



CASES

INSIGHTS INTO ACUTE MYELOID LEUKEMIA

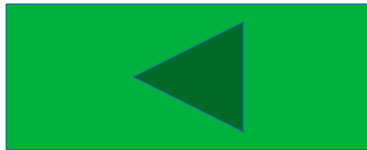
Saturday, October 26, 2019

Seattle, WA

HOW TO NAVIGATE THIS REPORT



Click to move to topic of interest or ARS supporting data



Click to return to previous slide

Topic

Study Objective



Report Snapshot



Participant Demographics



Key Insights – AML



Advisor Key Takeaways



ARS Data – AML: Management of Newly Diagnosed Disease



ARS Data – AML: Management of Relapsed/Refractory Disease



STUDY OBJECTIVE



To gain advisors' perspectives on the following

- > Management of newly diagnosed and relapsed/refractory acute myeloid leukemia (AML)

- > A moderated roundtable discussion focusing on treatment of AML was held on October 26, 2019, in Seattle, WA
- > Disease state and data presentations were developed in conjunction with a medical expert from UC Davis
- > The group of advisors comprised 10 community oncologists
- > Insights on the following AML therapies were obtained: azacitidine, cytarabine and daunorubicin (ie, 7+3), decitabine, ivosidenib, enasidenib, gemtuzumab ozogamicin, gilteritinib, liposomal daunorubicin and cytarabine, midostaurin, sorafenib, venetoclax, glasdegib
- > Data collection was accomplished through use of audience response system questioning and in-depth moderated discussion



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Participant Demographics



PARTICIPANT DEMOGRAPHICS (1/2)

How many new patients with AML do you



How many unique patients with AML are



PARTICIPANT DEMOGRAPHICS (2/2)

What percentage of your AML patients fall



What percentage of your AML patients are



Source: American Society of Hematology (ASH) 2020. Data based on a survey of 1,000 hematologists. The survey was conducted from January to March 2020. The results are presented in this report.



