VOL 2 | ISSUE 2

Acute Leukemias™ UPDATE

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

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ABIM CME MOC ACCREDITED

CME Certified

Acute Leukemias™ UPDATE

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Acute Leukemias Update

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

The treatment of acute leukemias remains a challenge for many healthcare professionals and patients despite recent gains made in the management of this group of diseases. Determining which approach is most appropriate requires careful consideration of patient and disease characteristics, physician expertise and available health-system resources. Published results from ongoing trials continually lead to the emergence of new therapeutic targets and regimens, thereby altering management algorithms. In order to offer optimal patient care, including the option of clinical trial participation, the practicing medical oncologist must be well informed of these advances.

To bridge the gap between research and patient care, this issue of *Acute Leukemias Update* features one-on-one discussions with leading hematology-oncology investigators. By providing information on the latest clinical developments in the context of expert perspectives, this CME activity assists medical oncologists, hematologists and hematology-oncology fellows with the formulation of evidence-based and current therapeutic strategies.

LEARNING OBJECTIVES

- Appraise current data on recent therapeutic advances and changing practice standards, including FDA approvals, in acute forms of leukemia, and integrate this information into clinical care.
- Recognize the clinical and prognostic significance of specific cytogenetic and molecular abnormalities, and use this information to refine diagnostic algorithms for acute myeloid leukemia (AML).
- Consider patient age, performance status and other disease-related factors in the selection and sequencing of therapy for AML.
- Understand the biologic rationale for and early efficacy and toxicity data with the use of chimeric antigen receptor-directed T-cell therapy for patients with relapsed acute lymphoblastic leukemia, and, where appropriate, facilitate patient access to this approach.
- Identify the mechanisms of action, efficacy and side effects of newly approved and investigational agents demonstrating promising activity in acute forms of leukemia, and refer appropriately selected patients for participation in clinical trials evaluating these approaches.

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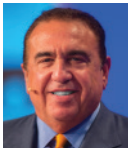

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Interview with Mark Levis, MD, PhD

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Track 2 Management of AML with p53 mutations

Track 3 Efficacy of hypomethylating agents with venetoclax in older patients with AML

Track 4 Therapeutic options for patients with AML and FLT3 mutations

Track 5 Monitoring and management of venetoclax-associated tumor lysis syndrome

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Track 7 Role of the FLT3 pathway in myeloid cell development and types of FLT3 mutations

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Track 11 **Case:** A 60-year-old man with AML and a FLT3-ITD mutation receives gilteritinib with standard 7 + 3 chemotherapy induction followed by allotransplant and maintenance gilteritinib on a clinical trial

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Track 20 Optimal use of tyrosine kinase inhibitors in the management of Philadelphia chromosome-positive ALL

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Tracks 1-23

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Track 4 Integration of venetoclax with hypomethylating agents into the clinical algorithm for AML

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Video Program

View the corresponding video interviews with (from left) Drs Levis and Ravandi by Dr Love at www.ResearchToPractice.com/AcuteLeukemiasUpdate119/Video

SELECT PUBLICATIONS

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Savona MR et al. **Phase Ib study of glasdegib, a hedgehog pathway inhibitor, in combination with standard chemotherapy in patients with AML or high-risk MDS.** *Clin Cancer Res* 2018;24(10):2294-303.

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Which of the following statements is true regarding venetoclax in combination with a hypomethylating agent for patients with AML?**
   a. This therapy elicits a response rate (CR + CRi) that is higher than 60%
   b. Responses are durable
   c. This therapy is approved for patients with AML irrespective of age or performance status
   d. All of the above
   e. Both a and b
   f. Both a and c

2. **The recently FDA-approved FLT3 inhibitor gilteritinib is effective in patients with relapsed or refractory AML and _____ mutations.**
   a. FLT3-TKD
   b. FLT3-ITD
   c. Both FLT3-TKD and FLT3-ITD

3. **Which of the following statements is true regarding the agent CPX-351 in the treatment of therapy-related AML or AML with myelodysplasia-related changes?**
   a. CPX-351 is a liposomal formulation of cytarabine and daunorubicin encapsulated at a 5:1 molar ratio
   b. The efficacy of CPX-351 is similar to that of traditional cytarabine and daunorubicin in terms of overall survival
   c. Both a and b

