

# Second Opinion

*Case-Based Discussion  
on the Management of Patients  
with Early and Advanced Breast Cancer*



A Special Audio Supplement to a CME Conference Held  
During the 2011 San Antonio Breast Cancer Symposium  
Featuring Expert Comments on Key New Data Sets Presented

## **Faculty Interview**

George W Sledge Jr, MD

## **Moderator**

Neil Love, MD

## **Contents**

1 Audio CD



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UPDATE

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## *CME Information: Second Opinion — Case-Based Discussion on the Management of Patients with Early and Advanced Breast Cancer*

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### **FACULTY**

George W Sledge Jr, MD  
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Professor of Medicine and Pathology  
Co-Director of the IUSCC Breast  
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### **MODERATOR**

Neil Love, MD  
Research To Practice  
Miami, Florida

### **OVERVIEW OF ACTIVITY**

Breast cancer is 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. To bridge the gap between research and patient care, this case-based CME activity features expert perspective on the latest research developments presented at the 2011 San Antonio Breast Cancer Symposium and discussion of relevant clinical issues to assist medical

oncologists, hematologists/oncologists and hematology-oncology fellows in the formulation of up-to-date clinical management strategies.

### **LEARNING OBJECTIVES**

- Integrate validated genomic assays into the clinical management of estrogen receptor (ER)-positive, node-negative and node-positive early breast cancer.
- Assimilate new clinical trial evidence into the therapeutic algorithm for advanced ER-positive breast cancer.
- Appraise the role of bone-directed systemic treatment in the management of breast cancer.
- Demonstrate knowledge of emerging research to support alternative or novel chemotherapeutic regimens in the adjuvant and metastatic settings, and integrate these findings into best-practice disease management strategies.
- Apply the results of emerging research to effectively integrate HER2-directed treatments into the systemic management of advanced HER2-positive breast cancer.
- Recognize the rationale for ongoing investigation of angiogenesis inhibitors in the adjuvant setting.

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## *CME Information (continued)*

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- Recall the results of pivotal trials introducing effective new breast cancer therapeutics, and identify their impact on existing treatment algorithms.

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**FACULTY** — **Dr Sledge** had no real or apparent conflicts of interest to disclose.

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## CME Information (continued)

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## Second Opinion: Virtual Symposium Presentation



Watch the recorded proceedings from this unique live event featuring clinical investigators Drs Eric P Winer, Julie R Gralow, George W Sledge Jr, Hope S Rugo and Ian E Smith addressing a number of actual breast cancer cases presented via video by the treating community-based oncologists. Visit [www.ResearchToPractice.com/SABCS12](http://www.ResearchToPractice.com/SABCS12) for more information.

## SELECT PUBLICATIONS

Baselga J et al. **Everolimus in postmenopausal hormone-receptor-positive advanced breast cancer.** *N Engl J Med* 2012;366(6):520-9.

Baselga J et al. **Lapatinib with trastuzumab for HER2-positive early breast cancer (NeoALTTO): A randomized, open-label, multicentre, phase 3 trial.** *Lancet* 2012;379(9816):633-40.

Baselga J et al. **Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer.** *N Engl J Med* 2012;366(2):109-19.

Gianni L et al. **First results of AVEREL, a randomized phase III trial to evaluate bevacizumab (BEV) in combination with trastuzumab (H) + docetaxel (DOC) as first-line therapy for HER2-positive locally recurrent/metastatic breast cancer (LR/mBC).** San Antonio Breast Cancer Symposium 2011; **Abstract S4-8.**

Gnant M et al. **Adjuvant endocrine therapy plus zoledronic acid in premenopausal women with early-stage breast cancer; 62-month follow-up from the ABCSG-12 randomised trial.** *Lancet Oncol* 2011;12(7):631-41.

Kaji D et al. **Adjuvant trastuzumab in HER2-positive breast cancer.** *N Engl J Med* 2012;366(7):663.

Mehta RS et al. **A phase III randomized trial of anastrozole versus anastrozole and fulvestrant as first-line therapy for postmenopausal women with metastatic breast cancer: SWOG S0226.** San Antonio Breast Cancer Symposium 2011; **Abstract S1-1.**

Powles T et al. **Randomized, placebo-controlled trial of clodronate in patients with primary operable breast cancer.** *J Clin Oncol* 2002;20(15):3219-24.

Solin LJ et al. **A quantitative multigene RT-PCR assay for predicting recurrence risk after surgical excision alone without irradiation for ductal carcinoma in situ (DCIS): A prospective validation study of the DCIS Score from ECOG E5194.** San Antonio Breast Cancer Symposium 2011;**Abstract S4-6.**

Tsang RY, Finn RS. **Beyond trastuzumab: Novel therapeutic strategies in HER2-positive metastatic breast cancer.** *Br J Cancer* 2012;106(1):6-13.

Van Cutsem E et al. **Lessons from the adjuvant bevacizumab trial on colon cancer: What next?** *J Clin Oncol* 2011;29(1):1-4.

