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

FACULTY INTERVIEWS
Joyce O’Shaughnessy, MD
Erica L Mayer, MD, MPH

EDITOR
Neil Love, MD
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

• Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and emerging targeted treatments.

• Consider published data to guide the use of biomarkers and genomic assays to assess risk and individualize therapy for patients with hormone receptor-positive BC in the neoadjuvant, adjuvant and extended-adjuvant settings.

• Develop an evidence-based algorithm for the treatment of advanced, hormone receptor-positive, pre- and postmenopausal BC, including the use of endocrine, biologic and chemotherapeutic agents.

• Appreciate the recent FDA approvals of the PARP inhibitors olaparib and talazoparib for patients with HER2-negative metastatic BC and a germline BRCA mutation, and discern how these agents can be appropriately and safely integrated into routine clinical practice.

• Counsel appropriately selected patients with BC about participation in ongoing clinical trials.

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**Dr O’Shaughnessy**  
Advisory Committee: AstraZeneca Pharmaceuticals LP, Celgene Corporation, Daiichi Sankyo Inc, Eisai Inc, Lilly, Merck, Novartis, Pfizer Inc, Roche Laboratories Inc, Sanofi Genzyme; Consulting Agreements: AstraZeneca Pharmaceuticals LP, Celgene Corporation, Daiichi Sankyo Inc, Eisai Inc, Genomic Health Inc, Lilly, Merck, Novartis, Pfizer Inc, Roche Laboratories Inc, Sanofi Genzyme; Contracted Research: Takeda Oncology.

**Dr Mayer**  
Advisory Committee: Eisai Inc, Lilly, Pfizer Inc; Contracted Research: Myriad Genetic Laboratories Inc, Pfizer Inc.


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Interview with Joyce O'Shaughnessy, MD

Tracks 1-24

Track 1  **Case:** A 51-year-old woman presents with ER-positive, HER2-positive metastatic breast cancer (mBC)

Track 2  Potential synergy of neratinib with endocrine therapy or capecitabine for ER-positive, HER2-positive mBC

Track 3  **Case:** A 56-year-old woman with heavily pretreated HER2-positive mBC develops thrombocytopenia after experiencing a complete response to T-DM1

Track 4  Exceptional clinical responses to HER2-targeted therapies

Track 5  Ongoing investigation of the biologic mechanisms underlying exceptional responses to HER2-targeted therapy

Track 6  **Case:** A 38-year-old woman with metastatic triple-negative BC (mTNBC) and a PI3KCA mutation achieves an excellent clinical response to irinotecan/carboplatin/cetuximab on a clinical trial

Track 7  Therapeutic approach for patients with ER-positive, HER2-positive mBC

Track 8  Duration of therapy for patients with ER-positive, HER2-positive mBC

Track 9  Use of CDK4/6 inhibitors for patients with ER-positive, HER2-positive BC

Track 10  Activity and side-effect profile of the highly selective tyrosine kinase inhibitor tucatinib in HER2-positive advanced BC

Track 11  **Case:** A 65-year-old woman with ER/PR-positive, HER2-negative BC receives a 21-gene assay Recurrence Score® (RS) of 24

Track 12  Selection of adjuvant endocrine therapy for premenopausal patients with ER-positive BC

Track 13  Incorporating TAILORx trial results in therapeutic decision-making with the 21-gene RS assay in ER-positive, HER2-negative, node-negative BC

Track 14  **Case:** A 45-year-old woman with ER-positive, HER2-negative BC and metastases to the liver and bones receives abemaciclib and fulvestrant

Track 15  Efficacy and tolerability of abemaciclib for ER-positive mBC

Track 16  Benefits and risks associated with palbociclib and ribociclib

Track 17  Choice of endocrine therapy to partner with a CDK4/6 inhibitor for ER-positive mBC

Track 18  Promising antibody-drug conjugates under investigation for BC

Track 19  Role of checkpoint inhibitors for patients with mTNBC

Track 20  Indications for BRCA mutation testing in patients with BC

Track 21  Side effects associated with PARP inhibitors

Track 22  **Case:** A 30-year-old woman with TNBC and a solitary metastasis to the liver receives eribulin and capecitabine

Track 23  Efficacy of eribulin for patients with TNBC

Track 24  Benefits and risks of PI3 kinase inhibitors for BC

Interview with Erica L Mayer, MD, MPH

Tracks 1-22

Track 1  Preliminary results from the Phase III KATHERINE study evaluating T-DM1 versus trastuzumab as adjuvant therapy for patients with HER2-positive early BC and residual disease after preoperative therapy

Track 2  Side effects and quality of life associated with T-DM1 treatment

Track 3  **Case:** A 57-year-old postmenopausal woman with an ER/PR-positive, HER2-positive infiltrating ductal carcinoma (IDC) and positive axillary lymph nodes achieves a clinical response to neoadjuvant paclitaxel/trastuzumab/pertuzumab (THP)

Track 4  Therapeutic options for patients with ER-positive, HER2-positive BC in the (neo)adjuvant setting

Track 5  Efficacy of CDK4/6 inhibitors for patients with ER-positive, HER2-negative mBC
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**Interview with Dr Mayer (continued)**

**Video Program**

View the corresponding video interviews with (from left) Drs O’Shaughnessy and Mayer by Dr Love at www.ResearchToPractice.com/BCU318/Video

**Interview with Dr Mayer (continued)**

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6
SELECT PUBLICATIONS

A phase III, multicenter, randomized, open-label study comparing atezolizumab (anti PD-L1 antibody) in combination with adjuvant anthracycline/taxane-based chemotherapy versus chemotherapy alone in patients with operable triple negative breast cancer. NCT03498716

A phase III, multicenter, randomized, placebo-controlled study of atezolizumab (anti-PD-L1 antibody) in combination with nab-paclitaxel compared with placebo with nab-paclitaxel for patients with previously untreated metastatic triple-negative breast cancer. NCT02425891

A phase III, randomized clinical trial of standard adjuvant endocrine therapy +/- chemotherapy in patients with 1-3 positive nodes, hormone receptor-positive and HER2-negative breast cancer with Recurrence Score (RS) of 25 or less. RxPONDER: A clinical trial Rx for positive node, endocrine responsive breast cancer. NCT01272037


Freedman RA 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.


