Cancer Conference Update



Audio Reviews of Key Presentations from the 2016 American Society of Hematology Annual Meeting in San Diego, California

FACULTY INTERVIEWS

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From the publishers of:













Cancer Conference Update

A Continuing Medical Education Audio Series

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 2016 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.
- Appraise recent data on therapeutic advances and changing practice standards in multiple myeloma (MM), and integrate this
 information, as appropriate, into current clinical care.
- Evaluate new approaches to the treatment of AL amyloidosis, and consider promising investigational agents that may be
 available and appropriate for patients in ongoing clinical trials.
- 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.
- Translate an understanding of the emerging efficacy and side-effect data with novel agents and combination regimens into treatment planning for patients with indolent and aggressive B-cell non-Hodgkin lymphomas.
- Formulate an approach incorporating brentuximab vedotin and anti-PD-1/anti-PD-L1 antibodies alone or in combination regimens for the treatment of Hodgkin lymphoma.
- Assess emerging high-level evidence supporting the use of maintenance lenalidomide in the treatment of chronic lymphocytic leukemia.
- Recognize the potential role of novel agents and regimens in the management of newly diagnosed and relapsed/refractory
 acute and chronic leukemias and myelodysplastic syndromes.
- Examine therapeutic strategies under investigation for the treatment of myelofibrosis to inform patients about protocol and clinical options.

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CME INFORMATION

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: Dr Mikhael — Contracted Research: AbbVie Inc, Celgene Corporation, Sanofi Genzyme. Dr Flowers — Consulting Agreements: Celgene Corporation, OptumRx Inc; Contracted Research: Acerta Pharma, Celgene Corporation, Gilead Sciences Inc, Infinity Pharmaceuticals Inc, Janssen Biotech Inc, Onyx Pharmaceuticals, an Amgen subsidiary, Pharmacyclics LLC, an AbbVie Company, Takeda Oncology, TG Therapeutics Inc; Unpaid Consulting Agreements: Genentech BioOncology, Takeda Oncology. Dr Steensma — Consulting Agreements: Akebia Therapeutics, Amgen Inc, Celgene Corporation, Janssen Biotech Inc, Takeda Oncology.

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Interview with Joseph Mikhael, MD, MEd — Multiple Myeloma

Tracks 1-15

- Track 1 Abstract LBA-1: StaMINA trial —
 Comparison of autologous hematopoietic
 cell transplant (auto-HCT), bortezomib,
 lenalidomide and dexamethasone consolidation with lenalidomide maintenance
 versus tandem auto-HCT with lenalidomide maintenance versus auto-HCT
 with lenalidomide maintenance for
 up-front treatment of multiple myeloma
 (MM)
- Track 2 Abstract 674: Intergroupe Francophone du Myélome (IFM) Phase II study of the all-oral ixazomib/lenalidomide/dexamethasone (IRd) regimen before and after autologous stem cell transplantation (ASCT) followed by ixazomib maintenance in patients with newly diagnosed MM (NDMM)
- Track 3 Abstract 1142: IFM Phase II study of front-line therapy with carfilzomib, lenalidomide and dexamethasone (KRd) induction followed by ASCT, KRd consolidation and lenalidomide maintenance in NDMM
- Track 4 ENDURANCE: An ongoing Phase III study of RVd versus KRd followed by limited or indefinite lenalidomide maintenance in NDMM
- **Track 5** Perspective on trials adding daratumumab to front-line therapy regimens
- Track 6 Abstract 1149: PAVO multicenter, dose-escalation Phase Ib study of subcutaneous daratumumab in patients with relapsed or refractory MM (RRMM)

- Track 7 Abstract 1145: A multicenter, Phase I/II study of carfilzomib, pomalidomide and dexamethasone in patients with RRMM
- Track 8 Abstract 490: Pembrolizumab in combination with pomalidomide and dexamethasone for RRMM
- Track 9 Abstracts 488, 975: Venetoclax as monotherapy or in combination with bortezomib/dexamethasone for RRMM
- Track 10 Low rates of tumor lysis syndrome observed in patients with MM receiving venetoclax
- Track 11 Abstract 978: Results of the MYRE study comparing intensive hemodialysis with high-cutoff or standard high-flux dialyzer for myeloma cast nephropathy in patients receiving a bortezomib-based regimen
- Track 12 Abstract 976: A Phase II trial of elotuzumab, lenalidomide and dexamethasone in high-risk smoldering MM
- Track 13 Abstract 646: A Phase III trial of melphalan and dexamethasone versus bortezomib, melphalan and dexamethasone for untreated immunoglobulin light chain (AL) amyloidosis
- Track 14 Abstracts 643, 644: Monoclonal antibodies 11-1F4 and NEOD001 targeting light chain deposits in patients with AL amyloidosis
- Track 15 Abstract 4525: Hematologic responses and cardiac organ improvement in patients with heavily pretreated cardiac AL amyloidosis receiving daratumumab

