

Oncology Grand Rounds

Investigators Discuss New Agents and Novel Therapies



A special audio supplement to a CNE symposia series held during the 2017 ONS Annual Congress featuring expert comments on the application of emerging research to patient care

Faculty Interviews

Angeles Alvarez Secord, MD, MHSc
Ovarian Cancer

Ann S LaCasce, MD, MMSc
*Lymphomas and Chronic
Lymphocytic Leukemia*

Denise A Yardley, MD
Breast Cancer

Melissa L Johnson, MD
Non-Small Cell Lung Cancer

Editor

Neil Love, MD

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Oncology Grand Rounds: Investigators Discuss New Agents and Novel Therapies

A Continuing Nursing Education Audio Program

OVERVIEW OF ACTIVITY

The treatment of solid tumors and hematologic cancers remains a challenge for many healthcare professionals. The advent of biologic agents and immunotherapies has led to recent improvements in disease-free and overall survival in select patient populations, and published results from ongoing clinical trials lead to the continual emergence of new therapeutic agents and changes in the use of existing treatments. This dynamic therapeutic environment requires the practicing oncology nurse to stay up to date on the benefits and risks of a plethora of novel and emerging treatment options.

To bridge the gap between research and practice, this program features one-on-one interviews with 4 clinical investigators who participated in satellite symposia held in conjunction with the 2017 Oncology Nursing Society's Annual Congress. These faculty members discuss recent clinical research findings in breast cancer (BC), ovarian cancer (OC), non-small cell lung cancer (NSCLC) and lymphomas and chronic lymphocytic leukemia (CLL). Upon completion of this CNE activity, oncology nurses should be able to formulate an up-to-date and more complete approach to the care of patients with these cancers.

PURPOSE STATEMENT

To present the most current research developments and to provide the perspectives of clinical investigators on the diagnosis and treatment of BC, OC, NSCLC and lymphomas and CLL.

LEARNING OBJECTIVES

- Develop evidence-based strategies for the initial and long-term management of NSCLC, OC, BC, lymphomas and CLL.
- Use an understanding of tumor biomarkers, histology and targetable genetic alterations to individualize the care of patients with NSCLC, OC, BC, lymphomas and CLL.
- Refine or validate cancer-specific treatment algorithms based on existing and emerging research data.
- Evaluate the mechanisms of action, tolerability and efficacy of novel agents under investigation in these tumor types, and consider their potential implications for clinical practice.
- Recognize immune-related adverse events and other common side effects associated with approved and investigational immunotherapies in order to offer supportive management strategies.

ACCREDITATION STATEMENT

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CREDIT DESIGNATION STATEMENT

This educational activity for 2.75 contact hours is provided by Research To Practice during the period of December 2017 through December 2018.

This activity is awarded 2.75 ANCC pharmacotherapeutic contact hours.

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FOR SUCCESSFUL COMPLETION

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- 4 Denise A Yardley, MD**
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- 4 Melissa L Johnson, MD**
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5 SELECT PUBLICATIONS

6 POST-TEST

7 EDUCATIONAL ASSESSMENT AND CREDIT FORM

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EDITOR



Neil Love, MD
Research To Practice
Miami, Florida

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Ovarian Cancer — Interview with Angeles Alvarez Secord, MD, MHSc

Tracks 1-13

- Track 1** Clinical presentation, treatment and prognosis of ovarian cancer (OC)
- Track 2** Efficacy and tolerability of intraperitoneal chemotherapy
- Track 3** Approach to treatment of recurrent OC
- Track 4** Role of bevacizumab for patients with platinum-sensitive and platinum-resistant recurrent OC
- Track 5** Bevacizumab-associated complications
- Track 6** Subtypes of OC and commonly occurring mutations
- Track 7** Mechanism of action of PARP inhibitors
- Track 8** Activity and tolerability of olaparib for OC
- Track 9** FDA approval of rucaparib for patients with BRCA-mutated (germline and/or somatic) advanced OC who have received 2 or more lines of chemotherapy
- Track 10** Efficacy of niraparib and olaparib as maintenance therapy for patients with platinum-sensitive recurrent OC
- Track 11** Recognition and management of thrombocytopenia associated with niraparib
- Track 12** Perspective on the use of bevacizumab as maintenance therapy for platinum-sensitive recurrent OC
- Track 13** Comparison of the side-effect profiles of olaparib, niraparib and rucaparib

Lymphomas and Chronic Lymphocytic Leukemia — Interview with Ann S LaCasce, MD, MMSc

