

# Cancer Conference Update



Audio Reviews of 42 Presentations from the 2015 American Society of Hematology Annual Meeting in Orlando, Florida

## FACULTY INTERVIEWS

Noopur Raje, MD

Jeff Sharman, MD

Richard M Stone, MD

Michelle A Fanale, MD

## EDITOR

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## Cancer Conference Update

### A Continuing Medical Education Audio Series

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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 2015 American Society of Hematology Annual Meeting into the practical management of various hematologic cancers and related blood disorders.

#### LEARNING OBJECTIVES

- Recall new data with investigational agents demonstrating promising activity in hematologic cancers.
- Evaluate recent clinical findings with the JAK2 inhibitor ruxolitinib for patients with myelofibrosis and polycythemia vera in order to inform patients about protocol and clinical options.
- Recognize the recent FDA approvals of panobinostat, elotuzumab, daratumumab and ixazomib in multiple myeloma (MM), and effectively identify patients for whom treatment with these novel agents may be appropriate.
- Compare and contrast the benefits and risks of immunomodulatory agents, proteasome inhibitors or both as systemic treatment for active MM.
- Develop an understanding of the biologic rationale for and early efficacy and toxicity data with the use of immunotherapeutic approaches for patients with various lymphoma subtypes and MM.
- Appraise recent data on therapeutic advances and changing practice standards in MM, and integrate this information, as appropriate, into current clinical care.
- Develop an understanding of emerging efficacy and side-effect data with novel agents and combination regimens under evaluation for indolent and aggressive B-cell non-Hodgkin lymphomas.
- Recognize the potential role of novel agents and regimens in the management of newly diagnosed and relapsed/refractory acute and chronic leukemias.

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- Track 12** Abstract 471: Alliance 051103 — Rituximab/lenalidomide (R<sup>2</sup>) with ibrutinib for previously untreated follicular lymphoma

## Interview with Richard M Stone, MD

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- Track 6** Abstract 814: Brentuximab vedotin with R-CHOP as front-line therapy for intermediate- to high-risk DLBCL
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- Track 8** Abstract 518: Limitations of the Phase II SWOG-S1106 trial — R-hyper CVAD versus R/bendamustine → ASCT for patients with mantle-cell lymphoma

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Abbas Ali S et al. Remissions of multiple myeloma during a first-in-humans clinical trial of T cells expressing an anti-B-cell maturation antigen chimeric antigen receptor. *Proc ASH* 2015; **Abstract LBA-1**.

Altman JK et al. Antileukemic activity and tolerability of ASP2215 80mg and greater in FLT3 mutation-positive subjects with relapsed or refractory acute myeloid leukemia: Results from a phase 1/2, open-label, dose-escalation/dose-response study. *Proc ASH* 2015; **Abstract 321**.

Ansell S et al. Nivolumab in patients (pts) with relapsed or refractory classical Hodgkin lymphoma (R/R cHL): Clinical outcomes from extended follow-up of a phase 1 study (CA209-039). *Proc ASH* 2015; **Abstract 583**.

Armand P et al. PD-1 blockade with pembrolizumab in patients with classical Hodgkin lymphoma after brentuximab vedotin failure: Safety, efficacy, and biomarker assessment. *Proc ASH* 2015; **Abstract 584**.

Attal M et al. Autologous transplantation for multiple myeloma in the era of new drugs: A phase III study of the Intergroupe Francophone du Myelome (IFM/DFCI 2009 trial). *Proc ASH* 2015; **Abstract 391**.

Avet-Loiseau H et al. Evaluation of minimal residual disease (MRD) by next generation sequencing (NGS) is highly predictive of progression free survival in the IFM/DFCI 2009 trial. *Proc ASH* 2015; **Abstract 191**.

Badros AZ et al. A phase II study of anti PD-1 antibody pembrolizumab, pomalidomide and dexamethasone in patients with relapsed/refractory multiple myeloma (RRMM). *Proc ASH* 2015; **Abstract 506**.

Berenson J et al. Weekly carfilzomib with dexamethasone for patients with relapsed or refractory multiple myeloma: Updated results from the phase 1/2 study Champion-1 (NCT01677858). *Proc ASH* 2015; **Abstract 373**.

Byrd JC et al. Acalabrutinib (ACP-196) in relapsed chronic lymphocytic leukemia. *N Engl J Med* 2016;374(4):323-32.

Chari A et al. Open-label, multicenter, phase 1b study of daratumumab in combination with pomalidomide and dexamethasone in patients with at least 2 lines of prior therapy and relapsed or relapsed and refractory multiple myeloma. *Proc ASH* 2015; **Abstract 508**.

DeAngelo DJ et al. A multicenter phase II study using a dose intensified pegylated-asparaginase pediatric regimen in adults with untreated acute lymphoblastic leukemia: A DFCI ALL Consortium trial. *Proc ASH* 2015; **Abstract 80**.