Interview with Christopher Flowers, MD, MS — Lymphomas/Chronic Lymphocytic Leukemia (CLL)

Tracks 1-14

- Track 1 Abstract 6: Primary results of the Phase III GALLIUM study Obinutuzumab-based induction and maintenance therapy prolongs progression-free survival (PFS) for patients with previously untreated follicular lymphoma (FL)
- Track 2 Abstract 104: Brentuximab vedotin with R-CHP as front-line therapy in high-intermediate/high-risk diffuse large B-cell lymphoma (DLBCL)
- Track 3 Abstract 470: Final results of the Phase III GOYA study evaluating obinutuzumab or rituximab with CHOP in patients with previously untreated DLBCL

- Track 4 Abstracts 471, 474: Maintenance lenalidomide in patients with DLBCL
- Track 5 Clinical development of the antibodydrug conjugate denintuzumab mafodotin in combination with chemotherapy for patients with CD19-positive DLBCL
- Track 6 Abstract 619: Results from KEYNOTE-013 A Phase Ib study of pembrolizumab in relapsed/refractory primary mediastinal large B-cell lymphoma
- Track 7 Abstract 145: Final results of the Phase III LyMa study of rituximab maintenance after ASCT in younger patients with mantle cell lymphoma

Interview with Dr Flowers (continued)

- Track 8 Abstract 182: Phase III ALCANZA study

 Brentuximab vedotin demonstrates
 superior clinical outcomes compared
 to methotrexate or bexarotene in
 CD30-expressing cutaneous T-cell
 lymphoma
- Track 9 Abstract 1105: Brentuximab vedotin in combination with nivolumab for patients with relapsed or refractory Hodgkin lymphoma (HL)
- Track 10 Abstract 1106: Preliminary results from ECOG-ACRIN-E4412 (arms D and E) evaluating ipilimumab, nivolumab and brentuximab vedotin in relapsed/refractory HL
- Track 11 Abstracts 229, 230: Maintenance lenalidomide in the first-line (CLL M1 study) and second-line (CONTINUUM) settings in CLL
- Track 12 Abstract 637: Venetoclax monotherapy for patients with CLL and disease progression during or after treatment with ibrutinib or idelalisib
- Track 13 Abstract 231: Overall survival (OS) advantage in a Phase III study evaluating the addition of idelalisib to bendamustine/ rituximab in patients with relapsed/ refractory CLL
- Track 14 Incorporation of idelalisib into the clinical treatment algorithms for CLL and FL

Interview with David P Steensma, MD — Acute Myeloid Leukemia (AML), Myelodysplastic Syndromes (MDS) and Myeloproliferative Neoplasms

Tracks 1-18

- Track 1 Abstract 102: Venetoclax and low-dose cytarabine in patients age 65 or older with treatment-naïve AML
- Track 2 Abstract 449: Interim analyses of AMLSG 16-10 Effect of age and midostaurin dose on response and outcome for patients with AML with FLT3-ITD mutations
- Track 3 Clinically relevant molecular profiling in patients with AML
- Track 4 Abstract 1069: Final results of CHRYSALIS A first-in-human Phase I/II study of the oral FLT3/AXL inhibitor gilteritinib (ASP2215) in relapsed/refractory AML
- Track 5 Abstract 590: Antibody-drug conjugate vadastuximab talirine monotherapy in older patients with treatment-naïve CD33-positive AML
- Track 6 Abstract 591: A Phase I study of vadastuximab talirine with hypomethylating agents (HMAs) as front-line therapy for older patients with AML
- Track 7 Abstract 763: Rationale for and results of a Phase Ib/II study of azacitidine and nivolumab for relapsed AML
- Track 8 Abstract 905: CC-486 (oral azacitidine) in patients with hematologic cancers who received prior treatment with injectable hypomethylating agents
- Track 9 Abstract 1070: Isocitrate dehydrogenase 1 (IDH1) mutational burden and clearance in patients with IDH1 mutation-

- positive acute leukemias receiving the first-in-class inhibitor of IDH1 AG-120
- Track 10 Abstracts 223, 224: Lenalidomide with or without epoetin alfa in patients with MDS
- Track 11 Incorporation of lenalidomide into the clinical algorithm for patients with MDS with and without del(5q)
- Track 12 Abstract 343: Enasidenib (AG-221), a potent oral inhibitor of mutant IDH2 enzyme, induces hematologic responses in MDS
- Track 13 Abstract 344: Outcomes of a Phase II study evaluating nivolumab or ipilimumab and azacitidine as front-line therapy for MDS in patients after progression on a hypomethylating agent
- Track 14 Abstract 52: Longitudinal tracking of patients with MDS using next-generation sequencing as a predictive measure for azacitidine response
- Track 15 Abstract 478: A Phase II study of sotatercept (ACE-011) in myeloproliferative neoplasm-associated myelofibrosis (MF) and anemia
- Track 16 Abstract 1127: Ruxolitinib in combination with azacitidine as treatment for MF
- Track 17 Clinical development of other JAK2 inhibitors beyond ruxolitinib for the treatment of MF
- Track 18 Current investigational strategies in MF

SELECT PUBLICATIONS

Badros AZ et al. Pembrolizumab in combination with pomalidomide and dexamethasone for relapsed/refractory multiple myeloma (RRMM). Proc ASH 2016; Abstract 490.

