DATA AND PERSPECTIVES

Clinical Investigators Review Key Publications and Current Cases in Multiple Myeloma and Non-Hodgkin Lymphoma



A special audio supplement to a CME conference held during the 2014 ASCO Annual Meeting featuring expert comments on the application of emerging research to patient care

FACULTY INTERVIEWS

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2 Audio CDs

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Data and Perspectives: Clinical Investigators Review Key Publications and Current Cases in Multiple Myeloma and Non-Hodgkin Lymphoma

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Taken together, it is estimated that 156,420 new cases of lymphoma, multiple myeloma and leukemia will be identified in the United States in the year 2014, and 55,350 individuals will die of these diseases. Of importance, currently more than 60 drug products are labeled for use in the management of hematologic cancers, with more than 70 distinct FDA-approved indications. Although this extensive list of available treatment options is reassuring for patients and oncology healthcare professionals, it poses a challenge to the practicing clinician who must maintain up-to-date knowledge of appropriate clinical management strategies across a vast spectrum of liquid and solid tumors.

This special audio highlights program of a CME satellite symposium held during the 2014 ASCO annual meeting uses one-on-one interviews with 2 leading investigators in lymphoma and 1 in multiple myeloma to discuss cases and questions submitted by meeting attendees. By providing information on the latest research developments and their potential application to routine practice, this activity is designed to assist hematologists, medical oncologists and hematology-oncology fellows with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Compare and contrast completed and ongoing clinical trials evaluating novel investigational approaches for B-cell
 lymphomas and chronic lymphocytic leukemia (CLL), and prioritize clinical trial opportunities or expanded-access programs
 available to patients based on this information.
- 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 CLL.
- Customize the selection of systemic therapy for patients with progressive mantle-cell lymphoma, recognizing the recent
 addition of new FDA-endorsed options for these patients.
- Recognize the role of novel agents in the management of peripheral T-cell lymphoma and/or advanced-stage T-cell lymphomas, and ensure appropriate supportive care measures to minimize their associated side effects.
- Compare and contrast the benefits and risks of available immunomodulatory agents, proteasome inhibitors or both as systemic treatment for newly diagnosed active multiple myeloma (MM).
- Customize the use of maintenance therapeutic approaches for MM in the post-transplant and nontransplant settings based on patient- and disease-related factors, including cytogenetic profile.
- Consider available data on the selection, sequencing and/or combination of carfilzomib and pomalidomide in the management of relapsed/refractory MM.
- Assess the ongoing clinical trials evaluating innovative investigational approaches for non-Hodgkin lymphomas and MM, and refer appropriate patients for study participation.

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SELECT PUBLICATIONS

A multicentre, Phase III, open label, randomized study in previously untreated patients with advanced indolent non-Hodgkin's lymphoma evaluating the benefit of GA101 (RO5072759) + chemotherapy compared to rituximab + chemotherapy followed by GA101 or rituximab maintenance therapy in responders. NCT01332968

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. The "RELEVANCE" trial (rituximab lenalidomide versus any chemotherapy). NCT01650701

Advani RH et al. A phase II study of cyclophosphamide, etoposide, vincristine and prednisone (CEOP) alternating with pralatrexate as front-line therapy for patients with PTCL: Preliminary results from the T-cell consortium trial. Proc ASH 2013; Abstract 3044.

Barr PM et al. Phase 2 trial of GS-9973, a selective syk inhibitor, and idelalisib (idela) in chronic lymphocytic leukemia (CLL) and non-Hodgkin lymphoma (NHL). Proc ASCO 2014; Abstract 7059.

Casulo C et al. Early relapse of FL after R-CHOP uniquely defines patients at high risk for death: An analysis from the National LymphoCare Study. Proc ASH 2013; Abstract 510.

Coiffier B et al. Prespecified candidate biomarkers identify FL patients who achieved longer progression-free survival with bortezomib-rituximab versus rituximab. Clin Cancer Res 2013;19(9):2551-61.

