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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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EDITOR

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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, hematologists-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 long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and investigational targeted treatments.
- Consider the use of available biomarkers and genomic assays to assess risk and individualize therapy for patients in the neoadjuvant, adjuvant and extended-adjuvant settings.
- Appraise novel treatment strategies under investigation in advanced BC (eg, anti-PD-1/PD-L1 antibodies, antiandrogens).
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials investigating novel therapeutic agents and strategies.

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CME INFORMATION

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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: **Dr Rugo** — Contracted Research: Eisai Inc, Genentech BioOncology, GlaxoSmithKline, Lilly, MacroGenics Inc, Merck, Novartis Pharmaceuticals Corporation, Pfizer Inc, Plexxikon Inc, Roche Laboratories Inc; Speakers Bureau: Genomic Health Inc. **Dr Hurvitz** — Contracted Research: Amgen Inc, Bayer HealthCare Pharmaceuticals, BioMarin Pharmaceutical Inc, Boehringer Ingelheim Pharmaceuticals Inc, Dignitana, Genentech BioOncology, GlaxoSmithKline, Lilly, Novartis Pharmaceuticals Corporation, OBI Pharma Inc, Pfizer Inc, Puma Biotechnology Inc.

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Interview with Hope S Rugo, MD

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Bonus Audio Available Exclusively Online

Please visit www.ResearchToPractice.com/BCU116 for additional discussion.

Interview with Hope S Rugo, MD

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Topic 2 Mechanism of action and activity of the investigational immunotherapeutic agent OPT-822/OPT-821 in patients with mBC

Topic 3 Assessment of tumor-infiltrating lymphocytes and immune checkpoint expression in patients with BC

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Topic 14 **Case discussion:** A 30-year-old woman with TNBC and a BRCA1 deleterious mutation

Topic 15 ABC trial: TC versus anthracycline/taxane-based chemotherapy for high-risk HER2-negative BC

Topic 16 BCIRG 006: 10-year follow-up of a Phase III trial comparing AC → T, AC → TH and TC/trastuzumab (TCH) for HER2-positive early BC

Topic 17 Efficacy and tolerability of the PARP inhibitor talazoparib

Topic 18 Use of palbociclib/fulvestrant for mTNBC

Topic 19 **Case discussion:** A 36-year-old woman with ER/PR-positive, HER2-positive infiltrating ductal carcinoma treated with TCH in conjunction with the DigniCap scalp-cooling device

SELECT PUBLICATIONS

A phase 3, open-label, randomized, parallel, 2-arm, multi-center study of talazoparib (BMN 673) versus physician's choice in germline BRCA mutation subjects with locally advanced and/or metastatic breast cancer, who have received prior chemotherapy regimens for metastatic disease. NCT01945775

A randomized, placebo-controlled, double-blind, phase 3 study evaluating safety and efficacy of the addition of veliparib plus carboplatin versus the addition of carboplatin to standard neoadjuvant chemotherapy versus standard neoadjuvant chemotherapy in subjects with early stage triple negative breast cancer (TNBC). NCT02032277

Adams S et al. **Phase Ib trial of atezolizumab in combination with *nab*-paclitaxel in patients with metastatic triple-negative breast cancer (mTNBC).** *Proc ASCO* 2016;**Abstract 1009**.

Blum JL et al. **Interim joint analysis of the ABC (Anthracyclines in Early Breast Cancer) phase III trials (USOR 06-090, NSABP B-46I/USOR 07132, NSABP B-49 [NRG Oncology]) comparing docetaxel + cyclophosphamide (TC) v anthracycline/taxane-based chemotherapy regimens (TaxAC) in women with high-risk, HER2-negative breast cancer.** *Proc ASCO* 2016;**Abstract 1000**.

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.

Chlebowski RT et al. **Low-fat dietary pattern and breast cancer mortality in the Women's Health Initiative (WHI) randomized trial.** *Proc AACR* 2016;**Abstract CT043**.

Dickler MN et al. **MONARCH1: Results from a phase II study of abemaciclib, a CDK4 and CDK6 inhibitor, as monotherapy, in patients with HR+/HER2- breast cancer, after chemotherapy for advanced disease.** *Proc ASCO* 2016;**Abstract 510**.

Emens LA et al. **IMpassion130: A Phase III randomized trial of atezolizumab with *nab*-paclitaxel for first-line treatment of patients with metastatic triple-negative breast cancer (mTNBC).** *Proc ASCO* 2016;**Abstract TPS1104**.

