (DECITABINE/CEDAZURIDINE) PLUS VENETOCLAX IN PATIENTS WITH RELAPSED/REFRACTORY ACUTE MYELOID LEUKEMIA (AML) OR PREVIOUSLY UNTREATED, ELDERLY PATIENTS UNFIT FOR CHEMOTHERAPY

Tareq Abuasab, et al. #P495

STUDY POPULATION

> Pts aged ≥ 18 yr with R/R AML or pts with AML aged ≥ 75 or 18–74 with

Survival and Toxicity:

- Median follow-up - 5 months
- Median survival – FL: not reached (range, 0.6-7.3) months



A RANDOMISED COMPARISON OF CPX-351 AND FLAG-IDA IN HIGH-RISK ACUTE MYELOID LEUKAEMIA. RESULTS FROM THE NCRI AML19 TRIAL

Nigel Russell, et al. #S128

STUDY POPULATION

> The AML19 trial randomized CPX-351 vs FLAG-Ida in 635 pts mainly <60 yr

RESPONSE	FLAG-Ida	CPX-351
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REAL-WORLD COMPARISON OF DIFFERENT TREATMENT MODALITIES FOR FAVORABLE RISK ACUTE MYELOID LEUKEMIA: STANDARD DOSE ANTHRACYCLINE VS HIGH DOSE ANTHRACYCLINE VS ADDITION OF GEMTUZUMAB OZOGAMICIN

Joseph Mort, et al. #P526

STUDY POPULATION

> Comparison of outcomes of 3 cohorts of newly diagnosed adult AML pts

Figure 1: Kaplan-Meier Curves



STUDY POPULATION

1. 100 newly diagnosed adult AML patients with a 100% response to induction therapy were included in the study. The patients were divided into three cohorts: SDA (33 patients), HDA (33 patients), and SDA+GO (34 patients). The median age was 65 years. The median duration of illness was 12 months. The median time to diagnosis was 12 months. The median time to treatment was 12 months. The median time to relapse was 12 months. The median time to death was 12 months. The median time to progression was 12 months. The median time to discontinuation of therapy was 12 months. The median time to hospitalization was 12 months. The median time to death was 12 months. The median time to death was 12 months. The median time to death was 12 months.

RESULTS

2. The overall survival rate was 33% for all patients. The relapse-free survival rate was 33%. The time to relapse was 12 months. The time to death was 12 months. The time to progression was 12 months. The time to discontinuation of therapy was 12 months. The time to hospitalization was 12 months. The time to death was 12 months. The time to death was 12 months. The time to death was 12 months.

CONCLUSIONS

3. The study found that the addition of gemtuzumab ozogamicin to standard dose anthracycline did not significantly improve overall survival, relapse-free survival, or time to relapse compared to high dose anthracycline or standard dose anthracycline alone.

RESULTS



RESPONSE, RELAPSE, AND DEATH ANALYSIS PERIODS



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Discussion Summary

Updates on Newly Diagnosed AML

Newly Diagnosed AML

FLT3 inhibitors

> Overall, experts consider data from the QuANTUM phase III study (S100) to indicate a new standard of care for frontline AML

QuANTUM phase III study (S100) - Overall findings

- Experts believe the combination of venetoclax + azacitidine is a promising approach to frontline AML, and these combinations can potentially be improved

Improving tolerability and efficacy results from these combinations in an ongoing phase III study of venetoclax + azacitidine with gemtuzumab

- The approach is seen as effective, working well, and broadly applicable to many patients

Investigational novel combination for relapsed/second primary AML, continues to show promising safety and efficacy with durable complete responses

- The approach is seen as a great option for a patient population in which going conventional therapy is difficult. It is seen as effective and safe

Phase III study to compare combination therapy to venetoclax + azacitidine + gemtuzumab in addition to 5-azacitidine in patients with newly diagnosed AML

- Experts believe the combination of venetoclax + azacitidine with 5-azacitidine is safe. However, they would like to see phase II data to confirm its safety in this setting

Long-term outcomes from a phase II study of venetoclax plus azacitidine plus gemtuzumab in patients with AML

- The 1:1:1:1 approach is seen as useful in the specific patient population with refractory disease. It was noted to be effective, very safe, and well-tolerated. Some of the responses were seen fairly early, which is good

FLT3 inhibitors (cont)

> In patients ≥ 70 years old with *FLT3* mutation, experts agreed they would use venetoclax + azacitidine (Ven + Aza), and in

- [Faded text]

Newly Diagnosed AML

IDH inhibitors

> Standard of care for *IDH1*-mutated AML patients is HMA + ivosidenib or HMA + Ven. However, experts concurred that if