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Key Insights

ACUTE MYELOID LEUKEMIA

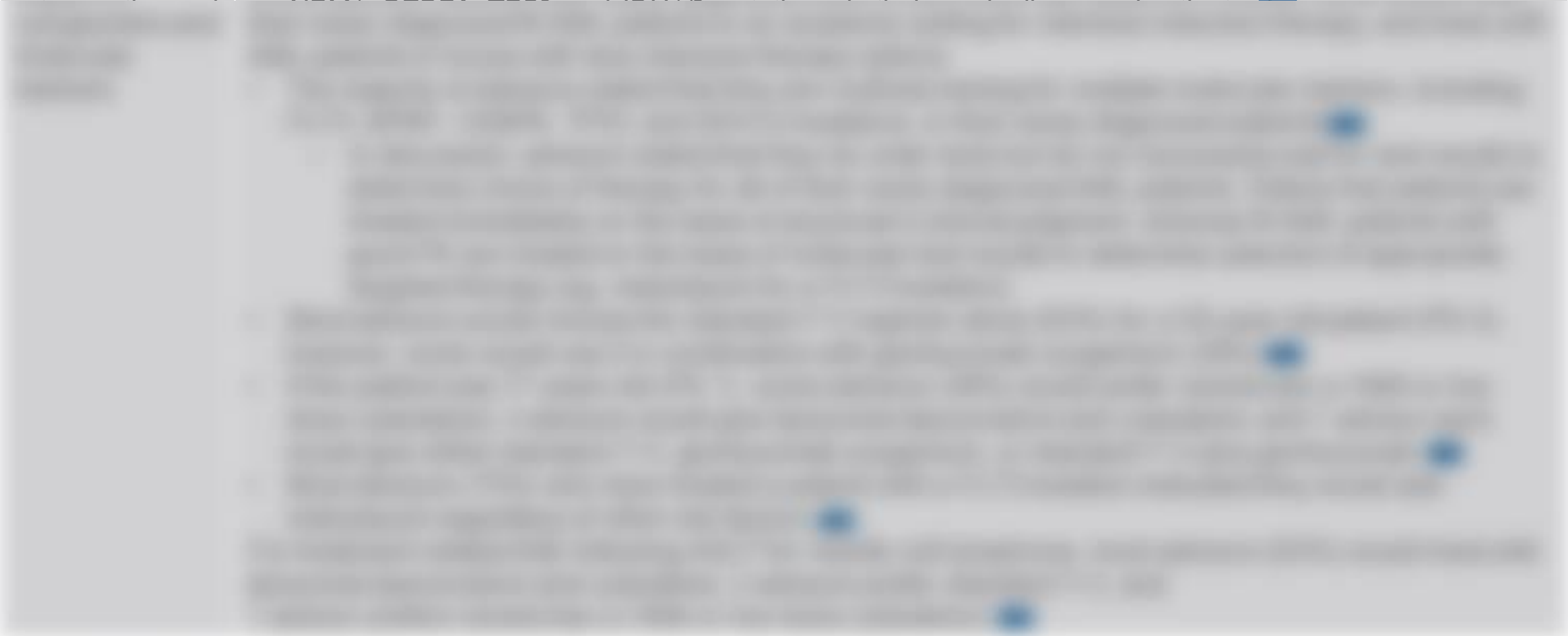
TOPLINE TAKEAWAYS – AML

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FIRST-LINE THERAPY (1/3)

Topic	Insights and Data
Impact of	<ul style="list-style-type: none">• Almost all advisors stated that they are routinely testing for all molecular markers, including <i>FLT3</i>,



Topic	Insights and Data
Patient cases	<ul style="list-style-type: none"> • If they had to treat a younger patient (50 yr) with PS 0, all advisors would choose the standard 7+3 regimen alone (63%), or in combination with gemtuzumab ozogamicin (38%) ▶ • If the patient was 77 years old (PS 1), half of the advisors (50%) would prefer venetoclax (± HMA or low-dose cytarabine), while 2 advisors would give low-dose Ara-C (± HMA), and 1 each would prefer liposomal daunorubicin and cytarabine or gemtuzumab ozogamicin ▶ • For treatment-related AML following ASCT for mantle cell lymphoma with unknown genomic profile, 1/3 of advisors would treat with standard 7+3, and another 1/3 prefer liposomal daunorubicin and cytarabine. Almost 1/4 of the advisors would treat with venetoclax (± HMA or low-dose cytarabine) ▶ • Most advisors (70%) currently treat a <i>FLT3</i> mutation-positive AML patient with standard induction chemotherapy plus midostaurin since the approval of midostaurin ▶
General treatment pattern	<p>Older fit patients</p> <ul style="list-style-type: none"> • During discussion, most advisors reported generally treating older fit patients with standard 7+3 regimen alone or in combination with gemtuzumab ozogamicin • For AML patients with a background of MDS, advisors consider transplant and reported inducing with standard 7+3 regimen; however, advisors seemed to be impressed with liposomal daunorubicin and cytarabine survival data compared with 7+3 <p>Older unfit patients</p> <ul style="list-style-type: none"> • While some advisors reported preferring venetoclax for older unfit patients, a few others tend to obtain a second opinion from leukemia experts <ul style="list-style-type: none"> – Some advisors are likely to refer to academic centers to start venetoclax and then manage the patient from the second cycle, due to lack of good supportive care in their community practice • For those patients with <i>IDH1</i> mutation, some advisors would prefer venetoclax or ivosidenib as the frontline therapy, and some advisors reported referring out those patients to leukemia specialists • For <i>FLT3</i> mutation patients, 1 advisor has used sorafenib off-label, but many are open to using venetoclax in the future

FIRST-LINE THERAPY (3/3)



Topic	Insights and Data
Perception of	<ul style="list-style-type: none">The majority of the advisors (78%) have not used liposomal daunorubicin and cytarabine, but some

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QUOTES – FIRST-LINE THERAPY

“The first-line therapy for patients with HIV is a combination of zidovudine, zalcitabine, and zalcitabine.”