Dimopoulos MA et al. Eloquent-2 update: A phase 3, randomized, open-label study of elotuzumab in combination with lenalidomide/dexamethasone in patients with relapsed/refractory multiple myeloma — 3-year safety and efficacy follow-up. *Proc ASH* 2015; **Abstract 28**.

Dimopoulos MA et al. Randomized phase 2 study of the all-oral combination of investigational proteasome inhibitor (PI) ixazomib plus cyclophosphamide and low-dose dexamethasone (ICd) in patients (pts) with newly diagnosed multiple myeloma (NDMM) who are transplant-ineligible (NCT02046070). *Proc ASH* 2015; **Abstract 26**.

Durie B et al. Bortezomib, lenalidomide and dexamethasone vs lenalidomide and dexamethasone in patients (pts) with previously untreated multiple myeloma without an intent for immediate autologous stem cell transplant (ASCT): Results of the randomized phase III trial SWOG S0777. *Proc ASH* 2015; **Abstract 25**.

Etienne G et al. Long-term follow-up of the French 1 Stop Imatinib study (STIM1) in chronic myeloid leukemia patients. *Proc ASH* 2015; **Abstract 345**.

Flinn IW et al. Safety and efficacy of a combination of venetoclax (GDC-0199/ABT-199) and obinutuzumab in patients with relapsed/refractory or previously untreated chronic lymphocytic leukemia — Results from a phase 1b study (GP28331). *Proc ASH* 2015; **Abstract 494**.

Fowler N et al. Ibrutinib plus rituximab in treatment-naïve patients with follicular lymphoma: Results from a multicenter, phase 2 study. *Proc ASH* 2015; **Abstract 470**.

Giagounidis A et al. Luspatercept treatment leads to long term increases in hemoglobin and reductions in transfusion burden in patients with low or intermediate-1 risk myelodysplastic syndromes (MDS): Preliminary results from the phase 2 PACE-MDS extension study. *Proc ASH* 2015; **Abstract 92**.

Giles FJ et al. Impact of age on efficacy and toxicity of nilotinib in patients with chronic myeloid leukemia in chronic phase (CML-CP): ENEST1st sub-analysis. *Proc ASH* 2015; **Abstract 479**.

Harrison CN et al. Long-term efficacy and safety in COMFORT-II, a phase 3 study comparing ruxolitinib with best available therapy for the treatment of myelofibrosis: 5-year final study results. *Proc ASH* 2015; **Abstract 59**.

Hughes TP et al. Dose-optimized nilotinib (NIL) in patients (pts) with newly diagnosed chronic myeloid leukemia in chronic phase (CML-CP): Final results from ENESTxtnd study. *Proc ASH* 2015;**Abstract 344**.

Johnston PB et al. Everolimus plus RCHOP-21 is safe and highly effective for new untreated diffuse large B-cell lymphoma (DLBCL): Results of the phase I trial NCCTG1085 (Alliance). *Proc ASH* 2015;**Abstract 813**.

Moreau P et al. Ixazomib, an investigational oral proteasome inhibitor (PI), in combination with lenalidomide and dexamethasone (IRd), significantly extends progression-free survival (PFS) for patients (pts) with relapsed and/or refractory multiple myeloma (RRMM): The phase 3 Tourmaline-MM1 study (NCT01564537). *Proc ASH* 2015;**Abstract 727**.

Moskowitz CH et al. A phase 1 study of denintuzumab mafodotin (SGN-CD19A) in relapsed/refractory B-lineage non-Hodgkin lymphoma. *Proc ASH* 2015;**Abstract 182**.

Oliva EN et al. Eltrombopag for the treatment of thrombocytopenia of low and intermediate-1 IPSS risk myelodysplastic syndromes: Interim results on efficacy, safety and quality of life of an international, multicenter prospective, randomized, trial. *Proc ASH* 2015;**Abstract 91**.

Palumbo A et al. Elotuzumab plus bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed/refractory multiple myeloma: 2-year follow-up. *Proc ASH* 2015;**Abstract 510**.

Salles GA et al. Updated safety and preliminary efficacy data from a phase 1b study combining venetoclax (GDC-0199, ABT-199) with bendamustine/rituximab in patients with relapsed/refractory or previously untreated chronic lymphocytic leukemia. *Proc ASH* 2015;**Abstract 829**.

San Miguel J et al. Pembrolizumab in combination with lenalidomide and low-dose dexamethasone for relapsed/refractory multiple myeloma (RRMM): Keynote-023. *Proc ASH* 2015;**Abstract 505**.