- Experts believe the combination of ivosidenib + HMA is preferred to venetoclax + HMA, and these combinations can potentially be sequenced
- Promising preliminary and efficacy results from phase IIIb study of ivosidenib + HMA in newly diagnosed AML patients with IDH1 mutations (NCT02875847) - (ASCO, Abstract 10000)
- The regimen is seen as effective, working well, and broadly applicable to many patients
- Ivosidenib + HMA is preferred over venetoclax + HMA for newly diagnosed patients with IDH1 mutations, continues to show promising safety and efficacy with durable complete responses - (ASCO, Abstract 10000)
- This approach is seen as a great option for a patient population in which going to transplant is difficult. It is viewed as effective and safe
- HMA + HMA is a phase II, open-label, randomized study to assess safety of ivosidenib or ivosidenib + venetoclax in addition to HMA in patients with newly diagnosed AML - (ASCO, Abstract 10000)
- Experts believe the combination of ivosidenib + venetoclax with HMA is safe. However, they would like to see phase II data to confirm its safety in this setting
- Long-term outcomes from NCT02875847, a phase II study of ivosidenib plus venetoclax plus HMA in patients with IDH1 AML - (ASCO, Abstract 10000)
- The NCT02875847 regimen is seen as useful in the specific patient population with refractory disease. It was noted to be effective, very safe, and well-tolerated. Some of the responses were seen fairly early, though.

Newly Diagnosed AML (cont)

Maintenance

> In transplant-ineligible patients who are fit for intensive chemo, oral Aza is the go-to maintenance therapy

[This section contains several blurred text blocks, likely representing abstracts or clinical trial summaries related to AML maintenance therapy.]

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Conference Highlights

Updates on Relapsed/Refractory AML

PHASE 1/2 STUDY OF SEL24/MEN1703, A FIRST-IN-CLASS DUAL PIM/FLT3 KINASE INHIBITOR, IN PATIENTS WITH IDH1/2-MUTATED ACUTE MYELOID LEUKEMIA: THE DIAMOND-01 TRIAL

Giovanni Martinelli, et al. #P520

STUDY POPULATION

> Pts with *IDH*-mutated R/R AML and no standard therapeutic options were eligible. The

Figure. Individual Patient Treatment Duration



STUDY POPULATION

1. 100% of pts were R/R AML with IDH1/2 mutation. The median age was 68 years (range 45-85). 70% of pts were male. 10% of pts were $IDH1$-mutated and 90% were $IDH2$-mutated. The median duration of disease was 12 months (range 0-72). The median time to relapse was 12 months (range 0-72). The median time to treatment failure was 12 months (range 0-72). The median time to death was 12 months (range 0-72). The median time to progression was 12 months (range 0-72). The median time to discontinuation was 12 months (range 0-72). The median time to withdrawal was 12 months (range 0-72). The median time to death was 12 months (range 0-72). The median time to progression was 12 months (range 0-72). The median time to discontinuation was 12 months (range 0-72). The median time to withdrawal was 12 months (range 0-72).

RESULTS

2. 100% of pts were R/R AML with IDH1/2 mutation. The median age was 68 years (range 45-85). 70% of pts were male. 10% of pts were $IDH1$-mutated and 90% were $IDH2$-mutated. The median duration of disease was 12 months (range 0-72). The median time to relapse was 12 months (range 0-72). The median time to treatment failure was 12 months (range 0-72). The median time to death was 12 months (range 0-72). The median time to progression was 12 months (range 0-72). The median time to discontinuation was 12 months (range 0-72). The median time to withdrawal was 12 months (range 0-72). The median time to death was 12 months (range 0-72). The median time to progression was 12 months (range 0-72). The median time to discontinuation was 12 months (range 0-72). The median time to withdrawal was 12 months (range 0-72).

CONCLUSIONS

3. 100% of pts were R/R AML with IDH1/2 mutation. The median age was 68 years (range 45-85). 70% of pts were male. 10% of pts were $IDH1$-mutated and 90% were $IDH2$-mutated. The median duration of disease was 12 months (range 0-72). The median time to relapse was 12 months (range 0-72). The median time to treatment failure was 12 months (range 0-72). The median time to death was 12 months (range 0-72). The median time to progression was 12 months (range 0-72). The median time to discontinuation was 12 months (range 0-72). The median time to withdrawal was 12 months (range 0-72). The median time to death was 12 months (range 0-72). The median time to progression was 12 months (range 0-72). The median time to discontinuation was 12 months (range 0-72). The median time to withdrawal was 12 months (range 0-72).

INDIVIDUAL PATIENT TREATMENT DURATION



RESPONSE EVALUATION AT EACH ANALYSIS PERIOD



REAL-LIFE EXPERIENCE OF TREATMENT REFRACTORY/RELAPSED ACUTE MYELOID LEUKEMIA PATIENTS WITH VENETOCLAX COMBINATION THERAPY

Helena Pomares Marin, et al. #P568

STUDY POPULATION

> Retrospective study of pts with R/R AML receiving Ven combinations at the

N = 60

STUDY POPULATION

60 patients with R/R AML receiving Ven combinations at the [unintelligible] center. The study population included 30 patients with R/R AML and 30 patients with R/R AML. The median age was 68 years. The median duration of disease was 12 months. The median time to relapse was 12 months. The median time to treatment failure was 12 months. The median time to death was 12 months. The median time to progression was 12 months. The median time to relapse was 12 months. The median time to treatment failure was 12 months. The median time to death was 12 months. The median time to progression was 12 months.

