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Breast Cancer® UPDATE

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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ABIM CME MOC ACCREDITED

CME Certified

Breast Cancer® UPDATE

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OVERVIEW OF ACTIVITY

Breast cancer (BC) continues to be one of the most rapidly evolving fields in medical oncology. Results from numerous ongoing trials lead to the continual emergence of new therapeutic agents, treatment strategies and diagnostic and prognostic tools. In order to offer optimal patient care — including the option of clinical trial participation — the practicing cancer clinician must be well informed of these advances. Featuring information on the latest research developments along with expert perspectives, this CME activity is designed to assist medical oncologists, hematologist-oncologists and hematology-oncology fellows with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Develop an evidence-based algorithm for the treatment of hormone-sensitive advanced BC, including the use of endocrine, biologic and chemotherapeutic agents.
- Implement a clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and emerging targeted treatments.
- Consider published research findings and patient preferences in the selection and sequencing of available and investigational therapeutic agents for patients with metastatic triple-negative BC.
- Understand emerging efficacy data and side effects with the use of PARP inhibitors for patients with BRCA-mutated advanced BC, and consider potential therapeutic implications of these findings on future clinical care.
- Consider the use of available biomarkers and genomic assays to assess risk and individualize therapy for patients with BC in the neoadjuvant and adjuvant settings.
- Recall the results of pivotal trials introducing effective new BC therapeutic agents, and identify their potential effects on existing treatment algorithms.
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials investigating novel therapeutic agents and strategies.

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Interview with Karen A Gelmon, MD

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Track 21	Clinical significance of ESR1 mutations for patients with ER-positive BC
Track 22	Areas for investigation in BC research with the greatest potential for clinical and therapeutic application

SELECT PUBLICATIONS

Alternate approaches for clinical stage II or III estrogen receptor positive breast cancer neoadjuvant treatment (ALTERNATE) in postmenopausal women: A phase III study (A011106). NCT01953588

Blum JL et al. **Anthracyclines in early breast cancer: The ABC trials — USOR 06-090, NSABP B-46-I/USOR 07132, and NSABP B-49 (NRG Oncology).** *J Clin Oncol* 2017;35(23):2647-55.

Cardoso F et al. **70-gene signature as an aid to treatment decisions in early-stage breast cancer.** *N Engl J Med* 2016;375(8):717-29.

Carey LA. **De-escalating and escalating systemic therapy in triple negative breast cancer.** *Breast* 2017;34(Suppl 1):112-5.

Chan A et al; ExteNET Study Group. **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.

Finn RS et al. **Palbociclib and letrozole in advanced breast cancer.** *N Engl J Med* 2016;375(20):1925-36.

Freedman R et al. **TBCRC 022: Phase II trial of neratinib + capecitabine for patients (Pts) with human epidermal growth factor receptor 2 (HER2+) breast cancer brain metastases (BCBM).** *Proc ASCO* 2017;**Abstract 1005**.

Gluz O et al. **West German Study Group phase III PlanB trial: First prospective outcome data for the 21-gene Recurrence Score assay and concordance of prognostic markers by central and local pathology assessment.** *J Clin Oncol* 2016;34(20):2341-9.

Harris LN et al; American Society of Clinical Oncology. **Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology Clinical Practice Guideline.** *J Clin Oncol* 2016;34(10):1134-50.

King TA et al. **A prospective analysis of surgery and survival in stage IV breast cancer (TBCRC 013).** *Proc ASCO* 2016;**Abstract 1006**.

Krop I et al. **Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update.** *J Clin Oncol* 2017;35(24):2838-47.

Kuang Y et al. **The emergence of ESR1 mutations is associated with aromatase inhibitor and fulvestrant therapy.** *Proc AACR* 2017;**Abstract 4950**.

Love N et al. **HER2 and estrogen receptor status drive decisions regarding the use of neoadjuvant chemotherapy.** San Antonio Breast Cancer Symposium 2015;**Abstract P1-14-20**.

Malorni L et al. **A phase II trial of the CDK4/6 inhibitor palbociclib (P) as single agent or in combination with the same endocrine therapy (ET) received prior to disease progression, in patients (pts) with hormone receptor positive (HR+) HER2 negative (HER2-) metastatic breast cancer (mBC) (TREnd trial).** *Proc ASCO* 2017;**Abstract 1002**.

Partridge A, Carey L. **Unmet needs in clinical research in breast cancer: Where do we need to go?** *Clin Cancer Res* 2017;23(11):2611-6.

Ramhorst M et al. **A phase III trial of neoadjuvant chemotherapy with or without anthracyclines in the presence of dual HER2-blockade for HER2+ breast cancer: The TRAIN-2 study (BOOG 2012-03).** *Proc ASCO* 2017;**Abstract 507**.

Robson M et al. **Olaparib for metastatic breast cancer in patients with a germline BRCA mutation.** *N Engl J Med* 2017;377(6):523-33.

Shak S et al. **Breast cancer specific survival in 38,568 patients with node negative hormone receptor positive invasive breast cancer and Onco*type* DX Recurrence Score results in the SEER database.** San Antonio Breast Cancer Symposium 2015;**Abstract P5-15-01**.