Tracks 1-14

- Track 1** Selection of an up-front treatment regimen for patients with chronic lymphocytic leukemia (CLL) requiring active therapy
- Track 2** Mechanism of action, efficacy and safety of obinutuzumab versus rituximab for CLL
- Track 3** Activity and tolerability of ibrutinib and venetoclax for CLL
- Track 4** Preemptive measures to mitigate the risk of tumor lysis syndrome with venetoclax
- Track 5** Therapeutic options for patients with follicular lymphoma (FL) in the front-line setting
- Track 6** Subcutaneous versus intravenous administration of rituximab
- Track 7** Viewpoint on maintenance therapy for CLL and FL
- Track 8** Benefits and risks of lenalidomide/rituximab (R²) for FL
- Track 9** Biology, clinical presentation and up-front treatment of mantle cell lymphoma (MCL)
- Track 10** Sequencing bortezomib, lenalidomide, ibrutinib and venetoclax for relapsed/refractory MCL
- Track 11** Overview of Hodgkin lymphoma (HL)
- Track 12** Choice of second-line therapy for advanced HL
- Track 13** Mechanism of action, efficacy and side effects of brentuximab vedotin
- Track 14** Activity of the anti-PD-1 antibodies pembrolizumab and nivolumab for relapsed/refractory HL

Breast Cancer — Interview with Denise A Yardley, MD

Tracks 1-14

- Track 1** APHINITY: Results of a Phase III trial evaluating the addition of pertuzumab to chemotherapy/trastuzumab as adjuvant therapy for HER2-positive early breast cancer (BC)
- Track 2** Management of pertuzumab-associated rash and diarrhea
- Track 3** Clinical use of paclitaxel/trastuzumab as adjuvant therapy
- Track 4** ExeNET: Results of a Phase III trial investigating neratinib after trastuzumab-based adjuvant therapy for HER2-positive BC
- Track 5** Sequencing anti-HER2 therapies for patients with metastatic BC (mBC)
- Track 6** Monitoring and management of thrombocytopenia and hepatic toxicities associated with T-DM1
- Track 7** Role of CDK4/6 inhibitors for patients with ER-positive, HER2-negative mBC
- Track 8** Dosing, administration schedules and safety profiles of ribociclib, palbociclib and abemaciclib
- Track 9** Activity and tolerability of everolimus for ER-positive mBC
- Track 10** Mechanism of action of PARP inhibitors and efficacy in patients with BRCA germline-mutant mBC
- Track 11** Spectrum of toxicities associated with PARP inhibitors
- Track 12** Available data with olaparib for mBC in patients with BRCA germline mutations
- Track 13** Molecular profiling for patients with BC
- Track 14** Role of eribulin for patients with metastatic triple-negative BC

Non-Small Cell Lung Cancer — Interview with Melissa L Johnson, MD

Tracks 1-13

- Track 1** Identification of targetable mutations in lung cancer and treatment options for patients with EGFR mutations
- Track 2** Comparative side-effect profiles of afatinib, erlotinib and gefitinib
- Track 3** Development of T790M resistance mutations and response to osimertinib
- Track 4** Biology of ALK-rearranged non-small cell lung cancer (NSCLC) and sensitivity to ALK inhibitors
- Track 5** Activity and tolerability of the FDA-approved ALK inhibitors, crizotinib, ceritinib, alectinib and brigatinib
- Track 6** Treatment options for patients with BRAF V600E mutation-positive NSCLC
- Track 7** Approach to first-line therapy for metastatic squamous cell carcinoma (SCC) of the lung
- Track 8** Therapeutic options for patients with metastatic SCC of the lung and a low or intermediate PD-L1 tumor proportion score
- Track 9** Benefits and risks with the anti-EGFR antibody necitumumab for metastatic SCC of the lung
- Track 10** Efficacy and safety profiles of immune checkpoint inhibitors
- Track 11** Management of anti-PD-1/PD-L1 antibody-associated diarrhea/colitis and pneumonitis
- Track 12** Pembrolizumab in combination with chemotherapy as first-line therapy for previously untreated metastatic NSCLC
- Track 13** Integration of bevacizumab and ramucirumab into the treatment algorithm for nonsquamous NSCLC