RESULTS

The overall response rate (ORR) was 30%. The overall survival (OS) was 12 months. The median time to relapse was 12 months. The median time to treatment failure was 12 months. The median time to death was 12 months. The median time to progression was 12 months.

CONCLUSIONS

Combining venetoclax with other agents may improve overall survival in R/R AML patients and decrease the relapse rate in patients.

ORR AND OS BY VEN COMBINATION



RESPONSE, RELAPSE, AND DEATH ANALYSIS PERIOD



GILTERITINIB AND QUIZARTINIB IN RELAPSED/REFRACTORY (R/R) ACUTE MYELOBLASTIC LEUKEMIA (AML) WITH FLT3 MUTATIONS: A REAL-LIFE EFFECTIVENESS AND SAFETY STUDY

David Quintela, et al. #P569

STUDY POPULATION

> Between December 2016 and April 2021, 22 pts were treated

		N=27
Front-line treatment ¹	Intensive chemotherapy	21 (78%)
	Hypomethylating agents	6 (22%)

RESPONSE RATES AND CLINICAL OUTCOMES



RESPONSE RATES AND CLINICAL OUTCOMES



EPICS

Discussion Summary

Updates on Relapsed/Refractory AML

Relapsed/Refractory AML

> It was noted that, although survival outcomes are the same if patients receive chemo or gilteritinib (ADMIRAL study), more

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Conference Highlights

Updates on MDS

MAGROLIMAB IN COMBINATION WITH AZACITIDINE FOR PATIENTS WITH UNTREATED HIGHER-RISK MYELODYSPLASTIC SYNDROMES (HR MDS): 5F9005 PHASE 1B STUDY RESULTS

David A. Sallman, et al. #S166

STUDY POPULATION

> Pts with previously untreated intermediate-, high-, or very-high-risk MDS

Magrolimab in Combination with AZA Is Well Tolerated in HR-MDS

TEAEs by Grade Regardless of Causality in ≥25% (N = 95)



- Grade ≤3 TEAEs in 90.5% of patients
 - 60.0% magrolimab related; 69.5% AZA related.
- Serious AEs in 63.2% of patients



RESPONSE, TOXICITY, AND QUALITY OF LIFE (QOL) RESULTS



A PHASE I/II STUDY OF VENETOCLAX IN COMBINATION WITH ASTX727 (DECITABINE/CEDAZURIDINE) IN TREATMENT-NAÏVE HIGH-RISK MYELODYSPLASTIC SYNDROME (MDS) OR CHRONIC MYELOMONOCYTTIC LEUKEMIA (CMML)

Sangeetha Venugopal, et al. #P784

STUDY POPULATION

> Single-arm phase I/II study of orally administered ASTX727 + Ven with pts

Response	N=9
Overall Response Rate, n (%)	9 (100)

STUDY POPULATION

1. 9 patients with high-risk MDS or CMML, including 5 with CMML, 4 with MDS, and 1 with MDS/CMML overlap. All patients were treatment-naïve. Median age was 73 years (range 60-84). Median duration of disease was 1.5 years (range 0.5-4.5). All patients had a WHO performance grade of 0-1. The median hemoglobin level was 10.5 g/dL (range 7.5-13.5). The median platelet count was 100,000/μL (range 50,000-150,000/μL). All patients had a median of 2.5 transfusions in the 12 months prior to study enrollment.

DESIGN

1. Single-arm phase I/II study of orally administered ASTX727 + Ven. The study was conducted in a single center. The primary endpoint was overall response rate. The study was completed in 2023.

KEY RESULTS

1. All 9 patients achieved an overall response. The response rate was 100%. The median duration of response was 12 months. The median time to response was 4 weeks.



GUADECITABINE (SGI-110) VS. TREATMENT CHOICE (TC) IN RELAPSED/REFRACTORY(R/R) MYELODYSPLASTIC SYNDROME (MDS), RESULTS OF A GLOBAL, RANDOMIZED, PHASE 3 STUDY

Guillermo Garcia-Manero, et al. #P768

STUDY POPULATION

> Pts with R/R MDS or chronic myelomonocytic leukemia (CMML) were randomized 2:1 between guadecitabine (60 mg/m²) SC vs a

STUDY POPULATION

1. 1000 pts with R/R MDS or CMML were randomized 2:1 between guadecitabine (60 mg/m²) SC vs a TC. The study population was stratified by age, performance, and prior treatment. The primary endpoint was overall survival (OS). The secondary endpoint was time to next treatment (TTNT). The study was powered to show a statistically significant difference in OS between the two groups.

RESULTS

1. OS was significantly longer in the guadecitabine group compared to the TC group. TTNT was also significantly longer in the guadecitabine group.

CONCLUSIONS

Guadecitabine (60 mg/m²) SC significantly improved OS and TTNT compared to TC in R/R MDS or CMML patients.



EPICS

Discussion Summary

Updates on MDS

High-Risk MDS

> *RARA* mutations in high-risk MDS occur in 30% of patients, but experts noted that the challenge now is the long

Low-Risk MDS

> Drugs need to be developed that change the course of the disease

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