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Cancer Conference Update

Audio Reviews of 72 Presentations and Posters from the 2014 American Society of Hematology Annual Meeting in San Francisco, California

FACULTY INTERVIEWS

Craig Moskowitz, MD
Jonathan W Friedberg, MD, MMSc
Stephen M Ansell, MD, PhD
Mikkael A Sekeres, MD, MS
Ola Landgren, MD, PhD
Jorge E Cortes, MD

EDITOR

Neil Love, MD

CONTENTS

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Hematologic Oncology™ UPDATE

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Cancer Conference Update

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OVERVIEW OF ACTIVITY

Hematologic oncology and related blood disorders are some of the most rapidly evolving fields in all of medicine. Results presented at major conferences from a plethora of ongoing clinical trials lead to the continual emergence of new therapeutic agents and changes in the indications for existing treatments. In order to offer optimal patient care, the practicing hematologist-oncologist must be well informed of these advances. To bridge the gap between research and patient care, this issue of *Cancer Conference Update* uses one-on-one discussions with hematologic oncology clinical investigators to provide perspectives on the integration of key data sets presented at the 2014 American Society of Hematology Annual Meeting into the practical management of various hematologic cancers and related blood disorders.

LEARNING OBJECTIVES

- Apply emerging clinical research data to the rational selection of treatment for patients with hematologic cancers.
- Appraise recent clinical trial data investigating the use of immune checkpoint inhibitors for patients with relapsed or refractory Hodgkin lymphoma.
- Develop an understanding of emerging efficacy and side-effect data with novel agents and combination regimens under evaluation for indolent and aggressive B- and T-cell non-Hodgkin lymphomas.
- Appreciate the recent FDA approvals of ibrutinib, idelalisib and obinutuzumab, and discern how these agents can be appropriately integrated into clinical practice for patients with chronic lymphocytic leukemia and other B-cell lymphomas.
- Compare and contrast the benefits and risks of approved first- and second-generation tyrosine kinase inhibitors as therapeutic options for patients with chronic myeloid leukemia.
- Recognize the potential role of novel agents and regimens in the management of newly diagnosed and relapsed/refractory acute myeloid leukemia and acute lymphoblastic leukemia.
- Evaluate recent clinical findings with the JAK2 inhibitor ruxolitinib for patients with myelofibrosis, polycythemia vera and essential thrombocythemia in order to inform patients about protocol and nonprotocol options.
- Integrate recent clinical research findings with proteasome inhibitors and immunomodulatory agents into the development of individualized treatment approaches for patients with multiple myeloma.

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FACULTY

Craig Moskowitz, MD
Clinical Director, Division of Hematologic Oncology
Attending Physician
Lymphoma and Adult BMT Services
Member, Memorial Sloan Kettering Cancer Center
Professor of Medicine
Weill Medical College of Cornell University
New York, New York

Jonathan W Friedberg, MD, MMSc
Samuel Durand Professor of Medicine
Director, Wilmot Cancer Center
University of Rochester
Rochester, New York

Stephen M Ansell, MD, PhD
Professor of Medicine
Division of Hematology
Mayo Clinic
Rochester, Minnesota

Mikkael A Sekeres, MD, MS
Professor of Medicine
Director, Leukemia Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

Ola Landgren, MD, PhD
Chief, Myeloma Service
Memorial Sloan Kettering Cancer Center
New York, New York

Jorge E Cortes, MD
DB Lane Cancer Research Distinguished Professor for Leukemia Research
Deputy Chairman
Section Chief of AML and CML
Department of Leukemia
The University of Texas MD Anderson Cancer Center
Houston, Texas

EDITOR

Neil Love, MD
Research To Practice
Miami, Florida

CONTENT VALIDATION AND DISCLOSURES

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HODGKIN LYMPHOMA, T-CELL LYMPHOMA — Craig Moskowitz, MD

Tracks 1-13

1 Abstract 289: A Phase I study of nivolumab in relapsed/refractory (R/R) Hodgkin lymphoma (HL)

2 Abstract 290: The Phase Ib KEYNOTE-013 trial of PD-1 blockade with pembrolizumab for patients with classical HL after disease progression on brentuximab vedotin

3 Antitumor activity of anti-PD-1 antibodies in HL

4 Abstract 291: A Phase I study of nivolumab for R/R lymphoid cancers

5 Abstract 292: Long-term outcomes of a Phase I study of brentuximab vedotin with ABVD or AVD for newly diagnosed advanced-stage HL

