VOL 1 | ISSUE 2

Acute Leukemias™

UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Wendy Stock, MD

Eytan Stein, MD

EDITOR

Neil Love, MD

Acute Leukemias™ UPDATE

Contact Information	Neil Love, MD Research To Practice One Biscayne Tower 2 South Biscayne Boulevard, Suite 3600 Miami, FL 33131 Fax: (305) 377-9998 Email: DrNeilLove@ResearchToPractice.com
For CME/CNE Information	Email: CE@ResearchToPractice.com

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 existing 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 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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CME INFORMATION

FACULTY AFFILIATIONS

Wendy Stock, MD
Anjuli Seth Nayak Professor of Leukemia Research
Director, Leukemia Program
The University of Chicago Medicine
Chicago, Illinois

Eytan Stein, MD
Hematologic Oncologist
Memorial Sloan Kettering Cancer Center
New York, New York

EDITOR

Neil Love, MD
Research To Practice
Miami, Florida

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Interview with Wendy Stock, MD

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Track 2	Investigation of blinatumomab-based regimens as front-line therapy for ALL
Track 3	Dosing and tolerability of asparaginase preparations in ALL
Track 4	Chimeric antigen receptor T-cell (CAR-T) therapy in ALL
Track 5	Cytokine release syndrome and neurotoxicity with CAR-T therapy
Track 6	Durability of response to CAR-T therapy and use of the antibody-drug conjugate inotuzumab ozogamicin after disease progression
Track 7	Activity and tolerability of inotuzumab ozogamicin in ALL
Track 8	Anticipated roles of CAR-T therapy, blinatumomab and inotuzumab ozogamicin in clinical practice and integration into ALL treatment algorithms
Track 9	**Case:** A 78-year-old woman with a previously untreated antecedent myeloproliferative neoplasm experiences transformation to IDH2 mutation-positive acute myeloid leukemia (AML)
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Track 13	Recent FDA approvals of enasidenib, midostaurin, CPX-351 and gemtuzumab ozogamicin in AML
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Track 16	Investigational FLT3 inhibitors in AML
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Track 7	Biology of IDH1/2 mutations and incidence in hematologic versus solid tumors
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Track 10	Activity of venetoclax with or without hypomethylating agents in AML
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Track 13	Tolerability of CPX-351 compared to standard-formulation cytarabine/daunorubicin
Track 14	**Case:** A 37-year-old man with high-risk Philadelphia chromosome-negative B-cell ALL
Track 15	Pediatric-inspired induction chemotherapy for high-risk Philadelphia chromosome-negative ALL
Track 16	Use of blinatumomab for patients with minimal residual disease after induction chemotherapy
Track 17	CAR-T therapy for high-risk ALL; management of cytokine release syndrome
Track 18	Recent FDA approval of inotuzumab ozogamicin for relapsed/refractory B-cell precursor ALL
Track 19	Similarities and differences between CAR-T therapy and blinatumomab and sequencing these agents in ALL
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Track 21	Antibody-drug conjugate vadastuximab talirine in AML
Track 22	**Case:** A 35-year-old man with APL receives ATRA and arsenic trioxide
Track 23	Prompt administration of ATRA and decreasing early deaths in APL
Track 24	Epidemiology of APL; higher incidences among Hispanic women

Video Program

View the corresponding video interviews with (from left) Drs Stock and Stein by Dr Love at www.ResearchToPractice.com/AcuteLeukemiasUpdate217/Video

SELECT PUBLICATIONS

A master protocol for biomarker-based treatment of AML (the Beat AML trial). NCT03013998

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Amatangelo MD et al. **Enasidenib induces acute myeloid leukemia cell differentiation to promote clinical response.** *Blood* 2017;130(6):732-41.

Chen Y et al. **Acute promyelocytic leukemia: A population-based study on incidence and survival in the United States, 1975-2008.** *Cancer* 2012;118(23):5811-8.

Cortes J et al. **A phase 2 randomized study of low dose ara-c with or without glasdegib (PF-04449913) in untreated patients with acute myeloid leukemia or high-risk myelodysplastic syndrome.** *Proc ASH* 2016;**Abstract 99**.

Jillella A et al. **Decreasing early deaths in acute promyelocytic leukemia (APL) by using a simplified treatment algorithm and establishing a network with academic and community centres.** *Proc ASH* 2015;**Abstract 3779**.

Kantarjian H et al. **Blinatumomab versus chemotherapy for advanced acute lymphoblastic leukemia.** *N Engl J Med* 2017;376(9):836-47.

Kantarjian HM et al. **Inotuzumab ozogamicin versus standard therapy for acute lymphoblastic leukemia.** *N Engl J Med* 2016;375(8):740-53.

Kolitz JE et al. **Efficacy by consolidation administration site: Subgroup analysis of a phase III study of CPX-351 versus 7+3 in older adults with newly diagnosed, high-risk acute myeloid leukemia (AML).** *Proc ASCO* 2017;**Abstract 7036**.

Konopleva M et al. **Efficacy and biological correlates of response in a phase II study of venetoclax monotherapy in patients with acute myelogenous leukemia.** *Cancer Discov* 2016;6(10):1106-17.

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Lancet JE et al. **Survival following allogeneic hematopoietic cell transplantation in older high-risk acute myeloid leukemia patients initially treated with CPX-351 liposome injection versus standard cytarabine and daunorubicin: Subgroup analysis of a large phase III trial.** *Proc ASH* 2016;**Abstract 906**.

