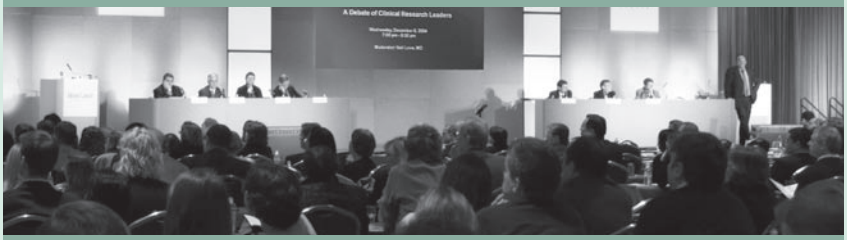
WHAT CLINICIANS WANT TO KNOW

Addressing the Most Common Questions and Controversies in the Current Clinical Management of Breast Cancer



Proceedings from a CME Satellite Symposium at the 32nd Annual San Antonio Breast Cancer Symposium

Moderator

Neil Love, MD

Faculty

Rowan T Chlebowski, MD, PhD
Luca Gianni, MD
Joyce O'Shaughnessy, MD
Bryan P Schneider, MD
Eric P Winer, MD

Bonus web audio featuring Drs Chlebowski and Winer answering clinical questions submitted by symposium attendees online at:

ResearchToPractice.com

From the publishers of:

Breast Cancer® UPDATE

CME Certified

Subscribe to Podcasts or download MP3s of this program at ResearchToPractice.com/SABCS10

What Clinicians Want To Know: Addressing the Most Common Questions and Controversies in the Current Clinical Management of Breast Cancer

A Continuing Medical Education Program

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, these proceedings from a case-based CME satellite symposium at the 2009 San Antonio Breast Cancer Symposium utilize the perspectives of clinical investigators, in addition to the exchange among these individuals, to apply evidence-based concepts to routine practice. By providing access to the latest research developments and expert opinions on the disease, this activity will assist medical oncologists, hematologists and hematology-oncology fellows in the formulation of up-to-date clinical management strategies for patients with breast cancer.

LEARNING OBJECTIVES

- Use currently available tissue-based genomic assays to assist with therapeutic decision-making in the management of node-negative and node-positive early breast cancer.
- Apply the results of existing data and emerging research when selecting the optimal duration and sequence of endocrine therapy for appropriate patients.
- Optimize the treatment of HER2-overexpressing breast cancer through rational integration of existing and emerging HER2-directed agents.
- Communicate the benefit-risk profile of bevacizumab and its evidence-based therapeutic partners to appropriate patients with metastatic breast cancer.
- Incorporate the findings from recent clinical trials into the individualized selection and sequence of chemotherapy for patients with early or advanced triple-negative breast cancer.
- Counsel appropriately selected patients about the availability of ongoing clinical trial participation.

ACCREDITATION STATEMENT

Research To Practice is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT

Research To Practice designates this educational activity for a maximum of 1.5 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

HOW TO USE THIS CME ACTIVITY

This CME activity contains an audio component. To receive credit, the participant should review the CME information, listen to the CD and complete the Post-test and Educational Assessment and Credit Form located in the back of this booklet or on our website at **CME.ResearchToPractice.com**.

This program is supported by educational grants from AstraZeneca Pharmaceuticals LP, Genentech BioOncology and Genomic Health Inc.

This educational activity contains discussion of published and/or investigational uses of agents that are not indicated by the Food and Drug Administration. Research To Practice does not recommend the use of any agent outside of the labeled indications. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications and warnings. The opinions expressed are those of the presenters and are not to be construed as those of the publisher or grantors.

