

Breast Cancer[®]

U P D A T E

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

FACULTY INTERVIEWS

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EDITOR

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Breast Cancer®

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Breast Cancer Update

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Breast cancer 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

- Implement a clinical plan for the management of metastatic HER2-positive breast cancer, incorporating existing and emerging targeted treatments.
- Develop an understanding of the efficacy data and toxicity profiles of PARP inhibitors for patients with HER2-negative and BRCA-mutated advanced breast cancer.
- Develop an evidence-based algorithm for the treatment of hormone-sensitive advanced breast cancer, including the use of endocrine, biologic and chemotherapeutic agents.
- Consider the use of available biomarkers and genomic assays to assess risk and individualize therapy for patients with breast cancer in the neoadjuvant and adjuvant settings.
- Recall the results of pivotal trials introducing effective new breast cancer therapeutic agents, and identify their potential effect on existing treatment algorithms.
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials.

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Interview with Mark Robson, MD

Tracks 1-21

Track 1	Side effects associated with PARP inhibitors	Track 13	Case: A 47-year-old woman with a 0.9-cm, Grade 2, ER/PR/HER2-positive invasive ductal carcinoma (IDC) receives adjuvant trastuzumab/paclitaxel
Track 2	Efficacy of olaparib for patients with BRCA germline-mutant metastatic triple-negative breast cancer (mTNBC)	Track 14	APHINITY trial: Results of a Phase III study evaluating the addition of pertuzumab to chemotherapy and trastuzumab as adjuvant therapy for patients with HER2-positive early BC
Track 3	OlympiAD: A Phase III trial of olaparib monotherapy versus chemotherapy for patients with HER2-negative metastatic breast cancer (mBC) and a germline BRCA mutation	Track 15	Adjuvant pertuzumab for patients with HER2-positive, node-positive mBC
Track 4	Somatic alterations in BRCA1/2 genes and response to PARP inhibitors	Track 16	Case: A 65-year-old woman with ER-positive, HER2-negative mBC receives fulvestrant and palbociclib after disease relapse on exemestane
Track 5	BRCA testing for patients with BC	Track 17	Therapeutic options for patients with ER-positive, HER2-negative mBC after disease progression on a CDK4/6 inhibitor
Track 6	Importance of genetic counseling for patients with germline mutations	Track 18	Targeting the androgen receptor in patients with mTNBC
Track 7	Clinical implications of the OlympiAD study results for patients with HER2-negative mBC	Track 19	Case: A 54-year-old woman with bilateral ER/PR-positive, HER2-negative BC, 2 positive sentinel lymph nodes and a high genomic risk by the 70-gene assay
Track 8	TNT trial: Results of a Phase III study of carboplatin versus docetaxel for patients with metastatic or recurrent locally advanced triple-negative or BRCA1/2 mutation-associated BC	Track 20	Use of the 21-gene assay for patients with ER-positive, node-positive BC
Track 9	Management of nausea and anemia associated with olaparib	Track 21	Case: A 49-year-old woman with BRCA mutation-positive mTNBC experiences rapid disease progression through several lines of therapy, including olaparib
Track 10	Case: A 49-year-old woman with BRCA-mutant mTNBC whose disease progresses through several lines of systemic therapy		
Track 11	Mutational landscape of BC		
Track 12	Ongoing trials of PARP inhibitors in the (neo)adjuvant setting		

Interview with Ian E Krop, MD, PhD

Tracks 1-22

Track 1	Case: A 68-year-old woman with ER/PR-positive, HER2-negative, moderately differentiated IDC and 5 of 20 positive axillary nodes	Track 4	Comparison of the 21-gene RS versus the 70-gene assay to determine benefit from chemotherapy in patients with ER-positive BC
Track 2	PALLAS: An ongoing Phase III trial evaluating the addition of palbociclib to adjuvant endocrine therapy for hormone receptor-positive, HER2-negative early BC	Track 5	Updated ASCO clinical practice guidelines on the use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive BC
Track 3	Role of the 21-gene Recurrence Score® (RS) in the neoadjuvant setting	Track 6	MINDACT trial: Utility of the 70-gene assay in selecting patients with BC and 1 to 3 positive nodes for adjuvant chemotherapy

Interview with Dr Krop (continued)

- Track 7** ABC trials: TC versus anthracycline/taxane-based chemotherapy for high-risk HER2-negative BC
- Track 8** Role of anthracyclines in patients with HER2-positive BC
- Track 9** **Case:** A 56-year-old woman with ER/PR-positive, HER2-negative invasive lobular BC and bone metastases
- Track 10** Emergence of ESR1 mutations in patients with ER-positive mBC
- Track 11** Clinical significance of ESR1 mutations in patients receiving fulvestrant for ER-positive mBC
- Track 12** Detection of ESR mutations in the plasma of patients with ER-positive BC
- Track 13** CDK4/6 inhibitors as first-line therapy for patients with ER-positive, HER2-negative mBC
- Track 14** Efficacy and tolerability of CDK4/6 inhibitors for patients with ER-positive, HER2-negative mBC
- Track 15** Activity and tolerability of abemaciclib
- Track 16** **Case:** A 52-year-old woman with a Stage I, ER/PR-negative, HER2-positive, poorly differentiated IDC
- Track 17** APT trial: Results after a 7-year follow-up of adjuvant paclitaxel/trastuzumab for lower-risk, HER2-positive BC
- Track 18** Results of the APHINITY trial evaluating adjuvant pertuzumab
- Track 19** ExteNET: Results of a Phase III trial investigating neratinib after trastuzumab-based adjuvant therapy for patients with HER2-positive BC
- Track 20** ATEMPT: An ongoing Phase II trial evaluating T-DM1 versus trastuzumab/paclitaxel for Stage I, HER2-positive BC
- Track 21** Efficacy of enzalutamide in BC
- Track 22** **Case:** A 40-year-old woman with mTNBC and a BRCA1 mutation receives olaparib on the OlympiAD trial

Video Program

View the corresponding video interviews with (from left) Drs Robson and Krop by Dr Love at www.ResearchToPractice.com/BCU117/Video



SELECT PUBLICATIONS

Aebi S et al. **Chemotherapy for isolated locoregional recurrence of breast cancer (CALOR): A randomised trial.** *Lancet Oncol* 2014;15(2):156-63.

