

Second Opinion

*An Interactive Case-Based Discussion on the
Management of Early and Advanced Breast Cancer*

Proceedings from a CME Satellite Symposium at the
30th Annual San Antonio Breast Cancer Symposium



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Breast Cancer[®]
U P D A T E

CME Information: Second Opinion

STATEMENT OF NEED/TARGET AUDIENCE

Breast cancer is one of the most rapidly evolving fields in medical oncology. Published results from a plethora of 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 — the practicing medical oncologist must be well informed of these advances.

To bridge the gap between research and patient care, this special issue of *Breast Cancer Update* utilizes case-based discussions among clinical investigators to present the most current research developments in the systemic management of early and advanced breast cancer.

LEARNING OBJECTIVES

- Develop an evidence-based treatment algorithm for the initial and extended adjuvant management of ER-positive early breast cancer, integrating knowledge gleaned from recent clinical advances and ongoing trials with aromatase inhibitors and tamoxifen.
- Review the current clinical approach and ancillary laboratory testing to support selection of endocrine therapy for the premenopausal patient and the patient with chemotherapy-induced amenorrhea or a perimenopausal presentation.

- Utilize standard clinical factors and novel tissue biomarkers to individualize cytotoxic, endocrine and/or biologic therapy in the early and advanced breast cancer treatment settings.
- Describe the unique risks and benefits of acceptable single-agent and combination chemotherapy and endocrine regimens, and use this information to tailor treatment decisions for patients with metastatic disease.
- Explore the emerging role of growth factor inhibition and anti-angiogenesis in the management of breast cancer, and explain the investigational rationale for and safety implications of combining these agents with standard therapeutic interventions.
- Counsel appropriately selected patients about the availability and relevance of ongoing breast cancer clinical trials.

PURPOSE OF THIS SPECIAL ISSUE

The purpose of this special edition of *Breast Cancer Update* is to support these objectives by offering the perspectives of Drs Budd, Chlebowski, Forbes, Hudis, O'Shaughnessy, Sledge and Sparano on the integration of emerging breast cancer research data into clinical practice.

CME Information (continued)

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This is an audio CME activity. To receive credit, the participant should review the CME information, listen to the CD and complete the Post-test and Evaluation Form located in the back of this book or on our website www.BreastCancerUpdate.com/SABCS_2007.

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CME Information (continued)

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Consulting Fees: AstraZeneca Pharmaceuticals LP, Pfizer Inc.

Dr Chlebowski

Consulting Fees: AstraZeneca Pharmaceuticals LP, Novartis Pharmaceuticals Corporation, Pfizer Inc.

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Prof Forbes

Consulting Fees: Novartis Pharmaceuticals Corporation.

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Dr Hudis

Consulting Fees: Abraxis BioScience, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Genentech BioOncology, Novartis Pharmaceuticals Corporation, Pfizer Inc, Roche Laboratories Inc, Sanofi-Aventis.

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Post-test: Second Opinion

1. In the 100-month update of the ATAC trial, a “carryover effect” for anastrozole was demonstrated with an increased difference in risk of recurrence between anastrozole and tamoxifen from the first five years of therapy to years five to nine after completion of therapy.
 - a. True
 - b. False
2. The updated ATAC data revealed a statistically significant improvement in overall survival for patients treated with anastrozole compared to tamoxifen.
 - a. True
 - b. False
3. In the ATAC trial between years five and nine after completion of therapy, the number of cases of endometrial cancer observed was _____ and _____ for anastrozole and tamoxifen, respectively.
 - a. One, 12
 - b. 12, one
 - c. 146, 140
4. The ABCSG-16 study assesses the effect of a further two versus five years of adjuvant treatment with _____ after an initial five years of adjuvant endocrine therapy.
 - a. Anastrozole
 - b. Exemestane
 - c. Letrozole
 - d. Fulvestrant
 - e. Tamoxifen
5. The ECOG-E2100 Phase III randomized study of paclitaxel with or without bevacizumab showed improvements in response rate and progression-free survival with the combination.
 - a. True
 - b. False
6. In the CALGB-40502 trial, evaluating weekly paclitaxel versus *nab* paclitaxel versus ixabepilone, all three arms are combined with _____.
 - a. Bevacizumab
 - b. Cetuximab
 - c. Panitumumab

Post-test (continued)