SELECT PUBLICATIONS

- Andorsky DJ et al. **Phase IIIb randomized study of lenalidomide plus rituximab (R2) followed by maintenance in relapsed/refractory NHL: Analysis of patients with double-refractory or early relapsed follicular lymphoma (FL).** *Proc ASCO 2017*; **Abstract 7502.**
- Barcenas C et al. **Incidence and severity of diarrhea with neratinib + intensive loperamide prophylaxis in patients (pts) with HER2+ early-stage breast cancer (EBC): Interim analysis from the multicenter, open-label, phase II CONTROL trial.** San Antonio Breast Cancer Symposium 2016; **Abstract P2-11-03.**
- Burke KA et al. **The landscape of somatic genetic alterations in BRCA1 and BRCA2 breast cancers.** San Antonio Breast Cancer Symposium 2016; **Abstract S2-02.**
- Chan A et al. **Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): A multicentre, randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet Oncol* 2016;17(3):367-77.
- Coleman RL et al. **Bevacizumab and paclitaxel-carboplatin chemotherapy and secondary cytoreduction in recurrent, platinum-sensitive ovarian cancer (NRG Oncology/Gynecologic Oncology Group study GOG-0213): A multicentre, open-label, randomised, phase 3 trial.** *Lancet Oncol* 2017;18(6):779-91.
- Davies A et al. **Efficacy and safety of subcutaneous rituximab versus intravenous rituximab for first-line treatment of follicular lymphoma (SABRINA): A randomised, open-label, phase 3 trial.** *Lancet Haematol* 2017;4(6):e272-82.
- Finn RS et al. **Palbociclib and letrozole in advanced breast cancer.** *N Engl J Med* 2016;375(20):1925-36.
- Garon EB et al. **Ramucirumab plus docetaxel versus placebo plus docetaxel for second-line treatment of stage IV non-small-cell lung cancer after disease progression on platinum-based therapy (REVEL): A multicentre, double-blind, randomised phase 3 trial.** *Lancet* 2014;384(9944):665-73.
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- Kaufman B et al. **Olaparib monotherapy in patients with advanced cancer and a germline BRCA1/2 mutation.** *J Clin Oncol* 2015;33(3):244-50.
- Langer C et al. **Randomized, phase 2 study of carboplatin and pemetrexed with or without pembrolizumab as first-line therapy for advanced NSCLC: KEYNOTE-021 cohort G.** *Proc ESMO 2016*; **Abstract LBA46_PR.**
- Ledermann JA et al. **Overall survival in patients with platinum-sensitive recurrent serous ovarian cancer receiving olaparib maintenance monotherapy: An updated analysis from a randomised, placebo-controlled, double-blind, phase 2 trial.** *Lancet Oncol* 2016;17(11):1579-89.
- 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.**
- Mirza MR et al. **Niraparib maintenance therapy in platinum-sensitive, recurrent ovarian cancer.** *N Engl J Med* 2016;375(22):2154-64.
- Oza AM et al. **Standard chemotherapy with or without bevacizumab for women with newly diagnosed ovarian cancer (ICON7): Overall survival results of a phase 3 randomised trial.** *Lancet Oncol* 2015;16(8):928-36.
- Robson M et al. **Olaparib for metastatic breast cancer in patients with a germline BRCA mutation.** *N Engl J Med* 2017;377(17):1700.
- Robson ME et al. **OlympiAD: Phase III trial of olaparib monotherapy versus chemotherapy for patients (pts) with HER2-negative metastatic breast cancer (mBC) and a germline BRCA mutation (gBRCAm).** *Proc ASCO 2017*; **Abstract LBA4.**
- Swain SM et al; CLEOPATRA Study Group. **Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer.** *N Engl J Med* 2015;372(8):724-34.
- Tolaney S et al. **Seven-year (yr) follow-up of adjuvant paclitaxel (T) and trastuzumab (H) (APT trial) for node-negative, HER2-positive breast cancer (BC).** *Proc ASCO 2017*; **Abstract 511.**
- Von Minckwitz G et al. **APHINITY trial (BIG 4-11): A randomized comparison of chemotherapy (C) plus trastuzumab (T) plus placebo (Pla) versus chemotherapy plus trastuzumab (T) plus pertuzumab (P) as adjuvant therapy in patients (pts) with HER2-positive early breast cancer (EBC).** *Proc ASCO 2017*; **Abstract LBA500.**

QUESTIONS (PLEASE CIRCLE ANSWER):

1. Rucaparib was recently approved by the FDA for patients with OC who have _____.
 - a. Received 2 or more prior chemotherapies
 - b. Germline but not somatic BRCA mutations
 - c. Both a and b

2. Results from the GOG-0213 trial investigating the addition of bevacizumab to platinum-based chemotherapy demonstrated a significant improvement in _____ for patients with platinum-sensitive recurrent OC.
 - a. Progression-free survival
 - b. Overall survival
 - c. Both a and b

3. Strategies to mitigate the risk of tumor lysis syndrome in patients starting therapy with venetoclax include which of the following?
 - a. Prophylactic hydration
 - b. Administration of allopurinol/rasburicase
 - c. Five-week ramp-up dosing schedule
 - d. All of the above

