Oncology Tumor Panel Series

Oncologist and Nurse Investigators Consult on Actual Patients from the Practices of the Invited Faculty

Part 1 — Lymphoma and Chronic Lymphocytic Leukemia

CNE Information

TARGET AUDIENCE

This activity has been designed to meet the educational needs of oncology nurses, nurse practitioners and clinical nurse specialists involved in the treatment of Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL).

OVERVIEW OF ACTIVITY

It is estimated that approximately 95,520 new cases of HL, NHL and chronic lymphocytic leukemia (CLL) will be identified in the United States in the year 2015, and 25,590 individuals will die from these diseases. Currently more than 60 drug products with more than 70 distinct FDA-approved indications are labeled for use in the management of hematologic cancers. 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. The past several years represent a period of substantial progress in the development and evaluation of novel agents across many lymphoma subtypes, and mature clinical trial results have illustrated the efficacy of several new investigational therapies, some of which have altered the therapeutic algorithms for HL and various subtypes of NHL.

These video proceedings from the first part of a 5-part integrated CNE curriculum originally held at the 2015 ONS Annual Congress feature discussions with leading hematologyoncology investigators and their nursing counterparts regarding actual patient cases and recent clinical research findings affecting the optimal therapeutic and supportive care for each patient scenario.

PURPOSE STATEMENT

This activity has been designed to meet the educational needs of oncology nurses, nurse practitioners and clinical nurse specialists involved in the treatment of HL and NHL.

LEARNING OBJECTIVES

 Provide patient-focused education to enhance clinical decision-making regarding the available systemic agents used in the management of indolent and aggressive forms of B-cell NHL, T-cell lymphomas and HL.

- Formulate supportive care strategies to manage the side effects associated with commonly employed therapeutic interventions for patients with NHL and HL.
- Evaluate preliminary safety data and reported outcomes with investigational agents and strategies, and counsel appropriately selected patients about the potential for enrollment in clinical trials.
- Identify opportunities to enhance the collaborative role of oncology nurses in the comprehensive biopsychosocial care of patients with lymphoma and CLL to optimize clinical and quality-of-life outcomes.

ACCREDITATION STATEMENT

Research To Practice is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

CREDIT DESIGNATION STATEMENT

This educational activity for 2.1 contact hours is provided by Research To Practice during the period of August 2015 through August 2016.

FOR SUCCESSFUL COMPLETION

This is a video CNE program. To receive credit, participants should read the learning objectives and faculty disclosures, watch the video, complete the Post-test with a score of 75% or better and fill out the Educational Assessment and Credit Form located at ResearchToPractice.com/ ONSLymphoma2015/CNE.

CONTENT VALIDATION AND DISCLOSURES

Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-theart education. We assess potential conflicts of interest with faculty, planners and managers of CNE activities. Real or apparent conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations. **FACULTY** — The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process:

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Consulting Agreements: Celgene Corporation, OptumRx Inc, Seattle Genetics, Spectrum Pharmaceuticals Inc; **Contracted Research:** Acerta Pharma, Celgene Corporation, Gilead Sciences Inc, Infinity Pharmaceuticals Inc, Janssen Biotech Inc, Onyx Pharmaceuticals, an Amgen subsidiary, Pharmacyclics Inc, Takeda Oncology; **Unpaid Consulting Agreements:** Genentech BioOncology, Takeda Oncology.

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No real or apparent conflicts of interest to disclose.

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Consulting Agreements: Amgen Inc, Bristol-Myers Squibb Company, Celgene Corporation, Genzyme Corporation, Kyowa Hakko Kirin Co Ltd, Seattle Genetics, Spectrum Pharmaceuticals Inc, Takeda Oncology; **Contracted Research:** Celgene Corporation, Infinity Pharmaceuticals Inc, Kyowa Hakko Kirin Co Ltd, Pharmacyclics Inc, Seattle Genetics, Spectrum Pharmaceuticals Inc, Takeda Oncology.