Neven P et al. Abemaciclib for pre/perimenopausal women with HR+, HER2- advanced breast cancer. Proc ASCO 2018; Abstract 1002.

Regan MM et al. Absolute improvements in freedom from distant recurrence with adjuvant endocrine therapies for premenopausal women with hormone receptor-positive (HR+) HER2-negative breast cancer (BC): Results from TEXT and SOFT. Proc ASCO 2018; Abstract 503.

Rimawi M et al. First-line trastuzumab plus an aromatase inhibitor, with or without pertuzumab, in human epidermal growth factor receptor 2-positive and hormone receptor-positive metastatic or locally advanced breast cancer (PERTAIN): A randomized, open-label phase II trial. J Clin Oncol 2018;36(28):2826–35.


Slamon DJ et al. Ribociclib (RIB) + fulvestrant (FUL) in postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2−) advanced breast cancer (ABC): Results from MONALEESA-3. Proc ASCO 2018; Abstract 1000.

Smith J II et al. Phase 2 study evaluating the efficacy and safety of eribulin mesylate administered biweekly for patients with human epidermal growth factor receptor 2-negative metastatic breast cancer. San Antonio Breast Cancer Symposium 2017; Abstract P6-14-05.


QUESTIONS (PLEASE CIRCLE ANSWER):

1. Results of the Phase III IMpassion 130 trial, which were presented at ESMO 2018 and published in *The New England Journal of Medicine*, demonstrated a statistically significant improvement in ________ with the addition of atezolizumab to *nab* paclitaxel as first-line treatment for advanced TNBC.
   a. Overall survival
   b. Progression-free survival
   c. Both a and b
   d. Neither a nor b

2. The TEXT and SOFT trials reported a statistically significant improvement in freedom from distant recurrence among premenopausal women with ER-positive BC who received exemestane and ovarian function suppression compared to tamoxifen alone.
   a. True
   b. False

3. Results from the Phase II PERTAIN study for ER-positive, HER2-positive locally advanced or metastatic BC demonstrated a statistically significant improvement in progression-free survival with the addition of ________ to first-line trastuzumab and an aromatase inhibitor.
   a. Neratinib
   b. Pertuzumab
   c. Pembrolizumab

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

5. The ongoing Phase II HER2CLIMB study is evaluating the addition of tucatinib to ________ for advanced HER2-positive BC.
   a. Capecitabine
   b. Trastuzumab
   c. Both a and b

6. In the Phase III TAILORx study for patients with node-negative, hormone receptor-positive, HER2-negative BC and an intermediate RS of 11 to 25, adjuvant endocrine therapy alone was ________ to endocrine therapy with chemotherapy in terms of invasive disease-free survival in the postmenopausal population.
   a. Inferior
   b. Noninferior

7. Patients who are pregnant and have been diagnosed with HER2-positive BC ________.
   a. Can receive trastuzumab/pertuzumab with chemotherapy during pregnancy
   b. Can receive chemotherapy during the second and third trimesters followed by trastuzumab/pertuzumab after delivery

8. Which Phase III trial is evaluating T-DM1 versus trastuzumab as adjuvant therapy for patients with HER2-positive early BC and residual disease after preoperative therapy?
   a. APHINITY
   b. HER2CLIMB
   c. KATHERINE

9. Which of the following categories reflects the mechanism of action of tucatinib?
   a. Antibody-drug conjugate
   b. Anti-PD-1/PD-L1 antibody
   c. CDK4/6 inhibitor
   d. Tyrosine kinase inhibitor

10. Results from the Phase III PALOMA-3 study, which were presented at ESMO 2018 and published in *The New England Journal of Medicine*, included a statistically significant improvement in overall survival with the addition of palbociclib to fulvestrant for patients with hormone receptor-positive, HER2-negative advanced BC who were sensitive to previous endocrine therapy.
    a. True
    b. False
EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update — Volume 17, 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?

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<thead>
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<td>inhibitors abemaciclib, palbociclib and ribociclib for ER-positive mBC</td>
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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:

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<th>3 = Will consider</th>
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<th>1 = Already doing</th>
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EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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

• Appreciate the recent FDA approvals of the PARP inhibitors olaparib and talazoparib for patients with HER2-negative metastatic BC and a germline BRCA mutation, and discern how these agents can be appropriately and safely integrated into routine clinical practice. .......................................................... 4 3 2 1 N/M N/A

• Counsel appropriately selected patients with BC 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: ........................................................................................................................................................................

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<table>
<thead>
<tr>
<th>Faculty</th>
<th>Knowledge of subject matter</th>
<th>Effectiveness as an educator</th>
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<tr>
<td>Joyce O’Shaughnessy, MD</td>
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<td>Erica L Mayer, MD, MPH</td>
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<td>Editor</td>
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<tr>
<td>Neil Love, MD</td>
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REQUEST FOR CREDIT — Please print clearly

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Professional Designation:
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