Sledge G et al. **MONARCH 2: Abemaciclib in combination with fulvestrant in women with HR+/HER2− advanced breast cancer who had progressed while receiving endocrine therapy.** *J Clin Oncol* 2017;35(25):2875-84.

Spoerke JM et al. **Heterogeneity and clinical significance of ESR1 mutations in ER-positive metastatic breast cancer patients receiving fulvestrant.** *Nat Commun* 2016;7:11579.

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. **Which of the following statements are true regarding the Phase III MONARCH 2 trial investigating the combination of abemaciclib and fulvestrant for women with ER-positive, HER2-negative advanced BC?**
   a. The patients in the study had not received prior therapy
   b. Abemaciclib was administered on a continuous schedule
   c. The combination significantly increased progression-free survival (PFS) compared to fulvestrant alone
   d. All of the above
   e. Both b and c
   f. Both a and b

2. **Recent results from the Phase II TREnd trial of palbociclib alone or in combination with the same endocrine therapy received prior to disease progression in ER-positive, HER2-negative mBC demonstrated no improvement in PFS with the addition of palbociclib.**
   a. True
   b. False

3. **In terms of treatment side effects, patients receiving abemaciclib may experience _____ neutropenia and _____ diarrhea in comparison to those receiving palbociclib and ribociclib.**
   a. Less, more
   b. Similar, similar
   c. Similar, more
   d. More, less

4. **The ExteNET trial investigating neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive BC showed a greater benefit in invasive disease-free survival in patients with _____.**
   a. Hormone receptor-positive disease
   b. Hormone receptor-negative disease
   c. Benefit was independent of hormone receptor status

5. **The Phase III CREATE-X trial demonstrated that the addition of adjuvant capecitabine after standard neoadjuvant chemotherapy elicited a greater benefit in terms of overall survival among patients with _____ BC and residual invasive disease.**
   a. HER2-negative (triple-negative)
   b. HER2-positive

6. **Final overall survival results of the PALOMA-1 (TRIO-18) trial of first-line letrozole with or without palbociclib in ER-positive, HER2-negative advanced BC _____ a statistically significant improvement in overall survival with the addition of palbociclib.**
   a. Demonstrated
   b. Did not demonstrate

7. **A Phase III trial comparing eribulin to capecitabine in patients with previously treated, advanced BC demonstrated that _____ in the overall population.**
   a. Eribulin was superior to capecitabine
   b. Capecitabine was superior to eribulin
   c. Both agents were equivalent

8. **The Phase III OlympiAD trial evaluated olaparib monotherapy versus chemotherapy for patients with HER2-negative mBC and _____.**
   a. Somatic BRCA mutations
   b. Germline BRCA mutations
   c. Both germline and somatic BRCA mutations

9. **Patients with ER-positive BC and ESR1 mutations are sensitive to _____.**
   a. Aromatase inhibitors
   b. Fulvestrant
   c. Both a and b

10. **The APHINITY trial investigating the addition of pertuzumab to adjuvant trastuzumab and chemotherapy for patients with HER2-positive early BC demonstrated better outcomes in patients with node-negative versus node-positive BC.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update — Volume 16, Issue 2

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
Clinical implications of the OlympiAD trial investigating olaparib versus chemotherapy for patients with metastatic HER2-negative BC	4 3 2 1	4 3 2 1
Efficacy and tolerability of neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive BC	4 3 2 1	4 3 2 1
FDA approval of abemaciclib and the integration of this CDK4/6 inhibitor into the clinical management of hormone receptor-positive, HER2-negative advanced BC	4 3 2 1	4 3 2 1
Results after a 7-year follow-up of the APT trial evaluating adjuvant paclitaxel/trastuzumab for node-negative, HER2-positive BC	4 3 2 1	4 3 2 1
CREATE-X: A Phase III trial of adjuvant capecitabine for patients with HER2-negative residual invasive BC after neoadjuvant chemotherapy	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 breast cancer do you see per year? ..... patients

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:

- Develop an evidence-based algorithm for the treatment of hormone-sensitive advanced BC, including the use of endocrine, biologic and chemotherapeutic agents. . . . . 4 3 2 1 N/M N/A
- Implement a clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and emerging targeted treatments. . . . . 4 3 2 1 N/M N/A
- Consider published research findings and patient preferences in the selection and sequencing of available and investigational therapeutic agents for patients with metastatic triple-negative BC. . . . . 4 3 2 1 N/M N/A
- Understand emerging efficacy data and side effects with the use of PARP inhibitors for patients with BRCA-mutated advanced BC, and consider potential therapeutic implications of these findings on future clinical care. . . . . 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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- Consider the use of available biomarkers and genomic assays to assess risk and individualize therapy for patients with BC in the neoadjuvant and adjuvant settings. . . . . 4 3 2 1 N/M N/A
- Recall the results of pivotal trials introducing effective new BC therapeutic agents, and identify their potential effects on existing treatment algorithms. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials investigating novel therapeutic agents and strategies. . . . . 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 addressed in future educational activities:

.....

Would you recommend this activity to a colleague?

☐ Yes ☐ No

If no, please explain: .....

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Karen A Gelmon, MD	4 3 2 1	4 3 2 1
Lisa A Carey, 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

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UPDATE

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