

# Beyond the Guidelines:

## Investigator Perspectives on Current Cases, Clinical Issues and Ongoing Research in the Management of Lymphomas and Multiple Myeloma



A special audio supplement to a CME symposia series held during the 2016 American Society of Hematology Annual Meeting featuring expert comments on the application of emerging research to patient care

### FACULTY INTERVIEWS

Morie A Gertz, MD, MACP  
Julie M Vose, MD, MBA

### EDITOR

Neil Love, MD

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1 Audio CD

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## *Beyond the Guidelines: Investigator Perspectives on Current Cases, Clinical Issues and Ongoing Research in the Management of Lymphomas and Multiple Myeloma* — A Continuing Medical Education Audio Program

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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 CME program uses one-on-one interviews with 2 leading investigators to discuss key data sets in addition to cases and questions submitted by attendees at a satellite symposium. This program will assist practicing clinicians in formulating up-to-date and appropriate clinical management strategies.

### LEARNING OBJECTIVES

- Use patient- and disease-related factors to customize the use of induction and maintenance therapeutic approaches in the transplant and nontransplant settings for patients with newly diagnosed multiple myeloma (MM).
- Consider available research data and other clinical factors in the selection, sequencing and combining of current and recently approved novel agents in the care of patients with relapsed/refractory MM.
- Recall data with recently approved and investigational agents demonstrating promising activity in Waldenström macroglobulinemia, and integrate these strategies into the care of patients.
- Consider existing and emerging clinical research data in the formulation of therapeutic recommendations for patients with newly diagnosed and relapsed/refractory follicular, mantle cell and diffuse large B-cell lymphomas.
- Individualize the selection and sequence of systemic therapy for patients with newly diagnosed and relapsed/refractory chronic lymphocytic leukemia, considering clinical presentation, biomarker profile and psychosocial status.
- Incorporate new therapeutic strategies into the best-practice management of newly diagnosed and relapsed/refractory Hodgkin lymphoma.
- Assess the benefits of CD30 testing for patients with peripheral T-cell lymphoma, and consider the activity and tolerability of therapeutic agents in formulating a clinical treatment algorithm for patients with relapsed disease.

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## CME INFORMATION

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## Interview with Morie A Gertz, MD, MACP

### Tracks 1-18

- |                |  |                 |  |
|----------------|--|-----------------|--|
| <b>Track 1</b> | Triplet versus doublet induction therapy for multiple myeloma (MM)   |                 | infusion administration of daratumumab   |
| <b>Track 2</b> | ECOG-E1A11: A Phase III trial of bortezomib/lenalidomide/dexamethasone versus carfilzomib/lenalidomide/dexamethasone → limited or indefinite maintenance lenalidomide for newly diagnosed MM | <b>Track 10</b> | Results of Phase III studies of daratumumab in combination with lenalidomide/dexamethasone (POLLUX) or with bortezomib/dexamethasone (CASTOR) for relapsed/refractory MM |
| <b>Track 3</b> | Use of once-weekly carfilzomib for relapsed/refractory MM  | <b>Track 11</b> | Incorporation of daratumumab into the therapeutic algorithm for MM   |
| <b>Track 4</b> | Incidence of cardiac events in patients with MM treated with carfilzomib   | <b>Track 12</b> | Dose of pomalidomide for patients with MM and renal failure  |
| <b>Track 5</b> | Continuous post-transplant lenalidomide maintenance therapy for patients with MM and no high-risk features   | <b>Track 13</b> | Results of the MYRE study evaluating intensive hemodialysis with high cut-off or standard high-flux dialyzer for patients with MM receiving a bortezomib-based regimen   |
| <b>Track 6</b> | Perspective on trials on the use of ixazomib, daratumumab or elotuzumab as a component of maintenance therapy for high-risk MM   | <b>Track 14</b> | Efficacy of venetoclax in patients with MM and treatment of tumor lysis syndrome   |
| <b>Track 7</b> | Therapeutic options for patients with MM and disease progression on maintenance lenalidomide   | <b>Track 15</b> | Activity of pembrolizumab with Rd for relapsed/refractory MM   |
| <b>Track 8</b> | Resolving daratumumab interference with blood compatibility testing  | <b>Track 16</b> | Front-line therapy options for patients with Waldenström macroglobulinemia (WM)  |
| <b>Track 9</b> | Management of daratumumab-associated infusion reactions and introduction of the subcutaneous   | <b>Track 17</b> | Approach for patients with WM and elevated IgM levels  |
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## Interview with Julie M Vose, MD, MBA

