



Visiting Professors

A case-based discussion on the management of breast cancer

CLINICAL INVESTIGATOR

Harold J Burstein, MD, PhD

EDITOR

Neil Love, MD

COMMUNITY ONCOLOGIST

Richard S Zelkowitz, MD

Featuring a clinical investigator's perspective on a day spent visiting patients with breast cancer in the clinic of a community oncologist



Subscribe to Podcasts or download MP3s of this program at ResearchToPractice.com/VPB111

From the publishers of:

Breast Cancer[®]
UPDATE



Visiting Professors: A case-based discussion on the management of breast cancer

OVERVIEW OF ACTIVITY

Individualized treatment decisions for patients with early, locally advanced or metastatic breast cancer are driven by disease- and patient-specific characteristics. The numerous therapeutic agents and regimens with significant activity in the management of breast cancer provide ample opportunity to deliver tailored care. However, the multiplicity of alternatives may also yield clinical scenarios in which several acceptable treatment options are available, with the optimal strategy being highly debatable and dependent on a thorough understanding of each agent's unique benefits and risks.

To provide clinicians with therapeutic strategies to address the disparate needs of patients with breast cancer, the *Visiting Professors* audio series employs an innovative case-based approach that unites the perspectives of leading breast cancer investigators and community oncologists as they explore the intricacies of making treatment decisions. Upon completion of this CME activity, medical oncologists should be able to formulate an up-to-date and more complete approach to the care of patients with breast cancer.

LEARNING OBJECTIVES

- Apply case-based learning, innovative communication strategies and shared clinical insight to provide comprehensive and compassionate oncology care.
- 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.
- Construct an evidence-based treatment algorithm integrating anti-HER2 therapies for the treatment of HER2-positive breast cancer in the neoadjuvant, adjuvant and metastatic settings.
- Effectively integrate biologic, hormonal and cytotoxic therapy into the multifaceted management of metastatic breast cancer.
- Apply the results of emerging research to effectively and safely integrate bevacizumab into the first- and second-line treatment of HER2-negative metastatic 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 enduring material for a maximum of 1.5 *AMA PRA Category 1 Credits™*. Physicians should claim only the 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, complete the Post-test with a score of 70 percent or better and fill out the Educational Assessment and Credit Form located in the back of this booklet or on our website at ResearchToPractice.com/VPB111/CME.

This activity is supported by educational grants from Genentech BioOncology and Genomic Health Inc.

Last review date: August 2011; Release date: August 2011; Expiration date: August 2012

CME INFORMATION

CLINICAL INVESTIGATOR



Harold J Burstein, MD, PhD
Associate Professor of Medicine
Harvard Medical School
Breast Oncology Center
Dana-Farber Cancer Institute
Boston, Massachusetts

COMMUNITY ONCOLOGIST



Richard S Zekowitz, MD
Chief, Section Hematology/
Oncology; Medical Director
Smilow Family Breast Center
Norwalk Hospital
Norwalk, Connecticut

EDITOR



Neil Love, MD
Research To Practice
Miami, Florida

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 Burstein** 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 Zekowitz** — *Speakers Bureau*: Genomic Health Inc.

EDITOR — 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: Allos Therapeutics, Amgen Inc, AstraZeneca Pharmaceuticals LP, Aureon Laboratories Inc, Bayer HealthCare Pharmaceuticals/Onyx Pharmaceuticals Inc, Biogen Idec, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Cephalon Inc, Daiichi Sankyo Inc, Dendreon Corporation, Eisai Inc, EMD Serono Inc, Genentech BioOncology, Genomic Health Inc, ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company, Lilly USA LLC, Millennium: The Takeda Oncology Company, Mundipharma International Limited, Myriad Genetics Inc, Novartis Pharmaceuticals Corporation, OSI Oncology, Sanofi and Seattle Genetics.

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.

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.

QUESTIONS (PLEASE CIRCLE ANSWER):