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MANAGEMENT OF RELAPSED/REFRACTORY DISEASE (1/3)



Topic	Insights and Data
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Mutational	<ul style="list-style-type: none">All advisors support the importance of repeat biomarker testing using a full biomarker profile for relapsed disease 
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MANAGEMENT OF RELAPSED/REFRACTORY DISEASE (2/3)



Topic	Insights and Data
Reinduction	<ul style="list-style-type: none">The majority of advisors (75%) will consider reinduction in their relapsed patients who achieve a CR1 of at least 6 months, while 25% prefer a CR1 of at least 12 months.



MANAGEMENT OF RELAPSED/REFRACTORY DISEASE (3/3)



Topic	Insights and Data
Perception of gilteritinib	<ul style="list-style-type: none">Advisors do not have experience with gilteritinibNone of the advisors have used gilteritinib in their AML patients

QUOTES – MANAGEMENT OF RELAPSED/REFRACTORY DISEASE

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STRATEGIC CONSIDERATIONS FOR TIBSOVO (1/2)



> Although none of the advisors have used Tibsovo in their AML patients, on the basis of the presentation and

[The following text is heavily blurred and illegible. It appears to be a list of points or a detailed discussion related to the strategic considerations for Tibsovo.]

STRATEGIC CONSIDERATIONS FOR TIBSOVO (2/2)



> Apart from educational materials, advisors expressed that direct communication with leukemia

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Advisor Key Takeaways



AML – KEY TAKEAWAYS (1/2)



Dr 1

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AML – KEY TAKEAWAYS (2/2)



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ARS Data – AML: Management of Newly Diagnosed Disease



IN ADDITION TO CYTOGENETICS, WHICH OF THE FOLLOWING MOLECULAR MARKERS ARE YOU ROUTINELY TESTING FOR IN YOUR NEWLY DIAGNOSED AML PATIENTS? (SELECT ALL THAT APPLY) (N = 8*)

FOR EXAMPLE PURPOSES ONLY

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG LIPOSOMAL DAUNORUBICIN AND CYTARABINE (VYXEOS)? (N = 9*)

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FOR EXAMPLE PURPOSES ONLY

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG GEMTUZUMAB OZOGAMICIN (MYLOTARG)? (N = 9*)

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IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG MIDOSTAURIN (RYDAPT)? (N = 9*)

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FOR EXAMPLE PURPOSES ONLY



IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG GILTERITINIB (XOSPATA)? (N = 9*)

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IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG ENASIDENIB (IDHIFA)? (N = 9*)

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IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG IVOSIDENIB (TIBSOVO)? (N = 9*)

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FOR EXAMPLE PURPOSES ONLY



IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG GLASDEGIB (DAURISMO)? (N = 9*)

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IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG VENETOCLAX TABLETS (VENCLEXTA)? (N = 9*)

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FOR EXAMPLE PURPOSES ONLY



WHAT INDUCTION REGIMEN DO YOU ROUTINELY RECOMMEND FOR A 50-YEAR-OLD PS 0 PATIENT WITH INTERMEDIATE-RISK AML (CD33+ AND WITHOUT *FLT3* MUTATION)? (N = 8*)

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FOR EXAMPLE PURPOSES ONLY

WHAT INDUCTION REGIMEN DO YOU ROUTINELY RECOMMEND FOR A 77-YEAR-OLD PS 1 PATIENT WITH INTERMEDIATE-RISK AML (CD33+ AND WITHOUT *FLT3* MUTATION)? (N = 8*)

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FOR EXAMPLE PURPOSES ONLY

WHAT INDUCTION REGIMEN DO YOU ROUTINELY RECOMMEND FOR A 70-YEAR-OLD PS 1 PATIENT WITH THERAPY-RELATED AML FOLLOWING TREATMENT FOR MANTLE CELL LYMPHOMA (INCLUDING AUTOLOGOUS STEM CELL TRANSPLANT)? GENOMIC PROFILING IS UNKNOWN (N = 9*)

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FOR EXAMPLE PURPOSES ONLY

WHAT INDUCTION REGIMEN DO YOU RECOMMEND FOR A 70-YEAR-OLD PS 2 PATIENT WITH INTERMEDIATE-RISK AML AND *IDH1* MUTATION REVEALED BY NGS? (N = 8*)