4. In comparison to intravenous administration, the subcutaneous administration of rituximab is associated with _____.
 - a. A shorter infusion time of 5 to 7 minutes
 - b. Similar efficacy
 - c. A higher rate of infusion reactions
 - d. All of the above
 - e. Both a and b
 - f. Both a and c
 - g. Both b and c

5. Which of the following categories reflects the mechanism of action of obinutuzumab?
 - a. Antibody-drug conjugate
 - b. Anti-PD-1/PD-L1 antibody
 - c. Anti-CD20 antibody
 - d. Tyrosine kinase inhibitor

6. Which of the following ALK inhibitors penetrates the central nervous system (CNS) well and thus exhibits significant activity in patients with NSCLC and CNS metastases?
 - a. Alectinib
 - b. Ceritinib
 - c. Brigatinib
 - d. All of the above
 - e. Only a and b

7. The third-generation EGFR inhibitor osimertinib targets both the T790M mutation and wild-type EGFR.
 - a. True
 - b. False

8. The OlympiAD trial evaluating olaparib monotherapy versus chemotherapy demonstrated an improvement in outcomes in the olaparib arm for which patients with HER2-negative metastatic BC?
 - a. All patients
 - b. Those with germline BRCA1 or 2 mutations

9. Results of the Phase III APHINITY trial evaluating the addition of pertuzumab to trastuzumab and chemotherapy demonstrated a modest improvement in invasive disease-free survival among patients with HER2-positive early BC who received the pertuzumab-containing regimen.
 - a. True
 - b. False

10. Prophylactic administration of anti-diarrheal medication and corticosteroids decreases by more than half the incidence of Grade 3 or higher diarrhea associated with neratinib.
 - a. True
 - b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Oncology Grand Rounds: Investigators Discuss New Agents and Novel Therapies

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
OlympiAD: Results of a Phase III trial evaluating olaparib versus chemotherapy for HER2-negative mBC	4 3 2 1	4 3 2 1
Activity and tolerability of CDK4/6 inhibitors in patients with ER-positive, HER2-negative mBC	4 3 2 1	4 3 2 1
Role of niraparib and olaparib as maintenance therapy for patients with platinum-sensitive recurrent OC	4 3 2 1	4 3 2 1
GOG-0213 trial: Improvement in overall survival with the addition of bevacizumab to platinum-based chemotherapy for patients with platinum-sensitive recurrent OC	4 3 2 1	4 3 2 1
Preemptive measures to mitigate the risk of tumor lysis syndrome with venetoclax	4 3 2 1	4 3 2 1
Indications for PD-L1 testing and role of pembrolizumab as first-line therapy for patients with NSCLC and a PD-L1 tumor proportion score higher than or equal to 50%	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).....

Approximately how many new patients with the following do you see per year?

Breast cancer Ovarian cancer Non-small cell lung cancer
 Chronic lymphocytic leukemia Follicular lymphoma Mantle cell lymphoma
 Hodgkin lymphoma

Was the activity evidence based, fair, balanced and free from commercial bias?

Yes No If no, please explain:.....

Will this activity help you improve patient care?

Yes No Not applicable

If yes, how will it help you improve patient care?.....

Did the activity meet your educational needs and expectations?

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:

- Develop evidence-based strategies for the initial and long-term management of NSCLC, OC, BC, lymphomas and CLL. 4 3 2 1 N/M N/A
- Use an understanding of tumor biomarkers, histology and targetable genetic alterations to individualize the care of patients with NSCLC, OC, BC, lymphomas and CLL. 4 3 2 1 N/M N/A
- Refine or validate cancer-specific treatment algorithms based on existing and emerging research data. 4 3 2 1 N/M N/A
- Evaluate the mechanisms of action, tolerability and efficacy of novel agents under investigation in these tumor types, and consider their potential implications for clinical practice. 4 3 2 1 N/M N/A
- Recognize immune-related adverse events and other common side effects associated with approved and investigational immunotherapies in order to offer supportive management strategies. 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

What other practice changes will you make or consider making as a result of this activity?

.....

What are the barriers to keep you from making a practice change based upon this educational activity?

.....

What additional information or training do you need on the activity topics or other oncology-related topics?

.....

Additional comments about this activity:

.....

PART 2 — Please tell us about the faculty and editor for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter				Effectiveness as an educator			
Angeles Alvarez Secord, MD, MHSc	4	3	2	1	4	3	2	1
Ann S LaCasce, MD, MMSc	4	3	2	1	4	3	2	1
Denise A Yardley, MD	4	3	2	1	4	3	2	1
Melissa L Johnson, MD	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

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and editor for this activity:

.....

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