### Tracks 1-16

- |                |   |                |   |
|----------------|---|----------------|---|
| <b>Track 1</b> | Primary results of the Phase III GALLIUM study: Obinutuzumab-versus rituximab-based induction and maintenance therapy for patients with previously untreated follicular lymphoma (FL) | <b>Track 5</b> | Choice of initial regimen for an otherwise healthy elderly patient with IGVH-mutated CLL and normal-risk cytogenetics             |
| <b>Track 2</b> | Therapeutic options for patients with relapsed/refractory FL  | <b>Track 6</b> | Use of ibrutinib as initial therapy for otherwise healthy younger patients with del(17p) CLL and a history of atrial fibrillation |
| <b>Track 3</b> | Clinical experience with idelalisib/rituximab in relapsed/refractory FL   | <b>Track 7</b> | Activity and tolerability of acalabrutinib versus ibrutinib   |
| <b>Track 4</b> | Selection of first-line therapy for younger patients with IGVH-mutated chronic lymphocytic leukemia (CLL) and normal-risk cytogenetics  | <b>Track 8</b> | CONTINUUM: Results of a Phase III trial of lenalidomide versus placebo as maintenance therapy after second-line treatment for CLL |
|                |   | <b>Track 9</b> | Treatment options for relapsed/refractory CLL with and without del(17p)   |

## Interview with Dr Vose (continued)

- |                 |  |                 |  |
|-----------------|--|-----------------|--|
| <b>Track 10</b> | Use of brentuximab vedotin as up-front therapy or as a bridge to transplant for patients with Hodgkin lymphoma (HL)                      | <b>Track 13</b> | Choice of induction regimen and duration of maintenance therapy for mantle cell lymphoma (MCL) |
| <b>Track 11</b> | Brentuximab vedotin as consolidation therapy after autologous stem cell transplant in patients with HL at risk of relapse or progression | <b>Track 14</b> | Sequencing of therapeutic options for relapsed/refractory MCL                                  |
| <b>Track 12</b> | Immune checkpoint inhibition in relapsed/refractory HL   | <b>Track 15</b> | Initial therapy for diffuse large B-cell lymphoma and treatment of relapsed/refractory disease |
|                 |  | <b>Track 16</b> | Activity and tolerability of therapeutic options for T-cell lymphomas                          |

## Related Video Program

Visit [www.ResearchToPractice.com/BeyondtheGuidelines16/Video](http://www.ResearchToPractice.com/BeyondtheGuidelines16/Video) to view video proceedings from the 2-part satellite symposia series preceding the 58<sup>th</sup> ASH Annual Meeting and earn additional **AMA PRA Category 1 Credit™**.



### Topics covered include:

#### Part I: Lymphoma/Chronic Lymphocytic Leukemia

- ▶ Chronic Lymphocytic Leukemia
- ▶ Follicular Lymphoma
- ▶ Hodgkin Lymphoma
- ▶ Mantle Cell Lymphoma
- ▶ Diffuse Large B-Cell Lymphoma
- ▶ T-Cell Lymphoma

#### Part II: Multiple Myeloma

- ▶ Up-Front Management of Newly Diagnosed Multiple Myeloma
- ▶ Smoldering Myeloma, Waldenström Macroglobulinemia and Primary Amyloidosis
- ▶ Consolidation and Maintenance Therapy
- ▶ Management of Relapsed/Refractory Disease

## SELECT PUBLICATIONS

### Multiple Myeloma

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

Berenson JR et al. **CHAMPION-1: A phase 1/2 study of once-weekly carfilzomib and dexamethasone for relapsed or refractory multiple myeloma.** *Blood* 2016;127(26):3360-8.

Bridoux F et al. **Treatment of myeloma cast nephropathy (MCN): A randomized trial comparing intensive haemodialysis (HD) with high cut-off (HCO) or standard high-flux dialyzer in patients receiving a bortezomib-based regimen (the MYRE study, by the Intergroupe Francophone du Myélome (IFM) and the French Society of Nephrology (SFNDT)).** *Proc ASH* 2016;**Abstract 978**.

Chapuy CI et al. **Resolving the daratumumab interference with blood compatibility testing.** *Transfusion* 2015;55(6 Pt 2):1545–54.