Sawas A et al. The combination of brentuximab vedotin (Bv) and bendamustine (B) demonstrates marked activity in heavily treated patients with relapsed or refractory Hodgkin lymphoma (HL) and anaplastic large T-cell lymphoma (ALCL): Results of an international multi center phase I/II experience. *Proc ASH* 2015;**Abstract 586**.

Sekeres MA et al. Additional analyses of a randomized phase II study of azacitidine combined with lenalidomide or with vorinostat vs azacitidine monotherapy in higher-risk myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML): North American Intergroup study SWOG S1117. *Proc ASH* 2015;**Abstract 908**.

Shah JJ et al. Oprozomib, pomalidomide, and dexamethasone (OPomd) in patients (pts) with relapsed and/or refractory multiple myeloma (RRMM): Initial results of a phase 1b study (NCT01999335). *Proc ASH* 2015;**Abstract 378**.

Shah JJ et al. Phase I/II trial of the efficacy and safety of combination therapy with lenalidomide/bortezomib/dexamethasone (RVD) and panobinostat in transplant-eligible patients with newly diagnosed multiple myeloma. *Proc ASH* 2015;**Abstract 187**.

Stein EM et al. Safety and efficacy of AG-221, a potent inhibitor of mutant IDH2 that promotes differentiation of myeloid cells in patients with advanced hematologic malignancies: Results of a phase 1/2 trial. *Proc ASH* 2015;**Abstract 323**.

Stilgenbauer S et al. Venetoclax (ABT-199/GDC-0199) monotherapy induces deep remissions, including complete remission and undetectable MRD, in ultra-high risk relapsed/refractory chronic lymphocytic leukemia with 17p deletion: Results of the pivotal international phase 2 study. *Proc ASH* 2015;**Abstract LBA-6**.

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 (mut): An international prospective randomized (rand) P-controlled double-blind trial (CALGB 10603/RATIFY [Alliance]). *Proc ASH* 2015;**Abstract 6**.

Tedeschi A et al. Results from the international, randomized phase 3 study of ibrutinib versus chlorambucil in patients 65 years and older with treatment-naïve CLL/SLL (RESONATE-2™). *Proc ASH* 2015;**Abstract 495**.

Ujjani CS et al. Phase I study of rituximab, lenalidomide, and ibrutinib in previously untreated follicular lymphoma (Alliance 051103). *Proc ASH* 2015;**Abstract 471**.

Usmani S et al. Clinical efficacy of daratumumab monotherapy in patients with heavily pretreated relapsed or refractory multiple myeloma. *Proc ASH* 2015;**Abstract 29**.

Vannucchi AM et al. Analysis of outcomes by patient subgroups in patients with myelofibrosis treated with pacritinib vs best available therapy (BAT) in the phase III Persist-1 trial. *Proc ASH* 2015;**Abstract 58**.

Verstovsek S et al. PRM-151 in myelofibrosis: Durable efficacy and safety at 72 weeks. *Proc ASH* 2015;**Abstract 56**.

## QUESTIONS (PLEASE CIRCLE ANSWER):

- 1. A study analyzing the predictive value of MRD in a subset of patients on the IFM/DFCI 2009 trial demonstrated that MRD negativity from testing by next-generation sequencing was highly predictive of PFS.**
  - a. True
  - b. False
- 2. The SWOG-S0777 trial evaluating Rvd versus Rd for previously untreated MM without an intent for immediate ASCT demonstrated statistically significant improvement(s) in \_\_\_\_\_ for patients who received Rvd.**
  - a. Median PFS
  - b. Median overall survival
  - c. Both a and b
  - d. Neither a nor b
- 3. The results of the Phase III TOURMALINE-MM1 trial of lenalidomide and dexamethasone with or without ixazomib for patients with relapsed/refractory MM failed to demonstrate a statistically significant improvement in PFS with the addition of ixazomib.**
  - a. True
  - b. False
- 4. \_\_\_\_\_ is a monoclonal antibody with single-agent activity that recently received FDA approval as treatment for patients with MM who have received at least 3 prior lines of therapy.**
  - a. Elotuzumab
  - b. Daratumumab
  - c. Ixazomib
- 5. The results of the Phase III RESONATE-2 trial evaluating ibrutinib versus chlorambucil for patients age 65 years or older with untreated CLL/small lymphocytic lymphoma without 17p deletion demonstrated that single-agent ibrutinib is superior to chlorambucil in terms of \_\_\_\_\_.**
  - a. PFS
  - b. Overall survival
  - c. Both a and b
  - d. Neither a nor b
- 6. A study by Byrd and colleagues evaluating the BTK inhibitor acalabrutinib (ACP-196) demonstrated \_\_\_\_\_ for patients with relapsed/refractory CLL.**
  - a. A high response rate and durable remissions
  - b. A high incidence of bleeding and atrial fibrillation
  - c. A favorable safety profile
  - d. Both a and b
  - e. Both a and c
- 7. A Phase II study evaluating venetoclax monotherapy for patients with relapsed/refractory CLL and del(17p) demonstrated an overall response rate of approximately \_\_\_\_\_ and undetectable MRD in some responders.**
  - a. 20%
  - b. 40%
  - c. 80%
- 8. The Phase III CALGB-10603 (RATIFY) trial evaluating midostaurin in combination with daunorubicin/cytarabine induction therapy and high-dose cytarabine consolidation and as maintenance therapy for patients with newly diagnosed AML with FLT3 mutations demonstrated improvements in overall survival for which of the following patient groups?**
  - a. Those with FLT3-TKD point mutations
  - b. Those with FLT3-ITD-low allelic burden
  - c. Those with FLT3-ITD-high allelic burden
  - d. All of the above
- 9. Patients with MF must harbor a JAK mutation in order to experience a response to ruxolitinib.**
  - a. True
  - b. False
- 10. Which of the following results best characterizes the activity of anti-PD-1 checkpoint inhibitors (eg, nivolumab, pembrolizumab) compared to brentuximab vedotin for Hodgkin lymphoma?**
  - a. Higher rates of complete remission
  - b. Longer duration of response
  - c. Both a and b