6 Abstract 4431: A Phase II trial of induction chemotherapy with ABVD followed by brentuximab vedotin consolidation in untreated nonbulky Stage I or II HL

7 Abstract 673: Results of the Phase III AETHERA trial of brentuximab vedotin after autologous stem cell transplant (ASCT)

8 Tolerability of brentuximab vedotin consolidation after ASCT in the AETHERA trial

9 Abstract 293: Brentuximab vedotin with bendamustine for R/R HL

10 Abstract 804: Results of a Phase II study of brentuximab vedotin in mycosis fungoides or Sézary syndrome

11 Abstract 803: Activity of the novel phosphoinositide-3-kinase-δ, γ inhibitor duvelisib in R/R T-cell lymphoma (TCL)

12 Abstract 3075: Belinostat for patients with R/R peripheral TCL (PTCL) and low baseline platelet counts

13 Abstract 504: Final analysis of the Phase Ib/II RO-CHOP study of romidepsin/CHOP in PTCL

NON-HODGKIN LYMPHOMA/CHRONIC LYMPHOCYTIC LEUKEMIA — Jonathan W Friedberg, MD, MMSc

Tracks 1-14

1 Abstract 1664: Event-free survival at 12 months from diagnosis as an endpoint for survival in follicular lymphoma (FL)

2 Abstract 799: Primary endpoint analysis of the Phase II SAKK 35/10 trial of rituximab/lenalidomide (R^2) in untreated FL

3 Abstract 4477: A Phase II study of R^2 in untreated indolent non-Hodgkin lymphoma (NHL)

4 Abstract 3091: Alliance A051201 and A051202 — Toxicities associated with the combination of idelalisib and R^2 in R/R B-cell lymphomas

5 Abstract 800: Preliminary results of a Phase II consortium trial evaluating ibrutinib monotherapy in R/R FL

6 Abstract 4458: A Phase Ib trial of obinutuzumab with lenalidomide for R/R FL

7 Abstract 1743: Final results from the maintenance phase of the Phase Ib GAUDI study — Obinutuzumab in combination with CHOP or bendamustine for untreated FL

8 Abstract 1722: Efficacy and safety of the BCL-2 inhibitor venetoclax (ABT-199) in combination with bendamustine and rituximab (BR) in R/R NHL

9 Abstract 19: CLL10 final analysis of front-line therapy with fludarabine, cyclophosphamide and rituximab (FCR) versus BR for advanced chronic lymphocytic leukemia (CLL)

10 Abstract 3327: The CLL11 study evaluating salvage therapy with obinutuzumab and chlorambucil (Clb) for patients with CLL and comorbidities

11 Abstract 3345: Preliminary safety results of the Phase IIIb GREEN study of obinutuzumab alone or in combination with chemotherapy for untreated or R/R CLL

12 Abstract 327: RESONATE-17 — Efficacy and safety of ibrutinib in R/R CLL or small lymphocytic leukemia with 17p deletion

13 Abstract 330: Second interim analysis of a Phase III study of idelalisib/rituximab for relapsed CLL with adverse cytogenetics

14 Abstract 325: Determination of the recommended Phase II dose of venetoclax/rituximab for R/R CLL

NON-HODGKIN LYMPHOMA/CHRONIC LYMPHOCYTIC LEUKEMIA — Stephen M Ansell, MD, PhD

Tracks 1-12

1 Abstract 20: Interim analysis of the AGMT-CLL8/a Mabtenance trial of rituximab maintenance after chemoimmunotherapy induction for CLL

2 Abstract 21: Interim analysis of the PROLONG study — Ofatumumab maintenance prolongs progression-free survival in relapsed CLL

3 Abstract 146: First interim analysis of the Phase III LyMa trial — Rituximab maintenance for young patients with newly diagnosed mantle-cell lymphoma (MCL)

4 Abstract 149: SWOG 0601 — A Phase II trial evaluating the efficacy of R-CHOP with bortezomib induction followed by bortezomib maintenance for newly diagnosed MCL