Finn RS et al. **PALOMA-2: Primary results from a phase III trial of palbociclib (P) with letrozole (L) compared with letrozole alone in postmenopausal women with ER+/HER2– advanced breast cancer (ABC).** *Proc ASCO* 2016;**Abstract 507**.

Goss PE et al. **A randomized trial (MA.17R) of extending adjuvant letrozole for 5 years after completing an initial 5 years of aromatase inhibitor therapy alone or preceded by tamoxifen in postmenopausal women with early-stage breast cancer.** *Proc ASCO* 2016;**Abstract LBA1**.

Huang CS et al. **Randomized phase II/III trial of active immunotherapy with OPT-822/OPT-821 in patients with metastatic breast cancer.** *Proc ASCO* 2016;**Abstract 1003**.

Hurvitz SA et al. **Pathologic complete response (pCR) rates after neoadjuvant trastuzumab emtansine (T-DM1 [K]) + pertuzumab (P) vs docetaxel + carboplatin + trastuzumab + P (TCHP) treatment in patients with HER2-positive (HER2+) early breast cancer (EBC) (KRISTINE).** *Proc ASCO* 2016;**Abstract 500**.

I-SPY 2 trial (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and moLecular Analysis 2). NCT01042379

monarcHER: A phase 2, randomized, multicenter, 3-arm, open-label study to compare the efficacy of abemaciclib plus trastuzumab with or without fulvestrant to standard-of-care chemotherapy of physician's choice plus trastuzumab in women with HR+, HER2+ locally advanced or metastatic breast cancer. NCT02675231

Nanda R et al. **Pembrolizumab in patients with advanced triple-negative breast cancer: Phase Ib KEYNOTE-012 study.** *J Clin Oncol* 2016;34(21):2460-7.

Piccart M et al. **Primary analysis of the EORTC 10041/BIG 3-04 MINDACT study: A prospective, randomized study evaluating the clinical utility of the 70-gene signature (MammaPrint) combined with common clinical-pathological criteria for selection of patients for adjuvant chemotherapy in breast cancer with 0 to 3 positive nodes.** *Proc AACR* 2016;**Abstract CT039**.

Rugo HS et al. **Heritage: A phase III safety and efficacy trial of the proposed trastuzumab biosimilar Myl-1401O versus Herceptin.** *Proc ASCO* 2016;**Abstract LBA503**.

Rugo HS et al. **Prevention of everolimus/exemestane (EVE/EXE) stomatitis in postmenopausal (PM) women with hormone receptor-positive (HR+) metastatic breast cancer (MBC) using a dexamethasone-based mouthwash (MW): Results of the SWISH trial.** *Proc ASCO* 2016;**Abstract 525**.

Rugo HS et al. **Preliminary efficacy and safety of pembrolizumab (MK-3475) in patients with PD-L1–positive, estrogen receptor-positive (ER+)/HER2-negative advanced breast cancer enrolled in KEYNOTE-028.** San Antonio Breast Cancer Symposium 2015;**Abstract S5-07**.

Slamon D et al. **Ten year follow-up of BCIRG-006 comparing doxorubicin plus cyclophosphamide followed by docetaxel (AC → T) with doxorubicin plus cyclophosphamide followed by docetaxel and trastuzumab (AC → TH) with docetaxel, carboplatin and trastuzumab (TCH) in HER2+ early breast cancer.** San Antonio Breast Cancer Symposium 2015;**Abstract S5-04**.

Toi M et al. **A phase III trial of adjuvant capecitabine in breast cancer patients with HER2-negative pathologic residual invasive disease after neoadjuvant chemotherapy (CREATE-X, JBCRG-04).** San Antonio Breast Cancer Symposium 2015;**Abstract S1-07**.

Urruticoechea A et al. **PHEREXA: A phase III study of trastuzumab (H) + capecitabine (X) ± pertuzumab (P) for patients (pts) who progressed during/after one line of H-based therapy in the HER2-positive metastatic breast cancer (MBC) setting.** *Proc ASCO* 2016;**Abstract 504**.

Vidula N et al. **Androgen receptor (AR) expression in primary breast cancer (BC): Correlations with clinical characteristics and outcomes.** *Proc ASCO* 2016;**Abstract 1072**.