Last review date: March 2010; Release date: March 2010; Expiration date: March 2011

CME INFORMATION

MODERATOR

Neil Love, MD
Editor, *Breast Cancer Update*
Research To Practice
Miami, Florida

Joyce O'Shaughnessy, MD
Co-Director, Breast Cancer Research Program
Baylor-Charles A Sammons Cancer Center
Texas Oncology, PA
US Oncology
Dallas, Texas

FACULTY

Rowan T Chlebowski, MD, PhD
Professor of Medicine
David Geffen School of Medicine at UCLA
Chief, Division of Medical Oncology and Hematology
Harbor-UCLA Medical Center
Torrance, California

Bryan P Schneider, MD
Assistant Professor
Department of Medicine
Division of Hematology/Oncology
The Indiana University Melvin and Bren Simon Cancer Center
Indianapolis, Indiana

Luca Gianni, MD
Director of Medical Oncology 1
Department of Medical Oncology
Istituto Nazionale Tumori di Milano
Milan, Italy

Eric P Winer, MD
Thompson Investigator in Breast Cancer Research
Chief, Division of Women's Cancers, Dana-Farber Cancer Institute; Professor of Medicine
Harvard Medical School
Boston, Massachusetts

CONTENT VALIDATION AND DISCLOSURES

Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-the-art education. We assess potential conflicts of interest with faculty, planners and managers of CME activities. Real or apparent conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent physician reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations.

FACULTY — **Dr Winer** had no real or apparent conflicts of interest to disclose. The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Chlebowski** — Consulting Agreements: Amgen Inc, AstraZeneca Pharmaceuticals LP, Lilly USA LLC, Novartis Pharmaceuticals Corporation, Sanofi-Aventis; Paid Research: Lilly USA LLC; Speakers Bureau: Abraxis BioScience, AstraZeneca Pharmaceuticals LP, Genentech BioOncology, Novartis Pharmaceuticals Corporation. **Dr Gianni** — Advisory Committee: Abraxis BioScience, Bristol-Myers Squibb Company, Celgene Corporation, Eisai Inc, Genentech BioOncology, GlaxoSmithKline, Novartis Pharmaceuticals Corporation, Roche Laboratories Inc, Sanofi-Aventis, Wyeth; Consulting Agreement: Millennium Pharmaceuticals Inc. **Dr O'Shaughnessy** — Speakers Bureau: Abraxis BioScience, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Lilly USA LLC, Sanofi-Aventis. **Dr Schneider** — Advisory Committee: Genentech BioOncology, Genomic Health Inc, GlaxoSmithKline; Paid Research: Genentech BioOncology.

MODERATOR — Dr Love is president and CEO of Research To Practice, which receives funds in the form of educational grants to develop CME activities from the following commercial interests: Abraxis BioScience, Amgen Inc, AstraZeneca Pharmaceuticals LP, Bayer Pharmaceuticals Corporation/Onyx Pharmaceuticals Inc, Biogen Idec, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Centocor Ortho Biotech Services LLC, Cephalon Inc, Eisai Inc, EMD Serono Inc, Genentech BioOncology, Genomic Health Inc, Genzyme Corporation, GlaxoSmithKline, ImClone Systems Incorporated, Lilly USA LLC, Millennium Pharmaceuticals Inc, Monogram BioSciences Inc, Novartis Pharmaceuticals Corporation, OSI Oncology, Roche Laboratories Inc, Sanofi-Aventis and Spectrum Pharmaceuticals Inc.

RESEARCH TO PRACTICE STAFF AND EXTERNAL REVIEWERS — The scientific staff and reviewers for Research To Practice have no real or apparent conflicts of interest to disclose.

