

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

## CME Information

### TARGET AUDIENCE

This activity is intended for hematologists, medical oncologists, hematology-oncology fellows and other healthcare providers involved in the treatment of multiple myeloma (MM).

### OVERVIEW OF ACTIVITY

Hematologic cancers include the lymphomas, the leukemias, multiple myeloma and other related disorders (eg, myelodysplastic syndrome, myeloproliferative diseases) stemming from lymphoid and myeloid progenitor cell lines. Importantly, currently nearly 70 drug products are labeled for use in the management of hematologic cancers with more than 120 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 is particularly true within the realm of MM, where the past several years have yielded a number of important clinical and research advances.

Consensus-based guidelines aim to support oncologists and other cancer clinicians in making rational treatment recommendations, but in situations in which multiple “acceptable” therapeutic options exist, such guidelines may not be particularly helpful at the time of decision-making. Because these resources simply enumerate all diagnostic or treatment strategies supported by diverse levels of evidence rather than providing perspectives on the benefits and risks of one strategy versus another, they often leave the clinician alone to contemplate the optimal clinical approach. These proceedings from a CME symposium during the ASH Annual Meeting use an innovative strategy to formally document and present the perspectives, experiences and preferred treatment approaches of 30 myeloma-specific investigators. By providing information on the latest research developments and their potential application to routine practice, this activity is designed to assist hematologists, medical oncologists, hematology-oncology fellows and other healthcare providers involved in the treatment of MM with the formulation of up-to-date clinical management strategies.

### LEARNING OBJECTIVES

- Develop a risk-adapted treatment plan for patients with smoldering MM, considering the roles of observation and active treatment.
- Use patient- and disease-related factors, including cytogenetic profile, to customize the use of induction and maintenance therapeutic approaches in the transplant and nontransplant settings.
- Consider available research data and other clinical factors in the best-practice selection, sequencing and combining of current and recently approved novel agents in the nonresearch care of patients with relapsed/refractory MM.
- Design and implement a plan of care to recognize and manage side effects and toxicities associated with recently approved systemic therapies in order to support quality of life and continuation of treatment.
- Develop an evidence-based algorithm for the use of stem cell transplant, chemotherapy and/or novel targeted agents in the management of primary amyloidosis.
- Recall new data with recently approved and investigational agents demonstrating promising activity in Waldenström macroglobulinemia, and, as applicable, integrate these strategies into the protocol and nonresearch care of patients.
- Identify ongoing trials of investigational approaches in MM, amyloidosis and Waldenström macroglobulinemia, and refer appropriate patients and obtain consent for study participation.

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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:

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#### **Hardware/Software Requirements:**

A high-speed Internet connection

A monitor set to 1280 x 1024 pixels or more

Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later

Adobe Flash Player 10.2 plug-in or later

Adobe Acrobat Reader

(Optional) Sound card and speakers for audio

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## Select Publications

### Ola Landgren, MD, PhD

Hitt R et al. **Centenarians: The older you get, the healthier you have been.** *Lancet* 1999;354(9179):652.

Kazandjian D et al. **Sustained minimal residual disease negativity in newly diagnosed multiple myeloma (NDMM) patients treated with carfilzomib (CFZ), lenalidomide (LEN), and dexamethasone (DEX) followed by 2 years of lenalidomide maintenance (CRd-R): Updated results of a phase 2 study.** *Proc ASH* 2016;Abstract 4527.

Korde N et al. **Treatment with carfilzomib-lenalidomide-dexamethasone with lenalidomide extension in patients with smoldering or newly diagnosed multiple myeloma.** *JAMA Oncol* 2015;1(6):746-54.

Kumar S et al. **International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma.** *Lancet Oncol* 2016;17(8):e328-46.

Landgren O. **Combination therapy for fit (younger and older) newly diagnosed multiple myeloma patients: Data support carfilzomib, lenalidomide, and dexamethasone independent of cytogenetic risk status.** *Seminars Oncol* 2016. Available at: [http://www.seminoncol.org/article/S0093-7754\(16\)30114-2/abstract](http://www.seminoncol.org/article/S0093-7754(16)30114-2/abstract)

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Landgren O et al. **Role of MRD status in relation to clinical outcomes in newly diagnosed multiple myeloma patients: A meta-analysis.** *Bone Marrow Transplant* 2016;51(12):1565-8.