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Foa R et al. Results of the Phase 3 study of lenalidomide versus placebo as maintenance therapy following second-line treatment for patients with chronic lymphocytic leukemia (the CONTINUUM trial). Proc ASH 2016; Abstract 230.

Garcia-Manero G et al. A Phase II study evaluating the combination of nivolumab (nivo) or ipilimumab (ipi) with azacitidine in pts with previously treated or untreated myelodysplastic syndromes (MDS). Proc ASH 2016; Abstract 344.

Garcia-Manero G et al. CC-486 (oral azacitidine) in patients with hematological malignancies who had received prior treatment with injectable hypomethylating agents (HMAs): Results from Phase 1/2 CC-486 studies. Proc ASH 2016; Abstract 905.

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Kaufman G et al. Hematologic responses and cardiac organ improvement in patients with heavily pretreated cardiac immunoglobulin light chain (AL) amyloidosis receiving daratumumab. *Proc ASH* 2016; Abstract 4525.

Kim T et al. Longitudinal tracking of MDS patients using next generation sequencing provides a predictive measure for azacitidine response and AML progression. Proc ASH 2016; Abstract 52.

Kim YH et al. Brentuximab vedotin demonstrates significantly superior clinical outcomes in patients with CD30-expressing cutaneous T cell lymphoma versus physician's choice (methotrexate or bexarotene): The Phase 3 Alcanza study. Proc ASH 2016; Abstract 182.

Kumar S et al. Venetoclax monotherapy for relapsed/refractory multiple myeloma: Safety and efficacy results from a Phase I study. *Proc ASH* 2016; Abstract 488.

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Marcus RE et al. Obinutuzumab-based induction and maintenance prolongs progression-free survival (PFS) in patients with previously untreated follicular lymphoma: Primary results of the randomized Phase 3 GALLIUM study. Proc ASH 2016; Abstract 6.

Moreau P et al. Ixazomib-lenalidomide-dexamethasone (IRd) combination before and after autologous stem cell transplantation (ASCT) followed by ixazomib maintenance in patients with newly diagnosed multiple myeloma (NDMM): A Phase 2 study from the Intergroupe Francophone Du MyeLome (IFM). Proc ASH 2016; Abstract 674.

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Usmani SZ et al. Open-label, multicenter, dose escalation Phase 1b study to assess the subcutaneous delivery of daratumumab in patients (pts) with relapsed or refractory multiple myeloma (PAVO). *Proc ASH* 2016; Abstract 1149.

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Vitolo U et al. Obinutuzumab or rituximab plus CHOP in patients with previously untreated diffuse large B-cell lymphoma: Final results from an open-label, randomized Phase 3 study (GOYA). Proc ASH 2016; Abstract 470.

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Zelenetz AD et al. Updated analysis of overall survival in randomized Phase III study of idelalisib in combination with bendamustine and rituximab in patients with relapsed/refractory CLL. Proc ASH 2016; Abstract 231.

Zinzani PL et al. Phase 1b study of pembrolizumab in patients with relapsed/refractory primary mediastinal large B-cell lymphoma: Results from the ongoing Keynote-013 trial. Proc ASH 2016; Abstract 619.

POST-TEST

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QUESTIONS (PLEASE CIRCLE ANSWER):

- Which of the following was demonstrated in the Phase III StaMINA trial evaluating transplant with RVD consolidation and lenalidomide maintenance versus tandem transplant and lenalidomide maintenance versus single transplant with lenalidomide maintenance?
 - a. Comparable PFS and OS for the 3 arms
 - b. Survival advantage with the addition of consolidation and maintenance treatment
 - c. Survival advantage for tandem transplant
 - d. None of the above
- 2. Which of the following has been observed regarding the gastrointestinal (GI) side effects associated with ixazomib?
 - a. GI side effects tend to occur later in the course of therapy as a cumulative effect of treatment
 - b. GI side effects tend to occur early during the first 3 weeks of treatment
 - c. GI side effects are rarely observed
- 3. Which of the following has been observed with venetoclax in patients with RRMM?
 - a. A low objective response rate
 - b. A high objective response rate
 - c. An objective response rate of 40% to 50% in patients with translocation 11;14
- 4. The addition of bortezomib to up-front treatment with melphalan/dexamethasone in patients with AL amyloidosis results in improved hematologic and organ responses, and bortezomib-containing regimens are a new standard therapy in this setting.
 - a. True
 - b. False
- 5. Which of the following was observed in the Phase III GALLIUM study evaluating obinutuzumab- versus rituximab-based induction and maintenance therapy in patients with previously untreated FL?
 - a. No difference in PFS
 - b. PFS favored rituximab
 - c. PFS favored obinutuzumab