POST-TEST

What Clinicians Want To Know: Addressing the Most Common Questions and Controversies in the Current Clinical Management of Breast Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **In the MD Anderson analysis of clinical outcomes among patients with node-negative breast cancer smaller than one centimeter, the five-year disease-free survival rate for patients with HER2-positive disease was _____ compared to 94 percent for those with HER2-negative disease.**
   a. 55 percent
   b. 77 percent
   c. 89 percent

2. **In a randomized trial for patients with heavily pretreated HER2-positive metastatic breast cancer with disease progression on trastuzumab, the combination of lapatinib/trastuzumab compared to lapatinib alone resulted in a significant _____ improvement in overall survival.**
   a. One-month
   b. Two-month
   c. Four-month

3. **T-DM1 contains the humanized anti-HER2 monoclonal antibody trastuzumab linked to a highly potent antimicrotubule drug (DM1) derived from maytansine.**
   a. True
   b. False

4. **In Kathy Albain's analysis of the Onco*type* DX® assay, postmenopausal patients with node-positive, ER-positive breast cancer at which of the following risk levels derived a breast cancer-specific survival benefit from CAF chemotherapy followed by tamoxifen versus tamoxifen alone?**
   a. Low risk
   b. Intermediate risk
   c. High risk
   d. Both b and c

5. **In the AVADO trial, response rate and progression-free survival improved with the addition of bevacizumab to docetaxel versus docetaxel alone for the first-line treatment of metastatic breast cancer.**
   a. True
   b. False

6. **Which of the following ongoing prospective trials evaluating Onco*type* DX includes patients with node-positive breast cancer?**
   a. TAILORx study
   b. Milan/European study
   c. Neither a nor b
   d. Both a and b

7. **In the CONFIRM trial, which compared fulvestrant 500 mg to 250 mg for postmenopausal women with ER-positive metastatic breast cancer, high-dose fulvestrant resulted in a _____ time to disease progression compared to standard-dose fulvestrant.**
   a. Equivalent
   b. Inferior
   c. Superior

8. **When combined with bevacizumab as first-line therapy for metastatic breast cancer, which of the following chemotherapeutic agents have been associated with improvement in time to disease progression compared to chemotherapy alone?**
   a. Taxanes
   b. Anthracyclines
   c. Capecitabine
   d. All of the above

9. **In a randomized Phase II study, the addition of the PARP inhibitor BSI-201 to gemcitabine/carboplatin resulted in a _____ reduction in the risk of death for patients with triple-negative metastatic breast cancer.**
   a. 20 percent
   b. 30 percent
   c. 50 percent

10. **A multicenter Phase III trial is currently evaluating gemcitabine/carboplatin with or without BSI-201 for patients with triple-negative metastatic breast cancer.**
    a. True
    b. False

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

EDUCATIONAL ASSESSMENT AND CREDIT FORM

What Clinicians Want To Know: Addressing the Most Common Questions and Controversies in the Current Clinical Management of Breast Cancer

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 ONE — 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
Risk of recurrence for patients with small, node-negative, HER2-positive breast cancer (BC)	4 3 2 1	4 3 2 1
Survival benefit of lapatinib/trastuzumab for patients with HER2-positive metastatic breast cancer (mBC) progressing on trastuzumab	4 3 2 1	4 3 2 1
Activity and tolerability of T-DM1 in patients with heavily pretreated HER2-positive mBC	4 3 2 1	4 3 2 1
Prognostic and predictive value of the Onco*type* DX assay for postmenopausal women with node-positive, ER-positive BC	4 3 2 1	4 3 2 1
Ongoing prospective trials of adjuvant therapy based on risk assessment with the Onco*type* DX assay	4 3 2 1	4 3 2 1
CONFIRM trial: Fulvestrant 250 mg versus 500 mg for postmenopausal women with ER-positive mBC	4 3 2 1	4 3 2 1
Chemotherapy/bevacizumab for HER2-negative mBC	4 3 2 1	4 3 2 1
Chemotherapy and the PARP inhibitor BSI-201 in triple-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:.....

Will this activity help you improve patient care?

☐ Yes ☐ No ☐ Not applicable

If no, please explain:.....

Did the activity meet your educational needs and expectations?