Mailankody S et al. **Minimal residual disease in multiple myeloma: Bringing the bench to the bedside.** *Nat Rev Clin Oncol* 2015;12(5):286-95.

### María-Victoria Mateos, MD, PhD

Attal M et al. **Lenalidomide (LEN) maintenance (MNTC) after high-dose melphalan and autologous stem cell transplant (ASCT) in multiple myeloma (MM): A meta-analysis (MA) of overall survival (OS).** *Proc ASCO* 2016;Abstract 8001.

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).** *Blood* 2015;126(23):391.

Attal M et al. **Maintenance therapy with thalidomide improves survival in patients with multiple myeloma.** *Blood* 2006;108(10):3289-94.

Avet-Loiseau H et al. **Efficacy and safety of carfilzomib, lenalidomide, and dexamethasone vs lenalidomide and dexamethasone in patients with relapsed multiple myeloma based on cytogenetic risk status: Subgroup analysis from the phase 3 study Aspire (NCT01080391).** *Blood* 2015;126(23):731.

Barlogie B et al. **Long-term follow-up of autotransplantation trials for multiple myeloma: Update of protocols conducted by the Intergroupe Francophone Du Myelome, Southwest Oncology Group, and University of Arkansas for Medical Sciences.** *J Clin Oncol* 2010;28(7):1209-14.

Barlogie B et al. **Thalidomide arm of Total Therapy 2 improves complete remission duration and survival in myeloma patients with metaphase cytogenetic abnormalities.** *Blood* 2008;112(8):3115-21.

Barlogie B et al. **Thalidomide and hematopoietic-cell transplantation for multiple myeloma.** *N Engl J Med* 2006;354(10):1021-30.

Benboubker L et al. **Lenalidomide and dexamethasone in transplant-ineligible patients with myeloma.** *N Engl J Med* 2014;371(10):906-17.

Bonanad S et al. **Development and psychometric validation of a brief comprehensive health status assessment scale in older patients with hematological malignancies: The GAH Scale.** *J Geriatr Oncol* 2015;6(5):353-61.

Cavo M et al. **Upfront autologous stem cell transplantation (ASCT) versus novel agent-based therapy for multiple myeloma (MM): A randomized phase 3 study of the European Myeloma Network (EMN02/HO95 MM trial).** *Proc ASCO* 2016;Abstract 8000.

Cavo M et al. **Double vs single autologous stem cell transplantation after bortezomib-based induction regimens for multiple myeloma: An integrated analysis of patient-level data from phase European III studies.** *Blood* 2013;122(21):767.

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Kumar S et al. **Safety and tolerability of ixazomib, an oral proteasome inhibitor, in combination with lenalidomide and dexamethasone in patients with previously untreated multiple myeloma: An open-label phase 1/2 study.** *Lancet Oncol* 2014;15(13):1503-12.

Lokhorst HM et al. **A randomized phase 3 study on the effect of thalidomide combined with Adriamycin, dexamethasone, and high-dose melphalan, followed by thalidomide maintenance in patients with multiple myeloma.** *Blood* 2010;115(6):1113-20.

Morgan GJ et al. **The role of maintenance thalidomide therapy in multiple myeloma: MRC Myeloma IX results and meta-analysis.** *Blood* 2012;119(1):7-15.

Palumbo A et al. **Bortezomib-melphalan-prednisone-thalidomide followed by maintenance with bortezomib-thalidomide compared with bortezomib-melphalan-prednisone for initial treatment of multiple myeloma: Updated follow-up and improved survival.** *J Clin Oncol* 2014;32(7):634-40.

Rosiñol L et al. **Superiority of bortezomib, thalidomide, and dexamethasone (VTD) as induction pretransplantation therapy in multiple myeloma: A randomized phase 3 PETHEMA/GEM study.** *Blood* 2012;120(8):1589-96.

Roussel M et al. **Bortezomib, lenalidomide, and dexamethasone (VRD) consolidation and lenalidomide maintenance in frontline multiple myeloma patients: Updated results of the IFM 2008 phase II VRD intensive program.** *Blood* 2011;118(21):1872.