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Consulting Agreements: Bayer HealthCare Pharmaceuticals, Celgene Corporation, Genentech BioOncology, Idera Pharmaceuticals Inc, Novartis Pharmaceuticals Corporation; **Speakers Bureau:** Genentech BioOncology.

MODERATOR — **Dr Love** is president and CEO of Research To Practice, which receives funds in the form of educational grants to develop CME activities from the following commercial interests: AbbVie Inc, Amgen Inc, Astellas Scientific and Medical Affairs Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Pharma Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Dendreon Corporation, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech BioOncology, Genomic Health Inc, Gilead Sciences Inc, ImmunoGen Inc, Incyte Corporation, Janssen Biotech Inc, Jazz Pharmaceuticals Inc, Lilly, Medivation Inc, Merck, Myriad Genetic Laboratories Inc, NanoString Technologies, Novartis Pharmaceuticals Corporation, Novocure, Onyx Pharmaceuticals, an Amgen subsidiary, Pharmacyclics Inc, Prometheus Laboratories Inc, Regeneron Pharmaceuticals, Sanofi, Seattle Genetics, Sigma-Tau Pharmaceuticals Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Teva Oncology, Tokai Pharmaceuticals Inc and VisionGate Inc.

RESEARCH TO PRACTICE STAFF AND EXTERNAL

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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

Last review date: August 2015 Expiration date: August 2016

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Select Publications

A multicenter, open-label, single-arm, phase IIIb, international study evaluating the safety of obinutuzumab alone or in combination with chemotherapy in patients with previously untreated or relapsed/refractory chronic lymphocytic leukemia. NCT01905943

A phase 3, randomized, open-label study evaluating the efficacy and safety of idelalisib in combination with obinutuzumab compared to chlorambucil in combination with obinutuzumab for previously untreated chronic lymphocytic leukemia. NCT01980875

A randomized, multi-center, open-label, phase 3 study of the Bruton's tyrosine kinase inhibitor ibrutinib in combination with obinutuzumab versus chlorambucil in combination with obinutuzumab in subjects with treatment-naïve chronic lymphocytic leukemia or small lymphocytic lymphoma. NCT02264574

A study to compare the efficacy and safety of obinutuzumab + GDC-0199 versus obinutuzumab + chlorambucil in patients with chronic lymphocytic leukemia. NCT02242942

Alduaij W et al. Novel type II anti-CD20 monoclonal antibody (GA101) evokes homotypic adhesion and actin-dependent, lysosome-mediated cell death in B-cell malignancies. *Blood* 2011;117(17):4519-29.

Ansell SM et al. **PD-1** blockade with nivolumab in relapsed or refractory Hodgkin's lymphoma. *N Engl J Med* 2015;372(4):311-9.

Byrd JC et al. Targeting BTK with ibrutinib in relapsed chronic lymphocytic leukemia. N Engl J Med 2013;369(1):32-42.

Coiffier B et al. Results from a pivotal, open-label, phase II study of romidepsin in relapsed or refractory peripheral T-cell lymphoma after prior systemic therapy. *J Clin Oncol* 2012;30(6):631-6.

Davids MS, Letai A. ABT-199: Taking dead aim at BCL-2. Cancer Cell 2013;23(2):139-41.

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.

Flinn IW et al. Randomized trial of bendamustine-rituximab or R-CHOP/R-CVP in first-line treatment of indolent NHL or MCL: The BRIGHT study. *Blood* 2014;123(19):2944-52.

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

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

Goede V et al. **Obinutuzumab plus chlorambucil in patients with CLL and coexisting conditions.** *N Engl J Med* 2014;370(12):1101-10.

Gopal AK et al. **PI3Kō** inhibition by idelalisib in patients with relapsed indolent lymphoma. *N Engl J Med* 2014;370(11):1008-18.

Herter S et al. Superior efficacy of the novel type II, glycoengineered CD20 antibody GA101 vs the type I CD20 antibodies rituximab and ofatumumab. *Proc ASH* 2010; Abstract 3925.

Horwitz SM et al. **Objective responses in relapsed T-cell lymphomas with single-agent brentuximab vedotin.** *Blood* 2014;123(20):3095-100.