- In elderly patients with DLBCL responding to R-CHOP, the addition of lenalidomide maintenance compared to observation resulted in
 - a. A deleterious effect on PFS
 - b. An improvement in PFS
 - c. No effect on PFS
- Which of the following was observed in a Phase III trial evaluating the addition of idelalisib to bendamustine/rituximab for patients with relapsed/refractory CLL?
 - a. Improvement in OS with idelalisib
 - b. Increased number of opportunistic infections with idelalisib
 - c. The study was closed early due to idelalisib-associated severe toxicity
 - d. Both a and b
 - e. Both b and c
- 8. Vadastuximab talirine is an ____
 - a. Anti-CD30 monoclonal antibody under investigation in HL
 - b. Anti-CD33 antibody-drug conjugate under investigation in AML and MDS
 - c. Anti-CD22 antibody-drug conjugate under investigation in acute lymphoblastic leukemia and CML
- 9. Approximately what percent of patients with MDS or AML who were refractory to prior hypomethylating agents (azacitidine or decitabine) responded to CC-486 (oral azacitidine)?
 - a. Less than 10%
 - b. 20%
 - c. 40%
- Mutations in the isocitrate dehydrogenase (IDH) genes IDH1 and IDH2 occur in approximately 25% to 30% of patients with AML and represent actionable targets for treatment.
 - a. True
 - b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

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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 $3 = Good$ $2 = Ad$	equate 1 :	= Suboptim
	BEFORE	AFTER
Efficacy of venetoclax alone and in combination with bortezomib/dexamethasone for patients with MM and specific genetic abnormalities	4 3 2 1	4 3 2 1
IFM study of the feasibility of the all-oral ixazomib/lenalidomide/dexamethasone regimen before and after ASCT followed by ixazomib maintenance therapy in NDMM	4 3 2 1	4 3 2 1
GALLIUM study: Efficacy and side effects of obinutuzumab- versus rituximab-based induction and maintenance therapy for patients with previously untreated FL	4 3 2 1	4 3 2 1
Activity and side effects of brentuximab vedotin in combination with R-CHP as front-line therapy in patients with CD30-positive and CD30-negative DLBCL	4 3 2 1	4 3 2 1
PFS benefit of maintenance lenalidomide in patients with DLBCL who are elderly and/or transplant ineligible	4 3 2 1	4 3 2 1
Mechanism of action of vadastuximab talirine and its efficacy and side effects when administered alone or in combination with hypomethylating agents in AML	4 3 2 1	4 3 2 1
Pyes No If no, please explain: Lease identify how you will change your practice as a result of completing this act 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): you intend to implement any changes in your practice, please provide 1 or more	ivity (select all	that apply
ne content of this activity matched my current (or potential) scope of practice. Yes No If no. please explain:		
ease respond to the following learning objectives (LOs) by circling the appropriate		
4 = Yes $3 = Will consider$ $2 = No$ $1 = Already doing$ $N/M = LO$ not met		plicable
s a result of this activity, I will be able to: Recall new data with investigational agents demonstrating promising activity in hematologic cancers.	4 3	
Appraise recent data on therapeutic advances and changing practice standards in might myeloma (MM), and integrate this information, as appropriate, into current clinical car Evaluate new approaches to the treatment of AL amyloidosis, and consider promising	e 4 3 :	2 1 N/M I
investigational agents that may be available and appropriate for patients in ongoing clinical trials.		2 1 N/M I
Develop an understanding of the biologic rationale for and early efficacy and toxicity data with the use of immunotherapeutic approaches for patients with various lymphor subtypes and MM.		2 1 N/M
Translate an understanding of the emerging efficacy and side-effect data with novel agents and combination regimens into treatment planning for patients with indolent		
and aggressive B-cell non-Hodgkin lymphomas	4 3 :	2 1 N/M I

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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

- Formulate an approach incorporating brentuximab vedotin and anti-PD-1/anti-PD-L1
- Assess emerging high-level evidence supporting the use of maintenance lenalidomide
- Recognize the potential role of novel agents and regimens in the management of newly diagnosed and relapsed/refractory acute and chronic leukemias and

• Examine therapeutic strategies under investigation for the treatment of myelofibrosis

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