Chari A et al. **Cardiac events in real-world multiple myeloma patients treated with carfilzomib: A retrospective claims database analysis.** *Proc ASH* 2016;[Abstract 3319](#).

Dimopoulos MA et al; POLLUX Investigators. **Daratumumab, lenalidomide, and dexamethasone for multiple myeloma.** *N Engl J Med* 2016;375(14):1319–31.

**ECOG-E1A11: A randomized Phase III trial of bortezomib, lenalidomide and dexamethasone (VRd) versus carfilzomib, lenalidomide, dexamethasone (CRd) followed by limited or indefinite lenalidomide maintenance in patients with newly diagnosed symptomatic multiple myeloma.** [NCT01863550](#)

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](#).

Mateos MV et al. **Pembrolizumab in combination with lenalidomide and low-dose dexamethasone for relapsed/refractory multiple myeloma (RRMM): Final efficacy and safety analysis.** *Proc ASCO* 2016;[Abstract 8010](#).

Mateos MV et al. **Pembrolizumab (MK-3475) in combination with lenalidomide and low-dose dexamethasone for relapsed/refractory multiple myeloma (RRMM): KEYNOTE-023.** *J Immunother Cancer* 2015;3(Suppl 2):P160.

Palumbo A et al; CASTOR Investigators. **Daratumumab, bortezomib, and dexamethasone for multiple myeloma.** *N Engl J Med* 2016;375(8):754–66.

Usmani SD 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](#).

#### Waldenström Macroglobulinemia

Treon SP et al. **Ibrutinib in previously treated Waldenström's macroglobulinemia.** *N Engl J Med* 2015;372(15):1430–40.

#### Chronic Lymphocytic Leukemia

Barr P et al. **Updated efficacy and safety from the phase 3 Resonate-2 study: Ibrutinib as first-line treatment option in patients 65 years and older with chronic lymphocytic leukemia/small lymphocytic leukemia.** *Proc ASH* 2016;[Abstract 234](#).

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

Fink AM et al. **Lenalidomide maintenance after front line therapy substantially prolongs progression free survival in high risk CLL: Interim results of a phase 3 study (CLL M1 study of the German CLL Study Group).** *Proc ASH* 2016;[Abstract 229](#).

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](#).

Jain P et al. **Causes of discontinuation and long-term outcomes of patients with CLL after discontinuing ibrutinib.** *Proc ASH* 2016;[Abstract 4390](#).

#### Diffuse Large B-Cell Lymphoma

Budde L et al. **Results of an ongoing phase 2 study of brentuximab vedotin with RCHP as frontline therapy in patients with high-intermediate/high-risk diffuse large B cell lymphoma (DLBCL).** *Proc ASH* 2016;[Abstract 104](#).

#### Follicular Lymphoma

**A Phase 3 open label randomized study to compare the efficacy and safety of rituximab plus lenalidomide (CC-5013) versus rituximab plus chemotherapy followed by rituximab in subjects with previously untreated follicular lymphoma (RELEVANCE).** [NCT01650701](#)

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](#).

#### Hodgkin Lymphoma

Moskowitz CH et al; AETHERA Study Group. **Brentuximab vedotin as consolidation therapy after autologous stem-cell transplantation in patients with Hodgkin's lymphoma at risk of relapse or progression (AETHERA): A randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet* 2015;385(9980):1853–62.



Beyond the Guidelines: Investigator Perspectives on Current Cases, Clinical Issues and Ongoing Research in the Management of Lymphomas and Multiple Myeloma

QUESTIONS (PLEASE CIRCLE ANSWER):