Winer E et al. **KEYNOTE-119: A randomized phase III study of single-agent pembrolizumab (MK-3475) vs single-agent chemotherapy per physician's choice for metastatic triple-negative breast cancer (mTNBC).** *Proc ASCO* 2016;**Abstract TPS1102**.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The Phase III PHEREXA trial evaluating trastuzumab/capecitabine with or without pertuzumab after disease progression on trastuzumab-based therapy for HER2-positive mBC met its primary endpoint of progression-free survival.**
   a. True
   b. False

2. **The Phase III HERITAGE trial comparing the trastuzumab biosimilar MyI-1401O to trastuzumab for patients with HER2-positive mBC demonstrated _____ efficacy with MyI-1401O.**
   a. Greater
   b. Lesser
   c. Equivalent

3. **Results presented at ASCO 2016 by Adams and colleagues evaluating atezolizumab in combination with *nab* paclitaxel for patients with mTNBC indicated that the combination is tolerable with promising activity.**
   a. True
   b. False

4. **The anti-PD-1 agent pembrolizumab and the anti-PD-L1 agent atezolizumab typically produce response rates of approximately _____ for patients with mTNBC.**
   a. 18% to 20%
   b. 35% to 40%
   c. 60% to 70%

5. **Results reported at ASCO 2016 by Rugo and colleagues from the Phase II SWISH trial demonstrated that prophylactic use of an oral dexamethasone solution markedly decreased the incidence and severity of stomatitis in patients receiving everolimus/exemestane for ER-positive mBC.**
   a. True
   b. False

6. **The Phase III EMBRACA trial is evaluating _____ for patients with BRCA mutation-positive locally advanced or metastatic BC.**
   a. Niraparib
   b. Olaparib
   c. Talazoparib
   d. Veliparib

7. **The Phase III MA17R trial evaluating the extension of adjuvant letrozole for 5 years after an initial 5 years of aromatase inhibitor therapy alone or preceded by tamoxifen for early-stage BC demonstrated no improvement in outcomes with the extended duration of aromatase inhibitor therapy.**
   a. True
   b. False

8. **Data presented at ASCO 2016 from the Phase III PALOMA-2 trial evaluating palbociclib with letrozole versus letrozole alone for patients with ER-positive, HER2-negative advanced BC who had not received prior systemic therapy for their advanced disease _____ the significant clinical benefit and safety of this combination previously reported by the Phase II PALOMA-1 trial.**
   a. Confirmed
   b. Failed to confirm

9. **Single-agent activity has been reported with which of the following CDK4/6 inhibitors in patients with ER-positive, HER2-negative mBC?**
   a. Abemaciclib
   b. Palbociclib
   c. Ribociclib
   d. None of the above

10. **Which of the following strategies is being evaluated in the Phase II MonarcHER trial?**
    a. Concurrent targeting of the HER2 and hormonal pathways
    b. Addition of a CDK4/6 inhibitor to anti-HER2 therapy
    c. Both a and b

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update — Issue 1, 2016

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
Efficacy of atezolizumab alone or in combination with *nab* paclitaxel for mTNBC	4 3 2 1	4 3 2 1
PHEREXA: Results of a Phase III trial of trastuzumab/capecitabine with or without pertuzumab after disease progression on trastuzumab-based therapy for HER2-positive mBC	4 3 2 1	4 3 2 1
Activity and tolerability of CDK4/6 inhibitors (abemaciclib, palbociclib, ribociclib) for ER-positive mBC	4 3 2 1	4 3 2 1
Use of the 70-gene MammaPrint assay to identify patients with early-stage BC who will not gain clinically meaningful benefit from chemotherapy	4 3 2 1	4 3 2 1
Results of the Phase III MA17R trial: Extending adjuvant letrozole for 5 years after initial 5 years of aromatase inhibitor therapy alone or preceded by tamoxifen for early-stage BC	4 3 2 1	4 3 2 1
Investigation of antiandrogens, PARP inhibitors and immune checkpoint inhibitors in mBC	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?

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☐ This activity validated my current practice

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☐ 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 long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and investigational targeted treatments. ..... 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 in the neoadjuvant, adjuvant and extended-adjuvant settings. . . . . 4 3 2 1 N/M N/A
- Appraise novel treatment strategies under investigation in advanced BC (eg, anti-PD-1/PD-L1 antibodies, antiandrogens). . . . . 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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Faculty	Knowledge of subject matter	Effectiveness as an educator
Hope S Rugo, MD	4 3 2 1	4 3 2 1
Sara A Hurvitz, 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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