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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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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

- 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.
- Consider published research and patient preferences in the selection and sequencing of available and investigational therapeutic agents for metastatic triple-negative BC.
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials.

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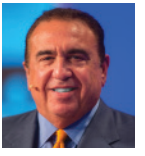

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Interview with Eric P Winer, MD

Tracks 1-28

Interview with Daniel F Hayes, MD

Tracks 1-14

Track 1 Weighing the risks and benefits of adjuvant chemotherapy for patients with BC

Track 2 Prospective validation of the 21-gene assay RS for ER-positive, HER2-negative BC

Track 3 Critical evaluation of the Phase III TAILORx trial results: Adjuvant chemotherapy guided by the 21-gene assay RS for ER-positive, node-negative BC

Track 4 Clinical basis for the ongoing Phase III RxPONDER trial evaluating standard adjuvant endocrine therapy with or without chemotherapy for patients with ER-positive, HER2-negative BC, 1 to 3 positive nodes and a RS of 25 or lower

Track 5 Application of the TAILORx trial results in clinical practice

Track 6 Updated results from the TEXT and SOFT trials: Adjuvant endocrine therapy with ovarian function suppression for premenopausal women with ER-positive, HER2-negative BC

Track 7 Importance of menopausal status, number of positive nodes and RS in the selection of an adjuvant endocrine therapy

Track 8 Use of genomic assays to guide neoadjuvant therapy decision-making

Track 9 Selection of hormonal therapy versus chemotherapy for patients with symptomatic ER-positive, HER2-negative mBC

Track 10 Activity and tolerability of CDK4/6 inhibitors for ER-positive, HER2-negative mBC

Track 11 Comparison of FDA-approved CDK4/6 inhibitors: Efficacy, tolerability and dosing

Track 12 Perspective on the investigation of immune checkpoint inhibitors in combination with chemotherapy for patients with metastatic TNBC

Track 13 Role of PARP inhibitors for patients with mBC and a germline BRCA mutation

Track 14 Use of trastuzumab/pertuzumab in the adjuvant setting and neratinib in the extended-adjuvant setting for patients with HER2-positive BC

Interview with Ingrid A Mayer, MD, MSCI

Tracks 1-15

Track 1 **Case:** A 43-year-old woman who previously declined adjuvant therapy for Stage II, ER/PR-positive, HER2-negative BC with 1 positive node presents 3 years later with symptomatic metastatic disease

Track 2 RxPONDER: An ongoing Phase III trial of standard adjuvant endocrine therapy with or without chemotherapy for patients with ER-positive, HER2-negative BC, 1 to 3 positive nodes and a RS of 25 or lower

Track 3 Perspective on ordering the 21-gene assay for patients with node-positive BC

Track 4 Prognostic and predictive value of the 21-gene assay RS for patients with ER-positive, HER2-negative, node-negative BC

Track 5 Clinical implications of the TAILORx trial results: Adjuvant chemotherapy guided by the 21-gene assay RS for ER-positive, HER2-negative, node-negative BC

Track 6 Discussion of the TAILORx trial results in premenopausal participants

Track 7 Perspective on the use of the 21-gene assay for postmenopausal women with limited nodal involvement

Track 8 TAILORx trial results: Risk of distant recurrence for premenopausal women

Track 9 Use of palliative radiation therapy for pathologic fracture before initiation of CDK4/6 inhibitor-based systemic therapy

Interview with Dr Mayer (continued)

Track 10 Strategies to combat primary and acquired resistance to endocrine therapies

Track 11 Magnitude of benefit with the addition of CDK4/6 inhibitors to endocrine therapy for ER-positive, HER2-negative mBC in the first- and second-line settings

Track 12 Exploring the value of continuing therapy with CDK4/6 inhibitors and switching endocrine therapy partner after disease progression

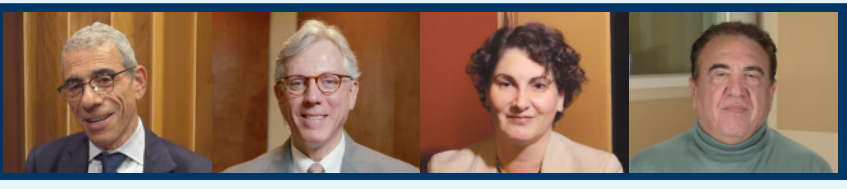
Track 13 Clinical experience with and management of everolimus-associated mucositis

Track 14 **Case:** A 48-year-old woman with ER-positive, HER2-positive mBC receives neoadjuvant trastuzumab/chemotherapy

Track 15 Factors driving the decision to administer trastuzumab/pertuzumab and/or neratinib to patients with HER2-positive early BC

Video Program

View the corresponding video interviews with (from left) Drs Winer, Hayes and Mayer by Dr Love at www.ResearchToPractice.com/BCU119/Video



Have Questions or Cases You Would Like Us to Pose to the Faculty?