ALternAtive 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.

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.**

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.

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.

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

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.

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;[Epub ahead of print].

Krop I et al. **A single-arm phase 2 study to assess clinical activity, efficacy and safety of enzalutamide with trastuzumab in HER2+ AR+ metastatic or locally advanced breast cancer.** San Antonio Breast Cancer Symposium 2016;**Abstract P4-22-08.**

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.**

PALbociclib coLlaborative Adjuvant Study: A randomized phase III trial of palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+)/human epidermal growth factor receptor 2 (HER2)-negative early breast cancer (PALLAS). [NCT02513394](#)

Robson M et al. **Olaparib for metastatic breast cancer in patients with a germline BRCA mutation.** *N Engl J Med* 2017;[Epub ahead of print].

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.**

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

Sparano JA et al. **Prospective trial of endocrine therapy alone in patients with estrogen receptor positive, HER2-negative, node-negative breast cancer: Results of the TAILORx low risk registry.** San Antonio Breast Cancer Symposium 2015;**Abstract P2-08-01.**

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):

- The goal of the MINDACT trial, for which initial results were recently published, was to evaluate the benefit of genomic profiling with the _____ in addition to standard clinical-pathological criteria for identifying patients with early BC and 0 to 3 positive lymph nodes who might safely forgo chemotherapy without compromising outcome.
 - PAM50 assay
 - 70-gene signature
 - 21-gene signature
- The ongoing randomized Phase II ATEMPT trial is comparing _____ to trastuzumab/paclitaxel for patients with Stage I HER2-positive BC.
 - Trastuzumab alone
 - Trastuzumab emtansine (T-DM1)
 - Pertuzumab/paclitaxel
- The Phase III OlympiAD trial of olaparib monotherapy versus chemotherapy for patients with HER2-negative mBC and a germline BRCA mutation demonstrated a statistically significant improvement in progression-free survival with olaparib.
 - True
 - False
- Which of the following toxicities is exhibited to a greater extent in patients receiving abemaciclib than in those receiving palbociclib or ribociclib for ER-positive mBC?
 - Diarrhea
 - Neutropenia
 - Myelosuppression
 - All of the above
- The Phase III ExteNET trial investigating neratinib versus placebo after trastuzumab-based adjuvant therapy for patients with HER2-positive BC _____ an invasive disease-free survival benefit with neratinib.
 - Demonstrated
 - Did not demonstrate
- Which of the following drug types reflects the mechanism of action of fulvestrant?
 - Selective estrogen receptor degrader
 - Selective estrogen receptor modulator
 - Both a and b
 - Neither a nor b
- Results of the APT trial evaluating adjuvant paclitaxel/trastuzumab for patients with node-negative, HER2-positive BC showed that the rate of distant recurrence after a 7-year follow-up analysis was _____.
 - 1%
 - 15%
 - 50%
- Joint analysis of the ABC trials comparing a taxane with anthracycline to nonanthracycline-based regimens for HER2-negative, early BC demonstrated the benefit of anthracyclines in patients with _____ disease.
 - Low-risk
 - High-risk
 - Both a and b
- The Phase III TNT trial comparing carboplatin to docetaxel for mTNBC demonstrated that in a subgroup of patients with BRCA1/2 mutations, a significant difference was evident in _____ in favor of carboplatin.
 - Overall response rate
 - Progression-free survival
 - Both a and b
- Results of the Phase III APHINITY trial demonstrated that the addition of pertuzumab to trastuzumab and chemotherapy significantly improved invasive disease-free survival for patients with HER2-positive early BC.
 - True
 - False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update — Volume 16, Issue 1

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 trial: Results of a Phase III trial evaluating olaparib versus chemotherapy for BRCA-mutant HER2-negative mBC	4	3	2	1
Clinical implications of the Phase III APHINITY trial and the potential role of pertuzumab as a component of adjuvant therapy for patients with early-stage HER2-positive BC	4	3	2	1
APT trial: Results after a 7-year follow-up of adjuvant paclitaxel/trastuzumab for node-negative, HER2-positive BC	4	3	2	1
Updated ASCO guideline recommendation regarding the use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive BC	4	3	2	1
Clinical significance of ESR1 mutations for patients with hormone receptor-positive mBC	4	3	2	1
Activity and tolerability of CDK4/6 inhibitors for patients with ER-positive, HER2-negative mBC	4	3	2	1
ExteNET: Results of a Phase III trial investigating neratinib after trastuzumab-based adjuvant therapy for patients with HER2-positive BC	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:

- Implement a clinical plan for the management of metastatic HER2-positive breast cancer, incorporating existing and emerging targeted treatments. 4 3 2 1 N/M N/A
- Develop an understanding of the efficacy data and toxicity profiles of PARP inhibitors for patients with HER2-negative and BRCA-mutated advanced breast cancer. 4 3 2 1 N/M N/A
- Develop an evidence-based algorithm for the treatment of hormone-sensitive advanced breast cancer, including the use of endocrine, biologic and chemotherapeutic agents... 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

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

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			
Mark Robson, MD	4	3	2	1	4	3	2	1
Ian E Krop, MD, PhD	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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