Eichhorst B et al. Chemoimmunotherapy with fludarabine (F), cyclophosphamide (C), and rituximab (R) (FCR) versus bendamustine and rituximab (BR) in previously untreated and physically fit patients (pts) with advanced chronic lymphocytic leukemia (CLL): Results of a planned interim analysis of the CLL10 trial, an international, randomized study of the German CLL Study Group (GCLLSG). Proc ASH 2013; Abstract 526.

Facon T et al. Initial Phase 3 results of the FIRST (frontline investigation of lenalidomide + dexamethasone versus standard thalidomide) trial (MM-020/IFM 07 01) in newly diagnosed MM patients ineligible for stem cell transplantation. *Proc ASH* 2013; Abstract 2.

Farooqui M et al. Single agent ibrutinib (PCI-32765) achieves equally good and durable responses in CLL patients with and without deletion 17p. Proc ASH 2013; Abstract 673.

Friedberg JW et al. Phase II study of alisertib, a selective Aurora A kinase inhibitor, in relapsed and refractory aggressive B- and T-cell non-Hodgkin lymphomas. *J Clin Oncol* 2014;32(1):44-50.

Furman RR et al. Idelalisib and rituximab in relapsed CLL. N Engl J Med 2014;370(11):997-1007.

Gandhi M et al. Impact of induction regimen and consolidative stem cell transplantation in patients with double hit lymphoma (DHL): A large multicenter retrospective analysis. *Proc ASH* 2013; Abstract 640.

Kapoor P et al. Importance of achieving stringent complete response after autologous stem-cell transplantation in MM. J Clin Oncol 2013;31(36):4529-35.

Leleu X et al. Pomalidomide plus low-dose dexamethasone in relapsed or refractory multiple myeloma (RRMM) with deletion (del)17p and/or translocation t(4;14). Proc ASH 2013; Abstract 689.

Mark TM et al. Sequence impact of pomalidomide and carfilzomib on treatment response in relapsed MM. Proc ASH 2013; Abstract 1954.

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

Richardson PG et al. Panorama 1: A randomized, double-blind, phase 3 study of panobinostat or placebo plus bortezomib and dexamethasone in relapsed or relapsed and refractory multiple myeloma. Proc ASCO 2014; Abstract 8510.

Ruan J et al. Combination biologic therapy without chemotherapy as initial treatment for MCL: Multi-center Phase II study of lenalidomide plus rituximab. *Proc ASH* 2013; Abstract 247.

Taverna CJ et al. Rituximab maintenance treatment for a maximum of 5 years in FL: Results of the randomized Phase III trial SAKK 35/03. Proc ASH 2013; Abstract 508.

Vaidya R, Witzig TE. Prognostic factors for diffuse large B cell lymphoma in the R(X)CHOP era. Ann Oncol 2014; [Epub ahead of print].

POST-TEST

Data and Perspectives: Clinical Investigators Review Key Publications and Current Cases in Multiple Myeloma and Non-Hodgkin Lymphoma

QUESTIONS (PLEASE CIRCLE ANSWER):

- An interim analysis of the CLL10 trial of fludarabine/cyclophosphamide/rituximab (FCR) versus bendamustine/rituximab (BR) for physically fit patients with previously untreated advanced CLL reported
 - a. Increased efficacy with FCR compared to BR
 - b. Higher rates of severe adverse events with FCR compared to BR
 - c. Both a and b
 - d. Neither a nor b
- A Phase II trial of idelalisib in combination with the SYK inhibitor GS-9973 in CLL and NHL was discontinued because of a high incidence of fatal pneumonitis.
 - a. True
 - b. False
- 3. Results of the Phase III PANORAMA 1 study, which evaluated the potent pan-deacetylase inhibitor panobinostat versus placebo in combination with bortezomib/dexamethasone for patients with relapsed/refractory MM, demonstrated improvements in _____ with the addition of panobinostat.
 - a. Complete response rate
 - b. Depth of response
 - c. Median progression-free survival
 - d. All of the above
- 4. The ongoing Phase III ECOG-E1A11 trial is evaluating lenalidomide/bortezomib/dexameth-asone (RVD) versus _______ followed by limited or indefinite lenalidomide maintenance for patients with newly diagnosed MM.
 - a. Carfilzomib/lenalidomide/dexamethasone (CRd)
 - b. Elotuzumab/lenalidomide/dexamethasone
 - c. Ixazomib/lenalidomide/dexamethasone
 - d. All of the above