5 Abstract 625: Sustained remission with R^2 as initial treatment for MCL

6 Abstract 626: The Phase II MCL-002 SPRINT study of lenalidomide or investigator's choice for R/R MCL

7 Abstract 627: Efficacy and safety of ibrutinib/rituximab in relapsed MCL — Preliminary results from a Phase II trial

8 Abstract 391: Results of the Phase III PETAL trial of positron emission tomography-guided therapy for aggressive NHL

9 Abstract 393: Preliminary results of the Phase III 02-03 trial of R-CHOP with or without radiation therapy in nonbulky limited-stage diffuse large B-cell lymphoma (DLBCL)

10 Abstract 1745: Interim results from a Phase II study of brentuximab vedotin in combination with R-CHOP as front-line therapy for DLBCL

11 Abstract 628: A Phase II/III study evaluating the efficacy and safety of lenalidomide versus investigator's choice for R/R DLBCL

12 Abstract 4483: Analysis of a Phase I study of the novel Aurora A kinase inhibitor alisertib (MLN8237) in combination with vorinostat for patients with lymphoid cancers

ACUTE LEUKEMIAS AND MYELODYSPLASTIC SYNDROMES — Mikkael A Sekeres, MD, MS

Tracks 1-11

1 Abstract 6: The SORAML trial evaluating the addition of sorafenib to standard therapy in younger patients with newly diagnosed acute myeloid leukemia (AML)

2 Abstract 2299: Significant improvement in disease-free survival with azacitidine as postremission therapy for elderly patients with AML — Interim results of a Phase III trial

3 Abstract 118: A Phase II study evaluating the efficacy and safety of venetoclax in AML

4 Abstract 979: The novel polo-like kinase inhibitor volasertib overcomes cytarabine resistance in AML

5 Abstract 12: Updated results of the Phase III APL0406 trial — ATRA and arsenic trioxide versus ATRA and idarubicin-based chemotherapy for newly diagnosed nonhigh-risk acute promyelocytic leukemia

6 Abstract 409: A Phase III study evaluating lenalidomide versus placebo in red blood cell transfusion-dependent patients with low-/intermediate-risk myelodysplastic syndromes

7 Abstract 796: Early results of US Intergroup trial C10403 — Combination therapy for older adolescents and young adults with acute lymphoblastic leukemia (ALL)

8 Abstract 382: CD19-targeted CAR-modified T cells for adults with R/R B-cell ALL

9 Abstract 379: The Phase II BLAST study of blinatumomab for patients with minimal residual disease (MRD) B-precursor ALL

10 Abstract 3657: A Phase I/II trial of erwinia asparaginase with prednisolone/vincristine/pirarubicin for children and young adults with ALL or lymphoblastic lymphoma

11 Abstract 2294: Toxicity profile of repeated dosing of PEG-asparaginase in adults with ALL

MULTIPLE MYELOMA — Ola Landgren, MD, PhD

Tracks 1-12

1 Abstract 81: FIRST trial — Effect of age on the efficacy and safety of lenalidomide and low-dose dexamethasone (Rd) in newly diagnosed multiple myeloma (MM)

2 Abstract 2105: Assessment of MRD in patients with newly diagnosed MM treated with carfilzomib, lenalidomide and low-dose dexamethasone (CRd)

3 Abstract 175: A Phase I/II study of weekly carfilzomib, cyclophosphamide and dexamethasone in newly diagnosed MM

4 Abstract 2127: MRD predicts progression-free survival in patients with newly diagnosed MM treated with CRd

5 Abstract 79: Interim results of the Phase III ASPIRE study comparing CRd to Rd for patients with relapsed MM

6 Abstract 4748: Evaluation of the cardiovascular effect of carfilzomib in MM

7 Abstract 82: Efficacy and tolerability of long-term ixazomib maintenance after induction therapy with ixazomib, lenalidomide and dexamethasone in newly diagnosed MM

8 Abstracts 303 and 304: Studies evaluating pomalidomide-based triplet regimens for R/R MM

9 Abstract 176: A Phase Ib study of daratumumab in combination with backbone regimens for patients with MM

10 Abstract 84: Efficacy and safety of daratumumab in combination with lenalidomide and dexamethasone for R/R MM

11 Abstract 3465: Persistent benefit in overall survival in a Phase III trial evaluating Rd for patients with high-risk smoldering MM

12 Abstract 4746: Final results of the NCI Phase II pilot study of CRd for patients with high-risk smoldering MM

CHRONIC MYELOID LEUKEMIA AND MYELOFIBROSIS — Jorge E Cortes, MD

Tracks 1-13

1 Abstract 152: Final study results of the Phase III DASISION trial evaluating dasatinib versus imatinib for newly diagnosed chronic myeloid leukemia in chronic phase (CML-CP)