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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

	<b>BEFORE</b>	<b>AFTER</b>
Implications of emerging Phase III data sets (eg, IFM/DFCI 2009, SWOG-S0777) on the selection of induction regimen for patients with MM	4 3 2 1	4 3 2 1
Responses with and tolerability of anti-PD-1 antibodies for patients with various lymphoma subtypes and MM	4 3 2 1	4 3 2 1
Activity of novel agents (eg, midostaurin, gilteritinib [ASP2215], AG-221) for patients with AML	4 3 2 1	4 3 2 1
Approaches to mitigation of venetoclax-associated tumor lysis syndrome	4 3 2 1	4 3 2 1
Considerations for ibrutinib as up-front treatment for patients with CLL	4 3 2 1	4 3 2 1
Efficacy of brentuximab vedotin-based treatment strategies for DLBCL, HL and anaplastic large T-cell lymphoma	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:**

- Recall new data with investigational agents demonstrating promising activity in hematologic cancers..... 4 3 2 1 N/M N/A
- Evaluate recent clinical findings with the JAK2 inhibitor ruxolitinib for patients with myelofibrosis and polycythemia vera in order to inform patients about protocol and clinical options. .... 4 3 2 1 N/M N/A
- Recognize the recent FDA approvals of panobinostat, elotuzumab, daratumumab and ixazomib in multiple myeloma (MM), and effectively identify patients for whom treatment with these novel agents may be appropriate. .... 4 3 2 1 N/M N/A
- Compare and contrast the benefits and risks of immunomodulatory agents, proteasome inhibitors or both as systemic treatment for active MM ..... 4 3 2 1 N/M N/A
- Develop an understanding of the biologic rationale for and early efficacy and toxicity data with the use of immunotherapeutic approaches for patients with various lymphoma subtypes and MM..... 4 3 2 1 N/M N/A
- Appraise recent data on therapeutic advances and changing practice standards in MM, and integrate this information, as appropriate, into current clinical care. .... 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:**

- Develop an understanding of emerging efficacy and side-effect data with novel agents and combination regimens under evaluation for indolent and aggressive B-cell non-Hodgkin lymphomas. . . . . 4 3 2 1 N/M N/A
- Recognize the potential role of novel agents and regimens in the management of newly diagnosed and relapsed/refractory acute and chronic leukemias. . . . . 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								
<b>Faculty</b>					<b>Knowledge of subject matter</b>					<b>Effectiveness as an educator</b>		
Noopur Rajee, MD	4	3	2	1	4	3	2	1	4	3	2	1
Jeff Sharman, MD	4	3	2	1	4	3	2	1	4	3	2	1
Richard M Stone, MD	4	3	2	1	4	3	2	1	4	3	2	1
Michelle A Fanale, MD	4	3	2	1	4	3	2	1	4	3	2	1
<b>Editor</b>					<b>Knowledge of subject matter</b>					<b>Effectiveness as an educator</b>		
Neil Love, MD	4	3	2	1	4	3	2	1	4	3	2	1

**REQUEST FOR CREDIT — Please print clearly**

Name:..... Specialty:.....

Professional Designation:  
 MD     DO     PharmD     NP     RN     PA     Other .....

Street Address:..... Box/Suite:.....

City, State, Zip:.....

Telephone:..... Fax:.....

Email: .....

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**I certify my actual time spent to complete this educational activity to be \_\_\_\_\_ hour(s).**

Signature:..... Date:.....

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**Additional information for MOC credit (required):**

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QID 1561

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# Cancer Conference Update

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