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*Post-test: Second Opinion — Case-Based Discussion on the Management of Patients with Early and Advanced Breast Cancer*

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- 1. In the Phase III CLEOPATRA study the addition of pertuzumab to trastuzumab/docetaxel as first-line therapy for HER2-positive metastatic breast cancer resulted in \_\_\_\_\_.**
  - Significant improvement in progression-free survival (PFS)
  - A trend toward improvement in overall survival (OS)
  - No improvement in PFS or OS
  - Both a and b
- 2. The majority of patients in the CLEOPATRA study had not previously received trastuzumab.**
  - True
  - False
- 3. The mechanism of action of pertuzumab is different from but complementary to that of trastuzumab in that it interferes with the dimerization of HER2 with \_\_\_\_\_.**
  - HER1
  - HER3
  - HER4
- 4. Which of the following is an antibody-drug conjugate under investigation for the treatment of HER2-positive metastatic breast cancer?**
  - Neratinib
  - Brentuximab vedotin
  - Lapatinib
  - T-DM1
- 5. In the follow-up study of the ABCSG-12 trial, adjuvant zoledronic acid resulted in a modest improvement in overall survival among premenopausal women who had undergone ovarian suppression.**
  - True
  - False
- 6. In the ECOG-E5194 study of patients with DCIS who were treated with lumpectomy alone, the Oncotype DX<sup>®</sup> DCIS Score<sup>™</sup> identified patients with a \_\_\_\_\_.**
  - High risk of developing distant metastases
  - Low long-term risk of developing invasive breast cancer
  - Neither a nor b

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*Post-test (continued)*

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7. In a randomized, Phase II study the addition of the HDAC inhibitor entinostat to exemestane in postmenopausal patients with ER-positive metastatic breast cancer whose disease progressed on a nonsteroidal aromatase inhibitor resulted in \_\_\_\_\_.
- No improvement in PFS
  - A significant improvement in PFS
  - An improvement in OS
  - Both b and c
8. The Phase III SWOG-S0226 study of anastrozole with or without fulvestrant demonstrated a clinical advantage with the combination therapy over anastrozole alone as first-line therapy for postmenopausal patients with ER-positive metastatic breast cancer.
- True
  - False
9. The addition of everolimus to exemestane in postmenopausal patients with ER-positive metastatic breast cancer whose disease progressed on first-line therapy with a nonsteroidal aromatase inhibitor resulted in a significant prolongation in PFS in the Phase III BOLERO-2 study.
- True
  - False
10. In the BOLERO-2 study, one of the most frequently observed toxicities in patients who received everolimus was \_\_\_\_\_.
- Pneumonitis
  - Headache
  - Mucositis



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## *Educational Assessment and Credit Form: Second Opinion — Case-Based Discussion on the Management of Patients with Early and Advanced Breast Cancer*

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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	
			<b>BEFORE</b>	<b>AFTER</b>
Impact of tumor size and anatomy on clinical utility and/or accuracy of the Oncotype DX assay			4 3 2 1	4 3 2 1
Results of a prospective validation study of the Oncotype DX DCIS Score			4 3 2 1	4 3 2 1
Emerging research strategies in the management of HER2-positive disease (eg, neratinib, T-DM1, pertuzumab)			4 3 2 1	4 3 2 1
CLEOPATRA: Docetaxel, trastuzumab and pertuzumab as first-line therapy for HER2-positive metastatic breast cancer			4 3 2 1	4 3 2 1
Evidence for an antitumor effect of adjuvant bisphosphonates — NSABP-B-34, AZURE and ABCSG-12			4 3 2 1	4 3 2 1
BOLERO-2 study: Everolimus with exemestane for postmenopausal women with advanced, ER-positive breast cancer refractory to letrozole or anastrozole			4 3 2 1	4 3 2 1

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## *Educational Assessment and Credit Form (continued)*

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**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:**

- Integrate validated genomic assays into the clinical management of estrogen receptor (ER)-positive, node-negative and node-positive early breast cancer. .... 4 3 2 1 N/M N/A
- Assimilate new clinical trial evidence into the therapeutic algorithm for advanced ER-positive breast cancer. .... 4 3 2 1 N/M N/A
- Appraise the role of bone-directed systemic treatment in the management of breast cancer. .... 4 3 2 1 N/M N/A

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## *Educational Assessment and Credit Form (continued)*

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- Demonstrate knowledge of emerging research to support alternative or novel chemotherapeutic regimens in the adjuvant and metastatic settings, and integrate these findings into best-practice disease management strategies. . . . . 4 3 2 1 N/M N/A
- Apply the results of emerging research to effectively integrate HER2-directed treatments into the systemic management of advanced HER2-positive breast cancer. . . . . 4 3 2 1 N/M N/A
- Recognize the rationale for ongoing investigation of angiogenesis inhibitors in the adjuvant setting. . . . . 4 3 2 1 N/M N/A
- Recall the results of pivotal trials introducing effective new breast cancer therapeutics, and identify their impact on existing treatment algorithms. . . . . 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: .....

**Additional comments about this activity:**.....

**As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.**

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

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

## *Educational Assessment and Credit Form (continued)*

### **PART 2 — Please tell us about the faculty and moderator for this educational activity**

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal	
<b>Faculty</b>	<b>Knowledge of subject matter</b>				<b>Effectiveness as an educator</b>
George W Sledge Jr, MD	4	3	2	1	4 3 2 1
<b>Moderator</b>	<b>Knowledge of subject matter</b>				<b>Effectiveness as an educator</b>
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:**

.....

### **REQUEST FOR CREDIT — Please print clearly**

Name: ..... Specialty: .....

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## *Educational Assessment and Credit Form (continued)*

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

Signature: ..... Date: .....

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