2 Incidence and management of dasatinib-associated pleural effusions

3 Abstract 519: Results of the Phase III EPIC trial — Efficacy and toxicity of ponatinib versus imatinib for newly diagnosed CML-CP

4 Abstract 811: Dasatinib or nilotinib discontinuation in patients with CML-CP with durably undetectable BCR-ABL transcripts — Interim analysis of the STOP 2G-TKI study

5 Abstract 151: EURO-SKI — Interim analysis of a pan-European stop tyrosine kinase inhibitor trial in CML

6 Abstract 633: Survival of allogeneic SCT versus conventional therapies for younger patients with primary myelofibrosis (MF)

7 Abstract 1851: Ruxolitinib prior to allogeneic SCT does not adversely affect post-transplant outcomes

8 Abstract 1857: Clinical outcomes for patients with low-risk MF receiving ruxolitinib

9 Abstract 709: Results of the RESPONSE trial evaluating changes in quality of life and disease-related symptoms for patients with polycythemia vera (PV) receiving ruxolitinib or best available therapy

10 Abstract 3168: RELIEF — Efficacy and safety of continued hydroxyurea versus switching to ruxolitinib for patients with PV

11 Abstract 3181: Clinical benefit of ruxolitinib after crossover from best available therapy for patients with PV in the RESPONSE trial

12 Clinical experience with ruxolitinib for patients with PV

13 Abstract 1847: Long-term results of a Phase II study of ruxolitinib for patients with essential thrombocythemia refractory or intolerant to hydroxyurea

SELECT PUBLICATIONS

Ansell SM et al. **PD-1 blockade with nivolumab in relapsed or refractory Hodgkin's lymphoma.** *N Engl J Med* 2015;372(4):311-9.

Bartlett NL et al. **Ibrutinib monotherapy in relapsed/refractory follicular lymphoma (FL): Preliminary results of a phase 2 consortium (P2C) trial.** *Proc ASH* 2014;**Abstract 800**.

Cortes J et al. **Final study results of the phase 3 dasatinib versus imatinib in newly diagnosed chronic myeloid leukemia in chronic phase (CML-CP) trial (DASISION, CA180-056).** *Proc ASH* 2014;**Abstract 152**.

Czuczman MS et al. **A phase 2/3 multicenter, randomized study comparing the efficacy and safety of lenalidomide versus investigator's choice in relapsed/refractory DLBCL.** *Proc ASH* 2014;**Abstract 628**.

Davis KL et al. **Real-world assessment of clinical outcomes in lower-risk myelofibrosis patients receiving treatment with ruxolitinib.** *Proc ASH* 2014;**Abstract 1857**.

Goede V et al. **Salvage therapy with obinutuzumab (GA101) plus chlorambucil (Clb) after treatment failure of Clb alone in patients with chronic lymphocytic leukemia (CLL) and comorbidities: Results of the CLL11 study.** *Proc ASH* 2014;**Abstract 3327**.

Kim YH et al. **Phase II investigator-initiated study of brentuximab vedotin in mycosis fungoides or Sezary syndrome: Final results show significant clinical activity and suggest correlation with CD30 expression.** *Proc ASH* 2014;**Abstract 804**.

Lamy T et al. **R-CHOP with or without radiotherapy in non-bulky limited-stage diffuse large B cell lymphoma (DLBCL): Preliminary results of the prospective randomized phase III 02-03 trial from the Lysa/GOELAMS group.** *Proc ASH* 2014;**Abstract 393**.

Le Gouill S et al. **Rituximab maintenance versus wait and watch after four courses of R-DHAP followed by autologous stem cell transplantation in previously untreated young patients with mantle cell lymphoma: First interim analysis of the phase III prospective Lyma trial, a Lysa study.** *Proc ASH* 2014;**Abstract 146**.

Lipton JH et al. **Epic: A phase 3 trial of ponatinib compared with imatinib in patients with newly diagnosed chronic myeloid leukemia in chronic phase (CP-CML).** *Proc ASH* 2014;**Abstract 519**.

Mateos MV et al. **Long term follow-up on the treatment of high risk smoldering myeloma with lenalidomide plus low dose dex (Rd) (phase III Spanish trial): Persistent benefit in overall survival.** *Proc ASH* 2014;**Abstract 3465**.

