VOL 1 | ISSUE 1

Acute Leukemias™ UPDATE

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

FACULTY INTERVIEWS

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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 treatment approach is most appropriate requires careful consideration of patient-specific 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 data on recent therapeutic advances and changing practice standards, including FDA approvals, in acute forms of leukemia, and integrate this information into current clinical care.
- Recognize the clinical and prognostic significance of specific cytogenetic and molecular abnormalities, and use this information in treatment decision-making for patients with acute forms of leukemia.
- Consider age, performance status and other disease-related factors in the identification of patients with acute lymphoblastic leukemia who are appropriate for targeted agents or chemotherapy.
- Counsel patients regarding the incidence and manifestation of side effects and toxicities associated with newly approved and investigational agents and regimens in the treatment of acute forms of leukemia.
- Identify the proposed mechanisms of action of and recall new data with investigational agents demonstrating promising activity in acute forms of leukemia, and refer appropriate patients for participation in ongoing trials evaluating these approaches.

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Interview with Daniel J DeAngelo, MD, PhD

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Track 2	Biologic rationale for the use of pediatric regimens for young adult patients with ALL
Track 3	Importance of Philadelphia chromosome status and Philadelphia-like signature in prognosis and treatment approach
Track 4	Cooperative care of patients with ALL between community practices and tertiary centers
Track 5	Treatment selection strategy for patients with ALL
Track 6	Comparison of treatment strategies for young adults with ALL
Track 7	Evolution of multiagent regimens in pediatric ALL
Track 8	Asparaginase preparations for ALL
Track 9	Activity and tolerability of inotuzumab ozogamicin
Track 10	Recognition and management of immune-related side effects of blinatumomab
Track 11	Cytokine release syndrome and neurotoxicity with chimeric antigen receptor T-cell (CAR-T) therapy
Track 12	Anticipated role of CAR-T therapy in clinical practice and potential integration into treatment algorithms for ALL
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Track 14	**Case:** A 35-year-old man presents with fatigue, fever and chills and is diagnosed with FLT3-ITD-negative acute myeloid leukemia (AML)
Track 15	Mechanism of action and efficacy of midostaurin for patients with FLT3 mutation-positive AML
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Track 18	IDH1/2 inhibitors for AML
Track 19	Efficacy of venetoclax alone and in combination with hypomethylating agents for AML
Track 20	Early data with the use of hedgehog inhibitors for AML
Track 21	Voluntary market removal of gemtuzumab ozogamicin and the potential for reintroduction
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Interview with Amir T Fathi, MD

Tracks 1-20

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Interview with Dr Fathi (continued)

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Track 12	Current status of the investigational hedgehog inhibitor glasdegib and the antibody-drug conjugate gemtuzumab ozogamicin
Track 13	CAR-T therapy and the aurora A kinase inhibitor alisertib for AML
Track 14	**Case:** A 50-year-old man with FLT3 wild-type myelodysplastic syndrome experiences disease transformation to FLT3-ITD mutation-positive AML
Track 15	**Case:** A 56-year-old man with heavily pretreated AML and a FLT3-ITD mutation receives sorafenib
Track 16	Conventional treatments and emerging therapies for ALL
Track 17	**Case:** A 55-year-old woman with relapsed Philadelphia chromosome-negative B-cell ALL receives blinatumomab
Track 18	Neurologic toxicities with blinatumomab in the treatment of ALL
Track 19	Toxicity with different preparations of asparaginase in older patients with ALL
Track 20	**Case:** A 45-year-old man with low-risk acute promyelocytic leukemia initially treated with all-trans retinoic acid and arsenic trioxide develops differentiation symptoms

Video Program

View the corresponding video interviews with (from left) Drs DeAngelo and Fathi by Dr Love at www.ResearchToPractice.com/AcuteLeukemiasUpdate117/Video

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Submit them to us via Facebook or Twitter and we will do our best to get them answered for you

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SELECT PUBLICATIONS

A phase II study of the aurora A kinase inhibitor alisertib in combination with 7 + 3 induction chemotherapy in patients with high-risk acute myeloid leukemia. NCT02560025

A phase III randomized trial of blinatumomab for newly diagnosed BCR-ABL-negative B lineage acute lymphoblastic leukemia in adults. NCT02003222

A phase III trial to evaluate the efficacy of the addition of inotuzumab ozogamicin (a conjugated anti-CD22 monoclonal antibody) to frontline therapy in young adults (ages 18-39 years) with newly diagnosed precursor B-cell ALL. NCT03150693

A phase 3 open-label, multicenter, randomized study of ASP2215 versus salvage chemotherapy in patients with relapsed or refractory acute myeloid leukemia (AML) with FLT3 mutation. NCT02421939

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Stone RM et al. **Midostaurin plus chemotherapy for acute myeloid leukemia with a FLT3 mutation.** *N Engl J Med* 2017;377(5):454-64.

Stone RM et al. **The multi-kinase inhibitor midostaurin (M) prolongs survival compared with placebo (P) in combination with daunorubicin (D)/cytarabine (C) induction (ind), high-dose C consolidation (consol), and as maintenance (maint) therapy in newly diagnosed acute myeloid leukemia (AML) patients (pts) age 18-60 with FLT3 mutations (muts): An international prospective randomized (rand), P-controlled double-blind trial (CALGB 10603/RATIFY [Alliance]).** *Proc ASH* 2015;**Abstract 6**.