4. **The tyrosine kinase inhibitor ponatinib is effective in patients with Philadelphia chromosome-positive ALL and T315I mutations but has been associated with cardiovascular side effects and pancreatitis.**
   a. True
   b. False

5. **Adverse events that have been associated with both the bispecific monoclonal antibody blinatumomab and CAR T-cell therapy include _____.**
   a. Cytokine release syndrome
   b. Neurologic toxicities
   c. Both a and b

6. **Enasidenib is FDA approved for the treatment of relapsed or refractory AML with a mutation in _____.**
   a. IDH1
   b. IDH2
   c. Bcl-2
   d. FLT3
   e. Both a and b

7. **In the Phase III RATIFY trial the addition of midostaurin to standard chemotherapy resulted in a significant improvement in overall survival for patients with newly diagnosed AML and _____ mutations.**
   a. FLT3-ITD
   b. FLT3-TKD
   c. Both a and b

8. **The antibody-drug conjugate gemtuzumab ozogamicin provides the most benefit for patients with CD33-positive AML who are at _____ risk.**
   a. Favorable
   b. Intermediate
   c. Poor

9. **Patients with AML who have a FLT3 mutation do not need to be retested at relapse because a patient's FLT3 mutation status does not change during the disease course.**
   a. True
   b. False

10. **_____ is a hedgehog inhibitor that was recently FDA approved for use in combination with low-dose cytarabine for the treatment of newly diagnosed AML in patients who are aged 75 or older or who have comorbidities that preclude intensive induction chemotherapy.**
    a. Gemtuzumab ozogamicin
    b. Glasdegib
    c. Ivosidenib
    d. Gilteritinib

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Acute Leukemias Update — Volume 2, Issue 2

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Activity and tolerability of approved and investigational FLT3 inhibitors in patients with AML	4 3 2 1	4 3 2 1
Biologic rationale for and activity of CPX-351 (liposomal cytarabine/daunorubicin) for secondary AML	4 3 2 1	4 3 2 1
Differentiation syndrome associated with the IDH inhibitors enasidenib and ivosidenib	4 3 2 1	4 3 2 1
Efficacy of venetoclax with a hypomethylating agent for previously untreated AML	4 3 2 1	4 3 2 1
Mechanism of action, activity and tolerability of blinatumomab for ALL	4 3 2 1	4 3 2 1
Emerging data with and current clinical role of CAR T-cell therapy for patients with relapsed ALL	4 3 2 1	4 3 2 1

Practice Setting:

☐ Academic center/medical school ☐ Community cancer center/hospital ☐ Group practice

☐ Solo practice ☐ Government (eg, VA) ☐ Other (please specify).....

Approximately how many new patients with the following do you see per year?

ALL..... AML..... APL.....

Was the activity evidence based, fair, balanced and free from commercial bias?

☐ Yes ☐ No If no, please explain: .....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

☐ This activity validated my current practice

☐ Create/revise protocols, policies and/or procedures

☐ Change the management and/or treatment of my patients

☐ Other (please explain): .....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

.....

The content of this activity matched my current (or potential) scope of practice.

☐ Yes ☐ No If no, please explain: .....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Appraise current data on recent therapeutic advances and changing practice standards, including FDA approvals, in acute forms of leukemia, and integrate this information into clinical care..... 4 3 2 1 N/M N/A
- Recognize the clinical and prognostic significance of specific cytogenetic and molecular abnormalities, and use this information to refine diagnostic algorithms for acute myeloid leukemia (AML)..... 4 3 2 1 N/M N/A
- Consider patient age, performance status and other disease-related factors in the selection and sequencing of therapy for AML..... 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Understand the biologic rationale for and early efficacy and toxicity data with the use of chimeric antigen receptor-directed T-cell therapy for patients with relapsed acute lymphoblastic leukemia, and, where appropriate, facilitate patient access to this approach. . . . . 4 3 2 1 N/M N/A
- Identify the mechanisms of action, efficacy and side effects of newly approved and investigational agents demonstrating promising activity in acute forms of leukemia, and refer appropriately selected patients for participation in clinical trials evaluating these approaches. . . . . 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

Would you recommend this activity to a colleague?

☐ Yes ☐ No

If no, please explain: .....

PART 2 — Please tell us about the faculty and editor for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter	Effectiveness as an educator
Mark Levis, MD, PhD	4 3 2 1	4 3 2 1
Farhad Ravandi, MD	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

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Acute Leukemias™ UPDATE

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