- 5. Which of the following novel monoclonal antibodies has demonstrated single-agent activity for patients with MM?
 - a. Daratumumah
 - b. Elotuzumab
 - c. Both a and b
 - d. Neither a nor b
- 6. The ongoing Phase III GALLIUM trial is evaluating ______ with chemotherapy versus rituximab with chemotherapy followed by maintenance therapy with ____ or rituximab for patients with untreated advanced indolent NHL.
 - a. Bortezomib
 - b. Ibritumomab tiuxetan
 - c. Obinutuzumah
 - d. All of the above
- 7. The Phase III RELEVANCE trial is evaluating rituximab/lenalidomide (R²) versus rituximab in combination with standard chemotherapy followed by rituximab maintenance therapy for patients with previously untreated FL.
 - a. True
 - b. False
- 8. Which of the following small molecule inhibitors is not FDA approved and is undergoing investigation for the treatment of CLL?
 - a. Ibrutinib
 - b. ABT-199
 - c. Idelalisib
 - d. Both b and c
 - e. All of the above

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Data and Perspectives: Clinical Investigators Review Key Publications and Current Cases in Multiple Myeloma and Non-Hodgkin Lymphoma

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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
Available trial data and ongoing evaluation of obinutuzumab for patients with CLL and indolent NHL	4 3 2 1	4 3 2 1
Differential effectiveness of approved and novel agents in the treatment of various subtypes of TCL	4 3 2 1	4 3 2 1
Effectiveness of ibrutinib in patients with CLL and a 17p deletion	4 3 2 1	4 3 2 1
Role of minimal residual disease assays in the management of MM	4 3 2 1	4 3 2 1
Activity and tolerability of oral proteasome inhibitors (eg, ixazomib, oprozomib) under development for MM	4 3 2 1	4 3 2 1
Practice Setting: Academic center/medical school Solo practice Government (eg, VA) Other (please speech specified by the content of the c	•	
Was the activity evidence based, fair, balanced and free from commercial bias Yes No If no, please explain:		
 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		
The content of this activity matched my current (or potential) scope of practic Yes No If no, please explain: Please respond to the following learning objectives (LOs) by circling the appro 4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not	e. priate selection	······
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 Compare and contrast the benefits and risks of available immunomodulatory ag proteasome inhibitors or both as systemic treatment for newly diagnosed active multiple myeloma (MM). 		3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result	of th	is activity,	I will	be	able	to:
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Customize the use of maintenance therapeutic a and nontransplant settings based on patient- and cytogenetic profile	d disease-re	elated	d factor	rs, İncludin	g '		.4 3	2 1	N/M	N/A
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Assess the ongoing clinical trials evaluating innovative investigational approaches for									NI/A	
non-Hodgkin lymphomas and MM, and refer appropriate patients for study participation 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										
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Yes, I am willing to participate in a follow-up No, I am not willing to participate in a follow-										
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4 = Excellent 3 = Good	d 2 =	= Ade	equate	1 =	= Subop	otima	al			
Faculty	Knowledg	ge of	subjec	t matter	Effec	tiver	ness a	is an	educa	itor
Jonathan W Friedberg, MD, MMSc	4	3	2	1		4	3	2	1	
Sagar Lonial, MD	4	3	2	1		4	3	2	1	
Martin Dreyling, MD, PhD	4	3	2	1		4	3	2	1	
Editor	Knowledge of subject matter						itor			
Neil Love, MD	4	3	2	1		4	3	2	1	
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