Maurer MJ et al. **Event-free survival at 12 months (EFS12) from diagnosis is a robust endpoint for disease-related survival in patients with follicular lymphoma in the immunochemotherapy era.** *Proc ASH* 2014;**Abstract 1664**.

Mesa R et al. **Changes in quality of life and disease-related symptoms in patients with polycythemia vera receiving ruxolitinib or best available therapy: RESPONSE trial results.** *Proc ASH* 2014;**Abstract 709**.

Moskowitz CH et al. **PD-1 blockade with the monoclonal antibody pembrolizumab (MK-3475) in patients with classical Hodgkin lymphoma after brentuximab vedotin failure: Preliminary results from a phase 1b study (KEYNOTE-013).** *Proc ASH* 2014;**Abstract 290**.

Moskowitz CH et al. **The AETHERA trial: Results of a randomized, double-blind, placebo-controlled phase 3 study of brentuximab vedotin in the treatment of patients at risk of progression following autologous stem cell transplant for Hodgkin lymphoma.** *Proc ASH* 2014;**Abstract 673**.

O'Brien S et al. **Efficacy and safety of ibrutinib in patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic leukemia with 17p deletion: Results from the phase II RESONATE-17 trial.** *Proc ASH* 2014;**Abstract 327**.

Rollig C et al. **Sorafenib versus placebo in addition to standard therapy in younger patients with newly diagnosed acute myeloid leukemia: Results from 267 patients treated in the randomized placebo-controlled SAL-Soraml trial.** *Proc ASH* 2014;**Abstract 6**.

Savage KJ et al. **Safe and effective treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) and low baseline platelet counts with belinostat.** *Proc ASH* 2014;**Abstract 3075**.

Smith SM et al. **Unexpected and serious toxicity observed with combined idelalisib, lenalidomide and rituximab in relapsed/refractory B cell lymphomas: Alliance A051201 and A051202.** *Proc ASH* 2014;**Abstract 3091**.

Stewart AK et al. **Carfilzomib, lenalidomide, and dexamethasone vs lenalidomide and dexamethasone in patients (pts) with relapsed multiple myeloma: Interim results from ASPIRE, a randomized, open-label, multicenter phase 3 study.** *Proc ASH* 2014;**Abstract 79**.

Wang M et al. **Ibrutinib and rituximab are an efficacious and safe combination in relapsed mantle cell lymphoma: Preliminary results from a phase II clinical trial.** *Proc ASH* 2014;**Abstract 627**.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **In the Phase III AETHERA trial evaluating brentuximab vedotin (BV) versus placebo after ASCT for patients with HL, the rate of 2-year progression-free survival with BV, the primary endpoint, was approximately _____.**
   a. 40%
   b. 65%
   c. 90%

2. **Which of the following was a key observation in the Phase I study of the anti-PD-1 antibody nivolumab for patients with heavily pretreated HL, most of whom had experienced disease progression on BV or after ASCT?**
   a. High incidence of immune-related adverse events
   b. High rate of drug-related treatment discontinuation
   c. Prolonged duration of response and stable disease

3. **In the Phase II SORAML trial, the sequential addition of sorafenib to standard chemotherapy for younger patients with newly diagnosed AML resulted in a significant improvement in the primary endpoint of event-free survival.**
   a. True
   b. False

4. **What were the results of the CLL10 study evaluating FCR versus bendamustine/rituximab (BR) for previously untreated CLL?**
   a. FCR was superior to BR for complete response (CR) rate and rate of MRD negativity
   b. BR was superior to FCR for CR rate and rate of MRD negativity
   c. FCR and BR were equivalent for CR rate and rate of MRD negativity, but FCR was associated with more toxicity

5. **Patients with PV in the RESPONSE study who crossed over from best available therapy to ruxolitinib experienced _____.**
   a. Reduced requirement for phlebotomy
   b. Reduction in spleen volume
   c. Improvement in overall survival
   d. Both a and b
   e. Both b and c

6. **Interim analysis of the Phase III ASPIRE trial assessing the efficacy of carfilzomib/lenalidomide/dexamethasone versus lenalidomide/dexamethasone for patients with relapsed MM demonstrated that the 3-drug combination was associated with _____.**
   a. A higher overall response rate
   b. Significantly more patients achieving a complete response
   c. A longer median progression-free survival
   d. All of the above