Lo-Coco F et al. **Retinoic acid and arsenic trioxide for acute promyelocytic leukemia.** *N Engl J Med* 2013;369(2):111-21.

Martinelli G et al. **Complete hematologic and molecular response in adult patients with relapsed/refractory Philadelphia chromosome-positive B-precursor acute lymphoblastic leukemia following treatment with blinatumomab: Results from a phase II, single-arm, multicenter study.** *J Clin Oncol* 2017;35(16):1795-802.

Medeiros BC et al. **Analysis of efficacy by age for patients aged 60-75 with untreated secondary acute myeloid leukemia (AML) treated with CPX-351 liposome injection versus conventional cytarabine and daunorubicin in a phase III trial.** *Proc ASH* 2016;**Abstract 902**.

Perl AE et al. **Selective inhibition of FLT3 by gilteritinib in relapsed or refractory acute myeloid leukaemia: A multicentre, first-in-human, open-label, phase 1-2 study.** *Lancet Oncol* 2017;18(8):1061-75.

Platzbecker U et al. **Improved outcomes with retinoic acid and arsenic trioxide compared with retinoic acid and chemotherapy in non-high-risk acute promyelocytic leukemia: Final results of the randomized Italian-German APL0406 trial.** *J Clin Oncol* 2017;35(6):605-12.

Stein EM et al. **Enasidenib in mutant IDH2 relapsed or refractory acute myeloid leukemia.** *Blood* 2017;130(6):722-31.

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

Wheeler S et al. **ATRA availability on formulary for the treatment of APL across hospitals in the state of Georgia.** *Proc ASH* 2015;**Abstract 4924**.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Which of the following categories reflects the mechanism of action of blinatumomab?**
   a. Anti-PD-1/PD-L1 antibody
   b. Bispecific T-cell engager
   c. CAR-T therapy
   d. IDH1/2 antibody

2. **Patients with acute leukemias who undergo CAR-T therapy and experience cytokine release syndrome-associated toxicities generally do so _____.**
   a. Acutely, typically in the first week of treatment
   b. Chronically as toxicities accumulate over a long time

3. **Patients with ALL who receive inotuzumab ozogamicin typically experience acute peripheral neuropathy.**
   a. True
   b. False

4. **Which of the following toxicities *does not* occur with CPX-351, the liposomal encapsulation of cytarabine and daunorubicin that was recently approved by the FDA for treatment of secondary AML, as compared to the standard formulation of this combination?**
   a. Cytopenias
   b. Hair loss
   c. Both toxicities occur irrespective of the formulation

5. **Which of the following novel agents was recently approved by the FDA for the treatment of AML?**
   a. CPX-351
   b. Enasidenib
   c. Gemtuzumab ozogamicin
   d. All of the above

6. **Patients with newly diagnosed FLT3 _____-positive AML who received midostaurin/chemotherapy on the Phase III CALGB-10603 (RATIFY) trial experienced a significant benefit with the addition of midostaurin.**
   a. Internal tandem duplication
   b. Kinase domain mutation
   c. Both a and b

7. **What is the mechanism of action of the investigational agents quizartinib, gilteritinib and crenolanib?**
   a. FLT3 inhibition
   b. IDH1/2 inhibition
   c. Bcl-2 inhibition

8. **Which of the following statements is true about IDH mutations in patients with AML?**
   a. The incidence of IDH1 mutations is much higher than the incidence of IDH2 mutations
   b. The vast majority of patients with IDH mutations harbor both IDH1 and IDH2 mutations
   c. Only a small proportion of patients with IDH mutations harbor both IDH1 and IDH2 mutations

9. **Cytokine release syndrome and neurotoxicity associated with blinatumomab and CAR-T therapy for patients with ALL can typically be managed with corticosteroids and tocilizumab.**
   a. True
   b. False

10. **For patients who present with symptoms consistent with a diagnosis of APL, ATRA should be administered _____.**
    a. Only after the diagnosis is confirmed
    b. Immediately

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Acute Leukemias Update — Volume 1, Issue 2

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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
Efficacy and tolerability of the recently FDA-approved antibody-drug conjugate inotuzumab ozogamicin for relapsed/refractory B-cell precursor ALL	4 3 2 1	4 3 2 1
Specificity, potency and treatment-related adverse events with investigational FLT3 inhibitors (ie, crenolanib, gilteritinib and quizartinib) in AML	4 3 2 1	4 3 2 1
Activity and tolerability of the IDH2 inhibitor enasidenib alone or in combination with azacitidine in patients with AML	4 3 2 1	4 3 2 1
Investigation of blinatumomab-based regimens as front-line therapy for ALL	4 3 2 1	4 3 2 1
Proposed rationale for the increased activity and delivery of the recently FDA-approved liposome-encapsulated formulation of cytarabine and daunorubicin (CPX-351) in secondary AML	4 3 2 1	4 3 2 1
Risk-benefit ratio with CAR-T therapy for patients with acute leukemias	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 .....

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.....

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- Appraise current 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

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. . . . . .

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Wendy Stock, MD	4 3 2 1	4 3 2 1
Eytan Stein, 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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Neil Love, MD
Research To Practice
One Biscayne Tower
2 South Biscayne Boulevard, Suite 3600
Miami, FL 33131

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