7. The XCalibr trial evaluated the efficacy of bevacizumab in combination with _____ as first-line therapy for metastatic breast cancer.
- Nab* paclitaxel
 - Gemcitabine
 - Capecitabine
 - All of the above
 - None of the above
8. In the global Phase III ABIDE trial, *nab* paclitaxel administered three out of four weeks is being compared to _____ in the front-line, metastatic setting.
- Docetaxel
 - Paclitaxel
 - Capecitabine
9. Compared to the standard formulation of paclitaxel, *nab* paclitaxel requires no premedication with steroids.
- True
 - False
10. In the North American trial comparing fulvestrant to anastrozole for postmenopausal women with advanced breast cancer progressing on prior endocrine therapy, fulvestrant _____ as effective as anastrozole.
- Was
 - Was not
11. Results from EFECT indicate that fulvestrant and exemestane have comparable efficacy in patients with metastatic disease progressing on _____.
- Tamoxifen
 - An aromatase inhibitor
12. The TAILORx study is randomly assigning patients with _____ *Oncotype* DX recurrence scores to hormonal therapy or combination chemotherapy followed by hormonal therapy.
- Low
 - Intermediate
 - High

Post-test answer key: 1a, 2b, 3a, 4a, 5a, 6a, 7c, 8a, 9a, 10a, 11b, 12b

Evaluation Form: Second Opinion

Research To Practice respects and appreciates your opinions. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please complete this Evaluation Form. A certificate of completion will be issued upon receipt of your completed Post-test and Evaluation Form.

Please answer the following questions by circling the appropriate rating:

5 =
Outstanding

4 =
Good

3 =
Satisfactory

2 =
Fair

1 =
Poor

LEARNING OBJECTIVES

To what extent does this CME activity address the following learning objectives?

- Develop an evidence-based treatment algorithm for the initial and extended adjuvant management of ER-positive early breast cancer, integrating knowledge gleaned from recent clinical advances and ongoing trials with aromatase inhibitors and tamoxifen... 5 4 3 2 1
- Review the current clinical approach and ancillary laboratory testing to support selection of endocrine therapy for the premenopausal patient and the patient with chemotherapy-induced amenorrhea or a perimenopausal presentation... 5 4 3 2 1
- Utilize standard clinical factors and novel tissue biomarkers to individualize cytotoxic, endocrine and/or biologic therapy in the early and advanced breast cancer treatment settings... 5 4 3 2 1
- Describe the unique risks and benefits of acceptable single-agent and combination chemotherapy and endocrine regimens, and use this information to tailor treatment decisions for patients with metastatic disease... 5 4 3 2 1
- Explore the emerging role of growth factor inhibition and anti-angiogenesis in the management of breast cancer, and explain the investigational rationale for and safety implications of combining these agents with standard therapeutic interventions... 5 4 3 2 1
- Counsel appropriately selected patients about the availability and relevance of ongoing breast cancer clinical trials... 5 4 3 2 1

Evaluation Form (continued)

EFFECTIVENESS OF THE INDIVIDUAL FACULTY MEMBERS

| Faculty | Knowledge of subject matter | Effectiveness as an educator |
|-----------------------------|-----------------------------|------------------------------|
| G Thomas Budd, MD | 5 4 3 2 1 | 5 4 3 2 1 |
| Rowan T Chlebowski, MD, PhD | 5 4 3 2 1 | 5 4 3 2 1 |
| John F Forbes, MD | 5 4 3 2 1 | 5 4 3 2 1 |
| Clifford Hudis, MD | 5 4 3 2 1 | 5 4 3 2 1 |
| Joyce O'Shaughnessy, MD | 5 4 3 2 1 | 5 4 3 2 1 |
| George W Sledge Jr, MD | 5 4 3 2 1 | 5 4 3 2 1 |
| Joseph A Sparano, MD | 5 4 3 2 1 | 5 4 3 2 1 |

OVERALL EFFECTIVENESS OF THE ACTIVITY

| | |
|-------------------------------------------------------------------------|-----------|
| Objectives were related to overall purpose/goal(s) of activity. | 5 4 3 2 1 |
| Related to my practice needs. | 5 4 3 2 1 |
| Will influence how I practice. | 5 4 3 2 1 |
| Will help me improve patient care. | 5 4 3 2 1 |
| Stimulated my intellectual curiosity. | 5 4 3 2 1 |
| Overall quality of material. | 5 4 3 2 1 |
| Overall, the activity met my expectations. | 5 4 3 2 1 |
| Avoided commercial bias or influence. | 5 4 3 2 1 |

Evaluation Form (continued)

Will the information presented cause you to make any changes in your practice?

Yes

No

If yes, please describe any change(s) you plan to make in your practice as a result of this activity:

.....

What other topics would you like to see addressed in future educational programs?

.....

.....

.....

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I certify my actual time spent to complete this educational activity to be _____ hour(s).

Signature: Date:.....

Evaluation Form (continued)

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