☐ 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:

- Use currently available tissue-based genomic assays to assist with therapeutic decision-making in the management of node-negative and node-positive early breast cancer. . . . . 4 3 2 1 N/M N/A
- Apply the results of existing data and emerging research when selecting the optimal duration and sequence of endocrine therapy for appropriate patients. . . 4 3 2 1 N/M N/A
- Optimize the treatment of HER2-overexpressing breast cancer through rational integration of existing and emerging HER2-directed agents. . . . . 4 3 2 1 N/M N/A
- Communicate the benefit-risk profile of bevacizumab and its evidence-based therapeutic partners to appropriate patients with metastatic breast cancer. . . . . 4 3 2 1 N/M N/A
- Incorporate the findings from recent clinical trials into the individualized selection and sequence of chemotherapy for patients with early or advanced triple-negative breast cancer. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients about the availability of ongoing clinical trial participation. . . . . 4 3 2 1 N/M N/A

What other practice changes will you make or consider making as a result of this activity?

.....

What additional information or training do you need on the activity topics or other oncology-related topics?

.....

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.

PART TWO — Please tell us about the faculty and moderator for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter	Effectiveness as an educator
Rowan T Chlebowski, MD, PhD	4 3 2 1	4 3 2 1
Luca Gianni, MD	4 3 2 1	4 3 2 1
Joyce O'Shaughnessy, MD	4 3 2 1	4 3 2 1
Bryan P Schneider, MD	4 3 2 1	4 3 2 1
Eric P Winer, 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:

.....

REQUEST FOR CREDIT — Please print clearly

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

Professional Designation:

☐ MD ☐ DO ☐ PharmD ☐ NP ☐ RN ☐ PA ☐ Other .....

Medical License/ME Number: ..... Last 4 Digits of SSN (required): .....

Street Address: ..... Box/Suite: .....

City, State, Zip: .....

Telephone: ..... Fax: .....

Email: .....

Research To Practice designates this educational activity for a maximum of 1.5 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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

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

To obtain a certificate of completion and receive credit for this activity, please complete the Post-test, fill out the Educational Assessment and Credit Form and fax both to (800) 447-4310, or mail both to Research To Practice, One Biscayne Tower, 2 South Biscayne Boulevard, Suite 3600, Miami, FL 33131. You may also complete the Post-test and Educational Assessment online at CME.ResearchToPractice.com.

SABCS10

Breast Cancer® UPDATE

Moderator	Neil Love, MD
Managing Editor and CME Director	Kathryn Ault Ziel, PhD
Scientific Director	Richard Kaderman, PhD
Senior Director, Medical Affairs	Aviva Asnis-Alibozek, PA-C, MPAS
Writer	Douglas Paley
Continuing Education Administrator for Nursing	Sally Bogert, RNC, WHCNP
Content Validation	Margaret Peng Erin Wall Clayton Campbell Gloria Kelly, PhD
Director, Creative and Copy Editing	Aura Herrmann
Creative Manager	Fernando Rendina
Graphic Designers	Jessica Benitez Jason Cunnius Tamara Dabney Deepti Nath
Senior Production Editor	Alexis Oneca
Traffic Manager	Tere Sosa
Copy Editors	Dave Amber Margo Harris David Hill Rosemary Hulce Kirsten Miller Pat Morrissey/Havlin Carol Peschke
Production Manager	Tracy Potter
Audio Production	Frank Cesarano
Web Master	John Ribeiro
Faculty Relations Manager	Melissa Vives
Contact Information	Neil Love, MD Research To Practice One Biscayne Tower 2 South Biscayne Boulevard, Suite 3600 Miami, FL 33131 Fax: (305) 377-9998 Email: DrNeilLove@ResearchToPractice.com
For CME/CNE Information	Email: CE@ResearchToPractice.com

Breast Cancer®
UPDATE

This program is supported by educational grants from
AstraZeneca Pharmaceuticals LP, Genentech BioOncology and Genomic Health Inc.

Research
To Practice®

Sponsored by Research To Practice.

Last review date: March 2010
Release date: March 2010
Expiration date: March 2011
Estimated time to complete: 1.5 hours