Vrooman et al. **Postinduction dexamethasone and individualized dosing of escherichia coli L-asparaginase each improve outcome of children and adolescents with newly diagnosed acute lymphoblastic leukemia: Results from a randomized study—Dana-Farber Cancer Institute ALL Consortium Protocol 00-01.** *J Clin Oncol* 2013;31(9):1202-10.

Wang ES et al. **CASCADE: A phase 3, randomized, double-blind study of vadastuximab talirine (33A) versus placebo in combination with azacitidine or decitabine in the treatment of older patients with newly diagnosed acute myeloid leukemia (AML).** *Proc ASCO* 2017;**Abstract TPS7066**.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Patients who present with FLT3 mutation-positive AML _____.**
   a. Are less likely to experience relapse after standard consolidation chemotherapy than are patients with FLT3 wild-type AML
   b. Have a 50% to 55% chance of cure after treatment with midostaurin in combination with standard induction and consolidation chemotherapy and stem cell transplant
   c. Are likely to respond to midostaurin monotherapy

2. **The mechanism of action of blinatumomab involves _____.**
   a. Binding to CD19 on tumor cells and CD3 on T cells
   b. Binding to FLT3
   c. Binding to IDH1

3. **Which of the following conclusions can be drawn regarding the use of CPX-351, the liposomal encapsulation of cytarabine and daunorubicin, for AML?**
   a. Phase III data demonstrated a survival benefit with CPX-351 for patients with primary AML
   b. The incidence of oral mucosal toxicity is higher for patients who receive CPX-351 than for those who receive the standard formulation
   c. Elderly patients who may be unable to tolerate the standard formulation are more likely to tolerate CPX-351

4. **The cytokine release syndrome and neurotoxicity associated with blinatumomab and CAR-T therapy in patients with ALL can be managed with early steroids and tocilizumab.**
   a. True
   b. False

5. **The mechanism of action of inotuzumab ozogamicin involves _____.**
   a. Binding to FLT3
   b. Binding to CD22
   c. Inhibiting IDH2

6. **The mechanism of action of the investigational agents quizartinib, gilteritinib and crenolanib besylate is to _____.**
   a. Inhibit FLT3
   b. Inhibit IDH1/2
   c. Inhibit Bcl-2

7. **Philadelphia chromosome status or Philadelphia-like signature is important in selecting front-line therapy for patients with ALL.**
   a. True
   b. False

8. **According to current clinical data, venetoclax _____.**
   a. Has no potential role in the treatment of AML because AML is Bcl-2 independent
   b. Has demonstrated remission rates as high as 70% as a single agent for AML
   c. Has demonstrated remission rates as high as 70% in combination with hypomethylating agents for older patients with AML

9. **In a Phase III study evaluating azacitidine or decitabine with or without vadastuximab talirine for older patients with newly diagnosed AML, higher rates of severe toxicities were observed among patients receiving vadastuximab talirine.**
   a. True
   b. False

10. **Which of the following statements is true about IDH mutations in patients with AML?**
    a. Patients with an IDH mutation are also likely to have a TET mutation
    b. IDH2 mutations are less common than IDH1 mutations in patients with myeloid cancers
    c. The response rate with IDH inhibitors is about 40% for patients with an IDH mutation

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Acute Leukemias Update — Volume 1, Issue 1

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
Results of the RATIFY Phase III study of midostaurin in combination with daunorubicin/cytarabine induction therapy, with high-dose cytarabine consolidation and as maintenance therapy for patients with newly diagnosed FLT3 mutation-positive AML	4 3 2 1	4 3 2 1
Biologic rationale for and efficacy and tolerability of the recently approved IDH2 inhibitor enasidenib for AML	4 3 2 1	4 3 2 1
Risk-benefit ratio with CAR-T therapy for patients with aggressive leukemias	4 3 2 1	4 3 2 1
Efficacy and tolerability of the FDA-approved agent blinatumomab for relapsed/refractory ALL	4 3 2 1	4 3 2 1
Proposed rationale for the increased activity/delivery of the recently approved liposome-encapsulated formulation of cytarabine and daunorubicin (CPX-351)	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.

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

- Appraise data on recent therapeutic advances and changing practice standards, including FDA approvals, in acute forms of leukemia, and integrate this information into current 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 in treatment decision-making for patients with acute forms of leukemia. ..... 4 3 2 1 N/M N/A
- Consider age, performance status and other disease-related factors in the identification of patients with acute lymphoblastic leukemia who are appropriate for targeted agents or chemotherapy. ..... 4 3 2 1 N/M N/A

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

- Counsel patients regarding the incidence and manifestation of side effects and toxicities associated with newly approved and investigational agents and regimens in the treatment of acute forms of leukemia. . . . . 4 3 2 1 N/M N/A
- Identify the proposed mechanisms of action of and recall new data with investigational agents demonstrating promising activity in acute forms of leukemia, and refer appropriate patients for participation in ongoing 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: . . . . . .

Additional comments about this activity:

. . . . . .

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

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Faculty	Knowledge of subject matter	Effectiveness as an educator
Daniel J DeAngelo, MD, PhD	4 3 2 1	4 3 2 1
Amir T Fathi, 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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