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### Sagar Lonial, MD

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de Weers M et al. **Daratumumab, a novel therapeutic human CD38 monoclonal antibody, induces killing of multiple myeloma and other hematological tumors.** *J Immunol* 2011;186(3):1840-8.

Donato F et al. **Monoclonal antibodies currently in Phase II and III trials for multiple myeloma.** *Expert Opin Biol Ther* 2014;14(8):1127-44.

Jansen JHM et al. **Daratumumab, a human CD38 antibody induces apoptosis of myeloma tumor cells via Fc receptor-mediated crosslinking.** *Blood* 2012;120(21):2974.

Krejci J et al. **Daratumumab depletes CD38+ immune regulatory cells, promotes T-cell expansion, and skews T-cell repertoire in multiple myeloma.** *Blood* 2016;128(3):384-94.

Lammerts van Bueren J et al. **Direct in vitro comparison of daratumumab with surrogate analogs of CD38 antibodies MOR03087, SAR650984 and Ab79.** *Blood* 2014;124(21):3474.

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### Morie A Gertz, MD, MACP

Ali SA et al. **T cells expressing an anti-B-cell maturation antigen chimeric antigen receptor cause remissions of multiple myeloma.** *Blood* 2016;128(13):1688-700.

Badros AZ et al. **Pembrolizumab in combination with pomalidomide and dexamethasone for relapsed/refractory multiple myeloma (RRMM).** *Blood* 2016;128(22):490.

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.

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Kumar S et al. **Phase I venetoclax monotherapy for relapsed/refractory multiple myeloma.** *Proc ASCO* 2016;Abstract 8032.

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.

Moreau P et al. **Oral ixazomib, lenalidomide, and dexamethasone for multiple myeloma.** *N Engl J Med* 2016;374(17):1621-34.

Ramasamy K et al. **Safety of treatment (Tx) with pomalidomide (POM) and low-dose dexamethasone (LoDEX) in patients (pts) with relapsed or refractory multiple myeloma (RRMM) and renal impairment (RI), including those on dialysis.** *Proc ASH* 2015;Abstract 374.

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### Robert Z Orlowski, MD, PhD

Caers J et al. **The changing landscape of smoldering multiple myeloma: A European perspective.** *Oncologist* 2016;21(3):333-42.

Cohen AD, Comenzo RL. **Systemic light-chain amyloidosis: Advances in diagnosis, prognosis, and therapy.** *Hematology Am Soc Hematol Educ Program* 2010;2010:287-94.

DiSalvo TG et al. **Case 3-2000 — A 66-year-old woman with diabetes, coronary disease, orthostatic hypotension, and the nephrotic syndrome.** *N Engl J Med* 2000;342(4):264-73.

Dispenzieri A et al. **Serum cardiac troponins and N-terminal pro-brain natriuretic peptide: A staging system for primary systemic amyloidosis.** *J Clin Oncol* 2004;22(18):3751-7.

Gertz MA et al. **First-in-human phase I/II study of NEOD001 in patients with light chain amyloidosis and persistent organ dysfunction.** *J Clin Oncol* 2016;34(10):1097-103.

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Langer AL et al. **Results of phase I study of chimeric fibril-reactive monoclonal antibody 11-1F4 in patients with AL amyloidosis.** *Proc ASH* 2015;Abstract 188.

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Mateos MV et al. **Lenalidomide plus dexamethasone for high-risk smoldering multiple myeloma.** *N Engl J Med* 2013;369(5):438-47.

Merlini G et al. **Long-term outcome of a phase 1 study of the investigational oral proteasome inhibitor (PI) ixazomib at the recommended phase 3 dose (RP3D) in patients (pts) with relapsed or refractory systemic light-chain (AL) amyloidosis (RRAL).** *Proc ASH 2014*;Abstract 3450.

Nuvolone M et al. **Systemic amyloidosis: Novel therapies and role of biomarkers.** *Nephrol Dial Transplant* 2016;[Epub ahead of print].

Palumbo A et al. **Revised international staging system for multiple myeloma: A report from International Myeloma Working Group.** *J Clin Oncol* 2015;33(26):2863-69.

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

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