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FOR EXAMPLE PURPOSES ONLY

I AM CURRENTLY TREATING ALL *FLT3* MUTATION-POSITIVE AML PATIENTS WITH STANDARD INDUCTION CHEMOTHERAPY PLUS MIDOSTAURIN, WHENEVER FEASIBLE, REGARDLESS OF OTHER RISK FACTORS (N = 10)

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FOR EXAMPLE PURPOSES ONLY

VENETOCLAX HAS RECENTLY BEEN APPROVED FOR NEWLY DIAGNOSED ADULT AML PATIENTS WHO ARE 75 YEARS OR OLDER, OR WHO HAVE COMORBIDITIES THAT PRECLUDE USE OF INTENSIVE INDUCTION CHEMOTHERAPY. DO YOU PLAN TO INCREASE YOUR USE OF THIS THERAPY OPTION IN NEWLY DIAGNOSED AML PATIENTS? (N = 10)

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FOR EXAMPLE PURPOSES ONLY



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**ARS Data – AML: Management
of Relapsed/Refractory Disease**



DO YOU ROUTINELY REPEAT BIOMARKER TESTING IN YOUR AML PATIENTS AT THE TIME OF RELAPSE? (N = 6*)

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FOR EXAMPLE PURPOSES ONLY

WHICH OF THE FOLLOWING MUTATIONS ARE MOST IMPORTANT TO BE CHECKED IN ALL PATIENTS WITH RELAPSED AML FOR THERAPEUTIC DECISION MAKING? (N = 7*)

FOR EXAMPLE PURPOSES ONLY

I GENERALLY REQUIRE A CR1 OF AT LEAST __ MONTHS BEFORE RECOMMENDING REINDUCTION IN MY RELAPSED AML PATIENTS (N = 8*)

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FOR EXAMPLE PURPOSES ONLY

WHAT PERCENTAGE OF THE R/R AML PATIENTS YOU SEE ARE *FLT3* MUTATED (ITD AND TKD INCLUDED)? (N = 8*)

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FOR EXAMPLE PURPOSES ONLY

WHAT PERCENTAGE OF THE R/R AML PATIENTS YOU SEE ARE *IDH* MUTATED (*IDH1* AND *IDH2* INCLUDED)? (N = 8*)

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FOR EXAMPLE PURPOSES ONLY

HOW OFTEN DO YOU RECHECK *FLT3* MUTATIONS AT RELAPSE, IRRESPECTIVE OF BASELINE *FLT3* MUTATION STATUS? (N = 9*)

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FOR EXAMPLE PURPOSES ONLY



PATIENT CASE

1. The patient is a 65-year-old male with a long history of hypertension, hyperlipidemia, and type 2 diabetes. He has been on treatment for these conditions for several years. He is currently on amlodipine, atorvastatin, and metformin. He has no known drug allergies and is not taking any other medications. He has a history of smoking 20 cigarettes per day for 30 years, which he quit 10 years ago. He has a family history of heart disease and stroke. He is currently experiencing chest pain and shortness of breath, which he attributes to his long-standing hypertension. He has been to the emergency department twice in the last few weeks, both times being discharged with a diagnosis of anxiety. He is seeking a second opinion from a cardiologist.

WHAT WOULD BE THE NEXT BEST STEP IN MANAGEMENT? (N = 9*)

FOR EXAMPLE PURPOSES ONLY

PATIENT CASE



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WHAT DO YOU TREAT HER WITH? (N = 7*)

FOR EXAMPLE PURPOSES ONLY



PATIENT CASE



[Blurred text area]

WHAT WOULD YOU CONSIDER NEXT? (N = 9*)

FOR EXAMPLE PURPOSES ONLY



PATIENT CASE



[Blurred text area containing patient case details]

WHAT DO YOU CONSIDER NEXT? (N = 7*)

FOR EXAMPLE PURPOSES ONLY



PATIENT CASE



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WHAT WOULD YOU RECOMMEND? (N = 9*)

FOR EXAMPLE PURPOSES ONLY



PATIENT CASE



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WHAT WOULD YOU CONSIDER NEXT? (N = 10)

FOR EXAMPLE PURPOSES ONLY

