Breast Cancer® UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY

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SPECIAL ISSUE

Proceedings from a Clinical Investigator Think Tank

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Breast Cancer Update
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OVERVIEW OF ACTIVITY

Breast cancer is one of the most rapidly evolving fields in medical oncology. Published results from ongoing clinical trials lead to the continuous emergence of new therapeutic agents and changes in the indications for existing treatments. In order to offer optimal patient care — including the option of clinical trial participation — clinicians must be well informed of these advances. To bridge the gap between research and practice, this program features leading oncology investigators debating the merits, applications and limitations of emerging data sets. By providing access to the latest research developments and expert perspectives, this CME program assists medical oncologists, hematologists and hematology-oncology fellows with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Determine the utility of genomic assays in counseling patients with ductal carcinoma in situ or ER-positive early breast cancer about their risk of recurrence and the potential benefits of radiation therapy or adjuvant chemotherapy, respectively.
- Develop evidence-based treatment approaches for patients diagnosed with HER2-positive breast cancer in the neoadjuvant, adjuvant and metastatic settings.
- Evaluate the unique mechanisms of action and emerging clinical trial data with novel anti-HER2 agents under investigation in breast cancer.
- Formulate individualized approaches to later-line therapy for patients with HER2-negative metastatic breast cancer.
- Recall emerging data on the role of mTOR inhibition in reversing resistance to endocrine therapy in metastatic breast cancer in preparation for the potential availability of this treatment approach.
- Discuss the clinical activity and safety of PARP inhibitors for patients with advanced BRCA-mutated or triple-negative breast cancer, and provide guidance about available ongoing clinical trials.
- Define the current role of bone-targeted therapy in the management of early breast cancer.
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials.

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SELECT PUBLICATIONS

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Miller KD et al. **PARP inhibition after preoperative chemotherapy in patients with triple-negative breast cancer (TNBC) or known BRCA 1/2 mutations: Hoosier Oncology Group BRE09-146.** San Antonio Breast Cancer Symposium 2011;**Abstract OT3-01-05**.

Mirtsching B et al. **A phase II study of weekly nanoparticle albumin-bound paclitaxel with or without trastuzumab in metastatic breast cancer.** *Clin Breast Cancer* 2011;11(2):121-8.

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Montero AJ, Vogel C. **Fighting fire with fire: Rekindling the bevacizumab debate.** *N Engl J Med* 2012;366(4):374-5.

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Solin LJ. **Selecting individualized treatment for patients with ductal carcinoma in situ of the breast: The search continues.** *J Clin Oncol* 2012;30(6):577-9.

Yardley DA et al. **Phase II study of neoadjuvant weekly nab-paclitaxel and carboplatin, with bevacizumab and trastuzumab, as treatment for women with locally advanced HER2+ breast cancer.** *Clin Breast Cancer* 2011;11(5):297-305.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The mechanism of action of pertuzumab _____.**
   a. Is the same as that of trastuzumab
   b. Is distinct from that of trastuzumab because pertuzumab binds to the dimerization domain of HER2
   c. Allows for potential use in combination with trastuzumab
   d. Both b and c

2. **The randomized Phase II neoadjuvant NEOSPHERE study demonstrated that the addition of pertuzumab to trastuzumab and chemotherapy resulted in no improvement in the pathologic complete response rate compared to the other treatment arms.**
   a. True
   b. False

3. **The Phase III randomized CLEOPATRA study demonstrated a statistically significant advantage in _____ with the addition of pertuzumab to trastuzumab and docetaxel in patients with mBC.**
   a. Overall survival
   b. Progression-free survival (PFS)
   c. Both a and b
   d. None of the above

4. **Results from the BOLERO-2 Phase III trial of exemestane with or without everolimus for postmenopausal patients whose disease is refractory to nonsteroidal aromatase inhibitors demonstrated significant improvements in response rate and PFS with the addition of everolimus to exemestane.**
   a. True
   b. False

5. **T-DM1 is a novel agent that combines a maytansine derivative with _____.**
   a. Docetaxel
   b. Trastuzumab
   c. Bevacizumab
   d. None of the above

6. **The results of a randomized Phase II trial of T-DM1 versus trastuzumab and docetaxel for patients with untreated HER2-positive mBC demonstrated a significant PFS advantage in addition to significantly less toxicity in favor of T-DM1.**
   a. True
   b. False