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Results from the Phase III IMpassion130 trial _____ a significant improvement in progression-free survival with the addition of atezolizumab to *nab* paclitaxel as first-line treatment for metastatic TNBC.**
   a. Demonstrated
   b. Did not demonstrate

2. **In a follow-up analysis of the APT trial evaluating adjuvant paclitaxel/trastuzumab for HER2-positive, node-negative BC, the 7-year disease-free survival rate was approximately _____.**
   a. 3%
   b. 50%
   c. 93%

3. **Updated results from the TEXT and SOFT trials included a statistically significant improvement in freedom from distant recurrence among premenopausal women with ER-positive, HER2-negative BC who received adjuvant exemestane and ovarian function suppression compared to tamoxifen alone.**
   a. True
   b. False

4. **Which of the following categories reflects the mechanism of action of alpelisib (BYL719)?**
   a. Antibody-drug conjugate
   b. Anti-PD-1/PD-L1 antibody
   c. CDK4/6 inhibitor
   d. PI3 kinase inhibitor
   e. Tyrosine kinase inhibitor

5. **In the Phase III TAILORx study evaluating adjuvant therapy for patients with hormone receptor-positive, HER2-negative, node-negative BC and an intermediate RS of 11 to 25, adjuvant endocrine therapy alone was _____ to chemoendocrine therapy in terms of invasive disease-free survival in the overall patient population.**
   a. Inferior
   b. Noninferior

6. **Which of the following CDK4/6 inhibitors appears to penetrate the CNS more effectively than do the others?**
   a. Abemaciclib
   b. Palbociclib
   c. Ribociclib
   d. None of the above (all appear to penetrate the CNS equally)

7. **Exploratory analyses of the TAILORx trial results suggest a potential benefit with chemotherapy for _____ patients with an intermediate-range RS, particularly those with a score between 16 and 25.**
   a. Premenopausal
   b. Postmenopausal
   c. Neither a nor b

8. **The Phase III RxPONDER study randomly assigns patients with ER-positive, HER2-negative, node-negative BC and a RS of 25 or higher to adjuvant endocrine therapy with or without chemotherapy.**
   a. True
   b. False

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

10. **In the Phase III PALOMA-3 study, the addition of palbociclib to fulvestrant resulted in a statistically significant improvement in overall survival for patients with HR-positive, HER2-negative advanced BC who were sensitive to previous endocrine therapy.**
    a. True
    b. False

SELECT PUBLICATIONS

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**

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Cristofanilli M et al. **Overall survival (OS) with palbociclib plus fulvestrant in women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2−) advanced breast cancer (ABC): Analyses from PALOMA-3.** *Proc ESMO* 2018;**Abstract LBA2_PR**.

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Murthy R et al. **Tucatinib with capecitabine and trastuzumab in advanced HER2-positive metastatic breast cancer with and without brain metastases: A non-randomised, open-label, phase 1b study.** *Lancet Oncol* 2018;19(7):880-8.

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; PERTAIN Study Group. **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.

Schmid P et al. **IMpassion130: Results from a global, randomised, double-blind, phase 3 study of atezolizumab (atezo) + *nab*-paclitaxel (*nab*-P) vs placebo + *nab*-P in treatment-naive, locally advanced or metastatic triple-negative breast cancer (mTNBC).** *Proc ESMO* 2018;**Abstract LBA1_PR**.

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Stearns V. **TAILORing adjuvant systemic therapy for breast cancer.** *N Engl J Med* 2018;379(2):191-2.

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Turner NC et al. **Overall survival with palbociclib and fulvestrant in advanced breast cancer.** *N Engl J Med* 2018;379(20):1926-36.

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update — Volume 17, 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
TAILORx: Results of a Phase III study of chemoendocrine therapy versus endocrine therapy alone for patients with hormone receptor-positive, HER2-negative, node-negative BC and an intermediate 21-gene assay RS	4 3 2 1	4 3 2 1
Available data with and choosing among the FDA-approved CDK4/6 inhibitors abemaciclib, palbociclib and ribociclib for ER-positive, HER2-negative mBC	4 3 2 1	4 3 2 1
Updated results from the TEXT and SOFT trials: Adjuvant endocrine therapy with ovarian function suppression for premenopausal women with ER-positive, HER2-negative BC	4 3 2 1	4 3 2 1
PERTAIN: Results of a Phase II trial of first-line trastuzumab and an aromatase inhibitor with or without pertuzumab for ER-positive, HER2-positive locally advanced or metastatic BC	4 3 2 1	4 3 2 1
Primary results from the Phase III IMpassion130 study of first-line *nab* paclitaxel alone or in combination with atezolizumab for advanced TNBC	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:

- Implement a long-term 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 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. . . . . 4 3 2 1 N/M N/A
- 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. . . . . 4 3 2 1 N/M N/A

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

- Consider published research and patient preferences in the selection and sequencing of available and investigational therapeutic agents for metastatic triple-negative BC. . . . . 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:

. . . . . .

. . . . . .

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☐ Yes ☐ No

If no, please explain: . . . . . .

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Faculty	Knowledge of subject matter	Effectiveness as an educator
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Daniel F Hayes, MD	4 3 2 1	4 3 2 1
Ingrid A Mayer, MD, MSCI	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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