1. The ongoing Phase III ECOG-E1A11 trial is evaluating bortezomib/lenalidomide/dexamethasone versus carfilzomib/lenalidomide/dexamethasone followed by \_\_\_\_\_ lenalidomide maintenance therapy for patients with newly diagnosed MM.
  - a. Limited
  - b. Indefinite
  - c. Limited or indefinite
  - d. None of the above
2. A study presented at the 2016 ASH meeting demonstrated that daratumumab \_\_\_\_\_ safely be administered via subcutaneous infusion.
  - a. Could
  - b. Could not
3. Results of the Phase I/II CHAMPION-1 study evaluating the use of once-weekly administration of carfilzomib for patients with relapsed/refractory MM did not demonstrate increased rates of dyspnea or hypertension.
  - a. True
  - b. False
4. The Phase III randomized CASTOR study evaluating daratumumab/bortezomib/dexamethasone versus bortezomib/dexamethasone \_\_\_\_\_ a significant improvement in progression-free survival (PFS) with the addition of daratumumab for patients with relapsed or refractory MM.
  - a. Demonstrated
  - b. Did not demonstrate
5. Which of the following statements is true of venetoclax in the treatment of CLL?
  - a. It acts by inhibiting Bcl-2
  - b. It is not effective in patients with del(17p) CLL
  - c. It can cause tumor lysis syndrome
  - d. All of the above
  - e. Both a and c
6. \_\_\_\_\_ is a next-generation proteasome inhibitor with demonstrated activity under active investigation for the treatment of WM.
  - a. Ixazomib
  - b. Oprozomib
  - c. Both a and b
  - d. Neither a nor b
7. Which of the following is the mechanism of action of obinutuzumab?
  - a. Anti-CD20 monoclonal antibody
  - b. Immunomodulatory drug
  - c. PD-1/PD-L1 antibody
  - d. Proteasome inhibitor
8. Primary results of the Phase III GALLIUM trial evaluating obinutuzumab or rituximab in combination with chemotherapy for newly diagnosed FL demonstrated a statistically significant improvement in \_\_\_\_\_ for patients who received obinutuzumab.
  - a. Overall survival (OS)
  - b. PFS
  - c. Both a and b
9. Data presented by Schuh and colleagues at the 2016 ASH meeting demonstrated \_\_\_\_\_ maintenance therapy to be efficacious after second-line therapy for patients with CLL.
  - a. Acalabrutinib
  - b. Lenalidomide
  - c. Venetoclax
10. Results of the Phase III AETHERA trial evaluating brentuximab vedotin versus placebo as consolidation therapy after autologous stem cell transplant in patients with HL at risk of relapse or progression demonstrated a statistically significant improvement in \_\_\_\_\_ for patients who received brentuximab vedotin.
  - a. Median PFS
  - b. Median OS
  - c. Both a and b
  - d. Neither a nor b



## EDUCATIONAL ASSESSMENT AND CREDIT FORM

### Beyond the Guidelines: Investigator Perspectives on Current Cases, Clinical Issues and Ongoing Research in the Management of Lymphomas and Multiple Myeloma

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		
Activity of daratumumab in combination with lenalidomide/dexamethasone or with bortezomib/dexamethasone for relapsed/refractory MM	4 3 2 1	4 3 2 1		
Efficacy of venetoclax in patients with MM and treatment of tumor lysis syndrome	4 3 2 1	4 3 2 1		
Resolution of daratumumab interference with blood compatibility testing in patients with MM	4 3 2 1	4 3 2 1		
Primary results of the Phase III GALLIUM study evaluating obinutuzumab and chemotherapy compared to rituximab and chemotherapy → obinutuzumab or rituximab maintenance for previously untreated FL	4 3 2 1	4 3 2 1		
Use of brentuximab vedotin as consolidation therapy after autologous stem cell transplant in patients with HL at risk of relapse or progression	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:

- Use patient- and disease-related factors to customize the use of induction and maintenance therapeutic approaches in the transplant and nontransplant settings for patients with newly diagnosed multiple myeloma (MM). ..... 4 3 2 1 N/M N/A
- Consider available research data and other clinical factors in the selection, sequencing and combining of current and recently approved novel agents in the care of patients with relapsed/refractory MM. .... 4 3 2 1 N/M N/A
- Recall new data with recently approved and investigational agents demonstrating promising activity in Waldenström macroglobulinemia, and integrate these strategies into the care of patients. .... 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:

- Consider existing and emerging clinical research data in the formulation of therapeutic recommendations for patients with newly diagnosed and relapsed/refractory follicular, mantle cell and diffuse large B-cell lymphomas. . . . . 4 3 2 1 N/M N/A
- Individualize the selection and sequence of systemic therapy for patients with newly diagnosed and relapsed/refractory chronic lymphocytic leukemia, considering clinical presentation, biomarker profile and psychosocial status. . . . . 4 3 2 1 N/M N/A
- Incorporate new therapeutic strategies into the best-practice management of newly diagnosed and relapsed/refractory Hodgkin lymphoma. . . . . 4 3 2 1 N/M N/A
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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

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Julie M Vose, MD, MBA	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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# Hematologic Oncology™

U P D A T E

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