Current Controversies in the Management of Early and Advanced Breast Cancer
A Tumor Panel Discussion Focused on Personal Cases of the Faculty

Proceedings from a CME Satellite Symposium at the 29th Annual San Antonio Breast Cancer Symposium

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CME Information: Current Controversies in the Management of Early and Advanced Breast Cancer

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, Breast Cancer Update uses one-on-one discussions with leading oncology investigators. By providing access to the latest research developments and expert perspectives, this CME program assists medical oncologists in the formulation of up-to-date clinical management strategies. The purpose of this special issue of Breast Cancer Update is to present the most current research developments in the systemic management of early and advanced breast cancer.

GLOBAL LEARNING OBJECTIVES
- Evaluate the emerging data on various adjuvant chemotherapy approaches, including dose-dense treatment and other taxane-based regimens, and explain the absolute risks and benefits of adjuvant chemotherapy regimens to patients.
- Counsel postmenopausal patients with ER-positive breast cancer about the risks and benefits of neoadjuvant and adjuvant aromatase inhibitors and of sequencing aromatase inhibitors after tamoxifen.
- Develop and explain a management strategy for patients with ER-positive, metastatic breast cancer, including sequencing of hormonal therapies.
- Describe and implement an algorithm for treatment of early and advanced HER2-positive breast cancer, including appropriate adjuvant chemotherapy regimens and endocrine therapy to combine with trastuzumab.

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 Burstein, Buzdar, Dixon, Hudis, Mackey, Tripathy and Vogel on the integration of emerging research data in systemic therapy of early and advanced breast cancer into clinical practice.

ACCREDITATION STATEMENT
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CME Information (continued)

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HOW TO USE THIS CME ACTIVITY
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 BreastCancerUpdate.com/SABCS_2006.

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CME Information (continued)

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John H Brebner, Richard Kaderman, PhD, Neil Love, MD, Douglas Paley, Michelle Paley, MD, Margaret Peng, Lilliam Sklaver Poltorack, PharmD, Ginelle Suarez, Erin Wall and Kathryn Ault Ziel, PhD — no real or apparent conflicts of interest to report; Sally Bogert, RNC, WHCNP — shareholder of Amgen Inc and Genentech BioOncology. Research To Practice receives education grants from Abraxis Oncology, Amgen Inc, AstraZeneca Pharmaceuticals LP, Bayer Pharmaceuticals Corporation/Onyx Pharmaceuticals Inc, Biogen Idec, Genentech BioOncology/OSI Pharmaceuticals Inc, Genomic Health Inc, Roche Laboratories Inc and Sanofi-Aventis, who have no influence on the content development of our educational activities.

In addition, the following faculty (and their spouses/partners) have reported real or apparent conflicts of interest that have been resolved through a peer review process:

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Speakers Bureau: Amgen Inc, Genentech BioOncology.

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Consulting Fees: AstraZeneca Pharmaceuticals LP, Genentech BioOncology, Pfizer Inc, Roche Laboratories Inc; Contracted Research: AstraZeneca Pharmaceuticals LP, Genentech BioOncology, Pfizer Inc, Roche Laboratories Inc, Taiho Pharmaceutical Co Ltd.

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**Charles L Vogel, MD**

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1. In the MSKCC pilot study of dose-dense AC → paclitaxel with trastuzumab, _____ patient(s) out of 70 experienced significant, protocol-defined declines in LVEF.
   a. One
   b. Four
   c. Seven

2. The results of the TAnDEM study in postmenopausal women with hormone receptor-positive, HER2-positive metastatic breast cancer demonstrated that the addition of trastuzumab to anastrozole resulted in ________________.
   a. No improvement in time to progression
   b. A doubling of the time to progression
   c. A tripling of the time to progression

3. An unplanned subset analysis of CALGB data by Don Berry and colleagues suggested that dose-dense therapy provides a better disease-free survival rate for patients with ER-negative, PR-negative disease compared to those with ER-positive, PR-positive disease.
   a. True
   b. False

4. In a small neoadjuvant trial comparing chemotherapy to hormonal therapy (anastrozole or exemestane) in postmenopausal women with ER-positive and/or PR-positive disease, the _______ were higher with hormonal therapy.
   a. Clinical response rates
   b. Pathologic response rates
   c. Rates of breast-conserving surgery
   d. All of the above
   e. None of the above

5. Treatment guidelines recommend the use of prophylactic white blood cell growth factors if the rate of febrile neutropenia with adjuvant chemotherapy is greater than ______.
   a. One percent
   b. Five percent
   c. 10 percent
   d. 20 percent

6. The BCIRG 006 study reported that TCH caused statistically significantly less neutropenic infections compared to AC → TH.
   a. True
   b. False
7. In patients with hormone receptor-positive metastases with progression on a nonsteroidal aromatase inhibitor, the EFECT trial demonstrated that, in terms of efficacy and safety, __________.
   a. Fulvestrant was superior to exemestane
   b. Fulvestrant and exemestane were comparable
   c. Exemestane was superior to fulvestrant

8. In the second interim analysis of BCIRG 006, the incidence of cardiac events was significantly ________ in patients receiving TCH than in those receiving AC → TH.
   a. Lower
   b. Higher

9. Data from randomized Phase III adjuvant trials suggest that continuing an aromatase inhibitor beyond five years of tamoxifen reduces the risk of recurrence.
   a. True
   b. False

10. The EFECT trial used a loading dose of fulvestrant.
    a. True
    b. False

11. In an ongoing Phase II study of combined bevacizumab and trastuzumab as first-line treatment for patients with HER2-positive, metastatic breast cancer, an objective response rate of ________ was reported.
    a. 10 percent
    b. 25 percent
    c. 30 percent
    d. 46 percent
    e. None of the above

12. SWOG is conducting a Phase III trial comparing anastrozole with or without ________ as first-line therapy for postmenopausal women with hormone receptor-positive disease.
    a. Tamoxifen
    b. Exemestane
    c. Letrozole
    d. Fulvestrant

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

GLOBAL LEARNING OBJECTIVES

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

• Evaluate the emerging data on various adjuvant chemotherapy approaches, including dose-dense treatment and other taxane-based regimens, and explain the absolute risks and benefits of adjuvant chemotherapy regimens to patients. ............ 5 4 3 2 1

• Counsel postmenopausal patients with ER-positive breast cancer about the risks and benefits of neoadjuvant and adjuvant aromatase inhibitors and of sequencing aromatase inhibitors after tamoxifen. ................................. 5 4 3 2 1

• Develop and explain a management strategy for patients with ER-positive, metastatic breast cancer, including sequencing of hormonal therapies. ................. 5 4 3 2 1

• Describe and implement an algorithm for treatment of early and advanced HER2-positive breast cancer, including appropriate adjuvant chemotherapy regimens and endocrine therapy to combine with trastuzumab. ....................... 5 4 3 2 1
EFFECTIVENESS OF THE INDIVIDUAL FACULTY MEMBERS

<table>
<thead>
<tr>
<th>Faculty</th>
<th>Knowledge of subject matter</th>
<th>Effectiveness as an educator</th>
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<tbody>
<tr>
<td>Harold J Burstein, MD, PhD</td>
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<td>Charles L Vogel, MD</td>
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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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☐ 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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I certify my actual time spent to complete this educational activity to be _________ hour(s).

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