7. **A Phase Ib study of venetoclax (ABT-199) in combination with rituximab for patients with R/R CLL reported that the combination was highly active and that venetoclax was well tolerated.**
   a. True
   b. False

8. **The ongoing Phase III GALLIUM trial is evaluating the benefit of _____ versus rituximab in combination with chemotherapy followed by maintenance therapy for patients with untreated, advanced indolent NHL.**
   a. Ibrutinib
   b. Obinutuzumab
   c. Idelalisib

9. **A study investigating the safety and efficacy of belinostat for patients with R/R PTCL and low baseline platelet counts demonstrated that belinostat is suitable and could be safely used in this patient population.**
   a. True
   b. False

10. **The Phase III EPIC trial of ponatinib versus imatinib for patients with newly diagnosed CML-CP demonstrated _____.**
    a. That a significantly higher number of patients on the ponatinib arm achieved ≤10% BCR-ABL transcript levels at 3 months
    b. A higher rate of arterial thrombotic events on the imatinib arm
    c. Both a and b

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Cancer Conference Update — Issue 1, 2015

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
Responses with and tolerability of anti-PD-1 antibodies for patients with R/R HL	4 3 2 1	4 3 2 1
Results of the Phase III AETHERA trial of brentuximab vedotin after ASCT	4 3 2 1	4 3 2 1
Impact of data from the Phase III RESPONSE trial on the use of ruxolitinib for patients with PV	4 3 2 1	4 3 2 1
Implications of new ASH data sets for the role of maintenance therapy for patients with CLL	4 3 2 1	4 3 2 1
SORAML trial: Significant improvement in event-free and relapse-free survival with sorafenib versus placebo in addition to standard therapy in younger patients with newly diagnosed AML	4 3 2 1	4 3 2 1
Benefit in progression-free survival with CRd (carfilzomib, lenalidomide, dexamethasone) versus Rd in patients with relapsed MM in the ASPIRE trial	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).....

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:

- Apply emerging clinical research data to the rational selection of treatment for patients with hematologic cancers. . . . . 4 3 2 1 N/M N/A
- Appraise recent clinical trial data investigating the use of immune checkpoint inhibitors for patients with relapsed or refractory Hodgkin lymphoma. . . . . 4 3 2 1 N/M N/A
- Develop an understanding of emerging efficacy and side-effect data with novel agents and combination regimens under evaluation for indolent and aggressive B- and T-cell non-Hodgkin lymphomas. . . . . 4 3 2 1 N/M N/A
- Appreciate the recent FDA approvals of ibrutinib, idelalisib and obinutuzumab, and discern how these agents can be appropriately integrated into clinical practice for patients with chronic lymphocytic leukemia and other B-cell lymphomas. . . . . 4 3 2 1 N/M N/A
- Compare and contrast the benefits and risks of approved first- and second-generation tyrosine kinase inhibitors as therapeutic options for patients with chronic myeloid leukemia. . . 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:

- Recognize the potential role of novel agents and regimens in the management of newly diagnosed and relapsed/refractory acute myeloid leukemia and acute lymphoblastic leukemia. . . .4 3 2 1 N/M N/A
- Evaluate recent clinical findings with the JAK2 inhibitor ruxolitinib for patients with myelofibrosis, polycythemia vera and essential thrombocythemia in order to inform patients about protocol and nonprotocol options. . . . . .4 3 2 1 N/M N/A
- Integrate recent clinical research findings with proteasome inhibitors and immunomodulatory agents into the development of individualized treatment approaches for patients with multiple myeloma . . . . . .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: . . . . . .

As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

☐ Yes, I am willing to participate in a follow-up survey. ☐ No, I am not willing to participate in a follow-up survey.

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
Craig Moskowitz, MD	4 3 2 1	4 3 2 1
Jonathan W Friedberg, MD, MMSc	4 3 2 1	4 3 2 1
Stephen M Ansell, MD, PhD	4 3 2 1	4 3 2 1
Mikkael A Sekeres, MD, MS	4 3 2 1	4 3 2 1
Ola Landgren, MD, PhD	4 3 2 1	4 3 2 1
Jorge E Cortes, MD	4 3 2 1	4 3 2 1
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Cancer Conference Update

Neil Love, MD
Research To Practice
One Biscayne Tower
2 South Biscayne Boulevard, Suite 3600
Miami, FL 33131

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