Kluin-Nelemans HC et al. Treatment of older patients with mantle-cell lymphoma. N Engl J Med 2012;367(6):520-31.

Le Gouill S et al. Rituximab maintenance versus wait and watch after four courses of R-DHAP followed by autologous stem cell transplantation in previously untreated young patients with mantle cell lymphoma: First interim analysis of the phase III prospective LYMA trial, a LYSA study. *Proc ASH* 2014; Abstract 146.

Manteau 2007 SJ "LYMA" randomized, open-label, phase III study efficacy of rituximab maintenance therapy in patients 18 to 65 years, first-line treatment for MCL. NCT00921414

Moskowitz CH et al. 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.

Moskowitz CH et al. The AETHERA trial: Results of a randomized, double-blind, placebo-controlled phase 3 study of brentuximab vedotin in the treatment of patients at risk of progression following autologous stem cell transplant for Hodgkin lymphoma. *Proc ASH* 2014; Abstract 673.

Select Publications

Moskowitz CH et al. PD-1 blockade with the monoclonal antibody pembrolizumab (MK-3475) in patients with classical Hodgkin lymphoma after brentuximab vedotin failure: Preliminary results from a phase 1b study (KEYNOTE-013). *Proc ASH* 2014; Abstract 290.

Mössner E et al. Increasing the efficacy of CD20 antibody therapy through the engineering of a new type II anti-CD20 antibody with enhanced direct and immune effector cell-mediated B-cell cytotoxicity. *Blood* 2010;115(22):4393-402.

Niederfellner G et al. Epitope characterization and crystal structure of GA101 provide insights into the molecular basis for type I/II distinction of CD20 antibodies. *Blood* 2011;118(2):358-67.

O'Brien S et al. Efficacy and safety of ibrutinib in patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic leukemia with 17p deletion: Results from the phase II RESONATE™-17 trial. *Proc ASH* 2014; Abstract 327.

O'Connor OA et al. Pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma: Results from the pivotal **PROPEL study.** *J Clin Oncol* 2011;29(9):1182-9.

Peyrade F et al. Attenuated immunochemotherapy regimen (R-miniCHOP) in elderly patients older than 80 years with diffuse large B-cell lymphoma: A multicentre, single-arm, phase 2 trial. *Lancet Oncol* 2011;12(5):460-8.

Piekarz RL et al. Phase II multi-institutional trial of the histone deacetylase inhibitor romidepsin as monotherapy for patients with cutaneous T-cell lymphoma. *J Clin Oncol* 2009;27(32):5410-7.

Robak T et al. Bortezomib-based therapy for newly diagnosed mantle-cell lymphoma. N Engl J Med 2015;372(10):944-53.

Rummel MJ et al. Bendamustine plus rituximab versus CHOP plus rituximab as first-line treatment for patients with indolent and mantle-cell lymphomas: An open-label, multicentre, randomised, phase 3 non-inferiority trial. *Lancet* 2013;381(9873):1203-10.

Spigel DR et al. Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). *Proc ASCO* 2013; Abstract 8008.

Sub-cutaneous rituximab-miniCHOP versus sub-cutaneous rituximab-miniCHOP + lenalidomide (R2-miniCHOP) in diffuse large B-cell lymphoma for patients of 80 years old or more. A multicentric phase III study of the LYSA association. NCT02128061

Wang ML et al. Targeting BTK with ibrutinib in relapsed or refractory mantle-cell lymphoma. *N Engl J Med* 2013;369(6):507-16.

Wang ML et al. Ibrutinib and rituximab are an efficacious and safe combination in relapsed mantle cell lymphoma: Preliminary results from a phase II clinical trial. *Proc ASH* 2014; Abstract 627.

Woyach JA et al. The B-cell receptor signaling pathway as a therapeutic target in CLL. Blood 2012;120(6):1175-84.

Younes A et al. Results of a pivotal phase II study of brentuximab vedotin for patients with relapsed or refractory Hodgkin's lymphoma. *J Clin Oncol* 2012;30(18):2183-9.