- 1. Analysis of patients with HER2-positive early breast cancer receiving trastuzumab versus lapatinib in combination with neoadjuvant anthracycline/taxane-based chemotherapy in the GeparQuinto GBG 44 study revealed a higher pathologic complete response (pCR) rate with chemotherapy/trastuzumab than with chemotherapy/lapatinib.**
 - a. True
 - b. False
- 2. The neoadjuvant Phase III Neo-ALTT0 trial, which evaluated lapatinib, trastuzumab and the combination with paclitaxel for patients with HER2-positive primary breast cancer, reported the highest pCR rate on the paclitaxel/lapatinib arm.**
 - a. True
 - b. False
- 3. The NEOSPHERE trial found that the combination of pertuzumab, trastuzumab and docetaxel was associated with the highest response rate in comparison to docetaxel with either biologic agent alone.**
 - a. True
 - b. False
- 4. Which of the following side effects are associated with bevacizumab?**
 - a. Hypertension
 - b. Headache
 - c. Increased incidence of congestive heart failure
 - d. All of the above
- 5. What is the mechanism of action of eribulin?**
 - a. Microtubule inhibitor
 - b. Anti-VEGF
 - c. HER2 inhibitor
 - d. Pyrimidine analog
- 6. In the Phase III EMBRACE trial, single-agent eribulin _____ overall survival when compared to physician's choice of monotherapy or supportive care alone for patients with previously treated locally recurrent or metastatic breast cancer.**
 - a. Failed to improve
 - b. Significantly improved
- 7. Which of the following has been shown to be a predictor of chemotherapy benefit in ER-positive, node-negative breast cancer?**
 - a. Recurrence Score®
 - b. Recurrence Score-Pathology-Clinical
 - c. Both of the above
 - d. None of the above
- 8. T-DM1 is a novel agent that combines a maytansine derivative with _____.**
 - a. Docetaxel
 - b. Trastuzumab
 - c. Bevacizumab
 - d. None of the above
- 9. Patients with HER2-positive metastatic disease previously treated with HER2-directed therapies had a response rate of approximately _____ percent when treated with T-DM1.**
 - a. Five
 - b. 10
 - c. 30
 - d. 60
- 10. A Phase II study of the irreversible tyrosine kinase inhibitor neratinib published by Burstein and colleagues reported an approximate 25 percent response rate among patients with heavily pretreated advanced breast cancer.**
 - a. True
 - b. False

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			
Role of the Oncotype DX® Recurrence Score in clinical decision-making	4	3	2	1	4	3	2	1
Results of major neoadjuvant trials of anti-HER2-based therapy (GeparQuinto, Neo-ALTO, NEOSPHERE)	4	3	2	1	4	3	2	1
Efficacy and tolerability of T-DM1 for patients with HER2-positive metastatic breast cancer	4	3	2	1	4	3	2	1
Dose and schedule of capecitabine alone and in combination for HER2-negative breast cancer	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; no changes will be made
- 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 one 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:

- Apply case-based learning, innovative communication strategies and shared clinical insight to provide comprehensive and compassionate oncology care 4 3 2 1 N/M N/A
- 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
- Construct an evidence-based treatment algorithm integrating anti-HER2 therapies for the treatment of HER2-positive breast cancer in the neoadjuvant, adjuvant and metastatic settings. 4 3 2 1 N/M N/A
- Effectively integrate biologic, hormonal and cytotoxic therapy into the multifaceted management of metastatic breast cancer. 4 3 2 1 N/M N/A
- Apply the results of emerging research to effectively and safely integrate bevacizumab into the first- and second-line treatment of HER2-negative metastatic 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

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:

.....

Additional comments about this activity:

.....

.....

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

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal
Faculty	Knowledge of subject matter			Effectiveness as an educator
Harold J Burstein, MD, PhD	4	3	2	1
Richard S Zerkowitz, MD	4	3	2	1
Editor	Knowledge of subject matter			Effectiveness as an educator
Neil Love, MD	4	3	2	1

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and editor for this activity:

.....

.....

REQUEST FOR CREDIT — Please print clearly

Name: Specialty:

Professional Designation:

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

Street Address: Box/Suite:

City, State, Zip:

Telephone: Fax:

Email:

Research To Practice designates this enduring material for a maximum of 1.5 AMA PRA Category 1 Credits™. Physicians should claim only the 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 www.ResearchToPractice.com/VPB111/CME.

Visiting Professors

Editor	Neil Love, MD
Managing Editor and CME Director	Kathryn Ault Ziel, PhD
Scientific Director	Richard Kaderman, PhD
Editorial	Clayton Campbell Gloria Kelly, PhD Jean Pak Margaret Peng
Creative Manager	Fernando Rendina
Graphic Designers	Jessica Benitez Jason Cunnius Tamara Dabney Silvana Izquierdo Deepti Nath
Copy Editing Manager	Kirsten Miller
Senior Production Editor	Aura Herrmann
Copy Editors	Margo Harris David Hill Rosemary Hulce Pat Morrissey/Havlin Alexis Oneca Carol Peschke
Production Manager	Tracy Potter
Audio Production	Frank Cesarano
Web Master	John Ribeiro
Multimedia Project Manager	Marie Philemon
Faculty Relations Manager	Melissa Molieri
Continuing Education Administrator for Nursing	Julia W Aucoin, DNS, RN-BC, CNE
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

Copyright © 2011 Research To Practice. All rights reserved.

The compact disc, Internet content and accompanying printed material are protected by copyright. No part of this program may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording or utilizing any information storage and retrieval system, without written permission from the copyright owner.

The opinions expressed are those of the presenters and are not to be construed as those of the publisher or grantors.

Participants have an implied responsibility to use

the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management.

Any procedures, medications or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patients' conditions and possible contraindications or dangers in use, review of any applicable manufacturer's product information and comparison with recommendations of other authorities.

Copyright © 2011 Research To Practice.
This activity is supported by educational grants from
Genentech BioOncology and Genomic Health Inc.

Research To Practice®

Sponsored by Research To Practice.

Last review date: August 2011
Release date: August 2011
Expiration date: August 2012
Estimated time to complete: 1.5 hours