7. **The ongoing Phase III APHINITY trial is evaluating the addition of _____ to chemotherapy/trastuzumab as adjuvant therapy for HER2-positive early-stage BC.**
   a. Bevacizumab
   b. Pertuzumab
   c. T-DM1

8. **In the Phase III EMBRACE study, eribulin resulted in a significant improvement in overall survival compared to treatment of physician's choice in patients with previously treated mBC.**
   a. True
   b. False

9. **Which of the following is an eligibility criterion for the SWOG-S1007 (RxPONDER) Phase III study of adjuvant endocrine therapy with or without chemotherapy?**
   a. Node-positive (1 to 3 nodes only)
   b. ER-positive, HER2-negative
   c. Onco*type* DX RS ≤25
   d. All of the above

10. **A Phase II trial evaluating the PARP inhibitor veliparib (ABT-888) in combination with temozolomide for patients with mBC reported activity with the combination in patients with which of the following disease characteristics?**
    a. TNBC
    b. BRCA mutation-negative
    c. BRCA mutation-positive

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update — Think Tank Issue 1, 2012

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
Results of CLEOPATRA: A Phase III study of first-line docetaxel/trastuzumab with or without pertuzumab for HER2-positive mBC	4 3 2 1	4 3 2 1
Prospective validation of the Onco*type* DX DCIS Score for predicting recurrence risk after resection alone for DCIS	4 3 2 1	4 3 2 1
Results of BOLERO-2: Exemestane with or without everolimus in ER-positive locally advanced or metastatic BC refractory to nonsteroidal aromatase inhibitors	4 3 2 1	4 3 2 1
NEOSPHERE: A Phase II study of neoadjuvant pertuzumab and trastuzumab	4 3 2 1	4 3 2 1
Rational sequencing of late-line therapeutic options — eribulin, *nab* paclitaxel, ixabepilone, et cetera — in HER2-negative mBC	4 3 2 1	4 3 2 1

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:

- Determine the utility of genomic assays in counseling patients with ductal carcinoma in situ or ER-positive early breast cancer about their risk of recurrence and the potential benefits of radiation therapy or adjuvant chemotherapy, respectively. ..... 4 3 2 1 N/M N/A
- Develop evidence-based treatment approaches for patients diagnosed with HER2-positive breast cancer in the neoadjuvant, adjuvant and metastatic settings. ..... 4 3 2 1 N/M N/A
- Evaluate the unique mechanisms of action and emerging clinical trial data with novel anti-HER2 agents under investigation in breast cancer. ..... 4 3 2 1 N/M N/A
- Formulate individualized approaches to later-line therapy for patients with HER2-negative metastatic breast cancer. ..... 4 3 2 1 N/M N/A
- Recall emerging data on the role of mTOR inhibition in reversing resistance to endocrine therapy in metastatic breast cancer in preparation for the potential availability of this treatment approach. ..... 4 3 2 1 N/M N/A
- Discuss the clinical activity and safety of PARP inhibitors for patients with advanced BRCA-mutated or triple-negative breast cancer, and provide guidance about available ongoing clinical trials. ..... 4 3 2 1 N/M N/A
- Define the current role of bone-targeted therapy in the management of early breast cancer. ..... 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

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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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☐ Yes, I am willing to participate in a follow-up survey.

☐ No, I am not willing to participate in a follow-up survey.

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Faculty	Knowledge of subject matter				Effectiveness as an educator			
Ana Maria Gonzalez-Angulo, MD, MSc	4	3	2	1	4	3	2	1
William J Gradishar, MD	4	3	2	1	4	3	2	1
Daniel F Hayes, MD	4	3	2	1	4	3	2	1
Ian E Krop, MD, PhD	4	3	2	1	4	3	2	1
Hannah M Linden, MD	4	3	2	1	4	3	2	1
Eleftherios P Mamounas, MD, MPH	4	3	2	1	4	3	2	1
Kathy D Miller, MD	4	3	2	1	4	3	2	1
Charles L Vogel, MD	4	3	2	1	4	3	2	1
Moderator	**Knowledge of subject matter**				**Effectiveness as an educator**			
Neil Love, MD	4	3	2	1	4	3	2	1

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and moderator for this activity:

.....

.....

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