

Cancer Conference Update



An audio review of key presentations and posters from important scientific meetings

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29th Annual San Antonio
Breast Cancer Symposium
December 14th to 17th, 2006

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U P D A T E



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Cancer Conference Update

A Continuing Medical Education Audio Series

STATEMENT OF NEED/TARGET AUDIENCE

Oncology is one of the most rapidly evolving fields in medicine. Results presented at major cancer conferences 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, the practicing medical oncologist must be well informed of these advances.

To bridge the gap between research and patient care, Cancer Conference Update uses one-on-one discussions with leading oncology investigators to discuss key clinical trial results presented at major oncology symposia. 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.

GLOBAL LEARNING OBJECTIVES

- Critically evaluate the clinical implications of emerging clinical trial data in breast cancer treatment and incorporate these data into management strategies in the adjuvant, neoadjuvant, metastatic and preventive settings.
- Counsel postmenopausal patients with ER-positive breast cancer about the risks and benefits of adjuvant aromatase inhibitors and of switching to or sequencing aromatase inhibitors after tamoxifen.
- Describe and implement an algorithm for treatment of patients with HER2-positive breast cancer in the adjuvant and metastatic settings.
- Evaluate the emerging data on various adjuvant chemotherapy approaches and explain the absolute risks and benefits of adjuvant chemotherapy regimens to patients.
- Counsel appropriate patients with metastatic disease about selection and sequencing of endocrine therapy and about the risks and benefits of various chemotherapeutic and biologic options.

PURPOSE OF THIS ISSUE OF CANCER CONFERENCE UPDATE

The purpose of Issue 1 of Cancer Conference Update is to offer the perspectives of Drs Mackey, Ravdin and Hudis on the integration of data presented at the 2006 San Antonio Breast Cancer Symposium into the management of breast cancer.

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UPCOMING EDUCATIONAL EVENTS

NCCN 12th Annual Conference: Clinical Practice Guidelines and Quality Cancer Care

March 14-18, 2007

Hollywood, Florida

Event website: nccn.org

Preoperative Therapy in Invasive Breast Cancer: Reviewing the State of the Science and Exploring New Research Directions

March 26-27, 2007

Bethesda, Maryland

Event website: ctep.cancer.gov/bcmeeting

American Association for Cancer Research Annual Meeting

April 14-18, 2007

Los Angeles, California

Event website: aacr.org

NCCTG Semi-Annual Meeting

April 16-19, 2007

Rochester, Minnesota

Event website: ncctg.mayo.edu

NSABP Semi-Annual Meeting

April 27-30, 2007

Jacksonville, Florida

Event website: nsabp.org

SWOG Semi-Annual Meeting

May 2-6, 2007

Chicago, Illinois

Event website: swog.org

ASCO 2007 Annual Meeting

June 1-5, 2007

Chicago, Illinois

Event website: asco.org

PUBLICATIONS DISCUSSED BY JOHN MACKEY, MD

Abstracts listed in order of their review in the audio program

Slamon D et al. **BCIRG 006: 2nd interim analysis phase III randomized trial comparing doxorubicin and cyclophosphamide followed by docetaxel (ACT) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (ACTH) with docetaxel, carboplatin and trastuzumab (TCH) in Her2neu positive early breast cancer patients.** San Antonio Breast Cancer Symposium 2006; [Abstract 52](#).

Pegram M et al. **Phase II combined biological therapy targeting the HER2 proto-oncogene and the vascular endothelial growth factor using trastuzumab (T) and bevacizumab (B) as first line treatment of HER2-amplified breast cancer.** San Antonio Breast Cancer Symposium 2006; [Abstract 301](#).

Norris B et al. **Poor 10 yr breast cancer specific survival and relapse free survival for HER2 positive T1N0 tumors.** San Antonio Breast Cancer Symposium 2006; [Abstract 2031](#).

Xu L et al. **Capecitabine (X) + trastuzumab (H) as first-line treatment in patients (pts) with HER2-positive metastatic breast cancer (MBC): Phase II trial results.** San Antonio Breast Cancer Symposium 2006; [Abstract 2065](#).

Mackey JR et al. **Trastuzumab prolongs progression-free survival in hormone-dependent and HER2-positive metastatic breast cancer.** San Antonio Breast Cancer Symposium 2006; [Abstract 3](#).

Gradishar W et al. **Fulvestrant versus exemestane following prior non-steroidal aromatase inhibitor therapy: First results from EFECT, a randomized, phase III trial in postmenopausal women with advanced breast cancer.** San Antonio Breast Cancer Symposium 2006; [Abstract 12](#).

PUBLICATIONS DISCUSSED BY PETER M RAVDIN, MD, PHD

Ravdin PM et al. **A sharp decrease in breast cancer incidence in the United States in 2003.** San Antonio Breast Cancer Symposium 2006; [Abstract 5](#).

Mamounas E et al. **Benefit from exemestane (EXE) as extended adjuvant therapy after 5 years of tamoxifen (TAM): Intent-to-treat analysis of NSABP B-33.** San Antonio Breast Cancer Symposium 2006; [Abstract 49](#).

Dowsett M et al. **Relationship between quantitative ER and PgR expression and HER2 status with recurrence in the ATAC trial.** San Antonio Breast Cancer Symposium 2006; [Abstract 48](#).

Muss HB et al. **The benefits of letrozole in postmenopausal women with early stage breast cancer who have had five years of tamoxifen are independent of age.** San Antonio Breast Cancer Symposium 2006; [Abstract 102](#).

Cuzick J et al. **A detailed analysis of the benefits of anastrozole over tamoxifen for venous thromboembolic events (VTEs) after 5 years treatment.** San Antonio Breast Cancer Symposium 2006; [Abstract 104](#).

Brufsky A et al. **An integrated analysis of zoledronic acid (ZA) for prevention of aromatase inhibitor associated bone loss (AIBL) in postmenopausal women (PMW) with early breast cancer (BCa) receiving adjuvant letrozole (LET).** San Antonio Breast Cancer Symposium 2006; [Abstract 107](#).

Singh S et al. **Effect of anastrozole on cholesterol fractions in postmenopausal women with high risk of breast cancer: Results from IBIS-II breast cancer prevention study.** San Antonio Breast Cancer Symposium 2006; [Abstract 1055](#).

McCloskey E et al. **Complete data from the letrozole (L), exemestane (E), and anastrozole (A) pharmacodynamic (PD) LEAP trial: Direct comparison of safety parameters between aromatase inhibitors (AIs) in healthy postmenopausal women.** San Antonio Breast Cancer Symposium 2006; [Abstract 2092](#).

Partridge AH et al. **Adherence with adjuvant anastrozole therapy among women with early stage breast cancer.** San Antonio Breast Cancer Symposium 2006; [Abstract 4044](#).

Duffy S et al. **Anastrozole is associated with a lower risk of endometrial abnormalities than tamoxifen: First report of the ATAC trial endometrial sub-protocol at 6 years follow-up.** San Antonio Breast Cancer Symposium 2006; [Abstract 4055](#).

Van Poznak C et al. **The SABRE (study of anastrozole with the bisphosphonate risedronate) study: The effects of risedronate on BMD and bone metabolism in postmenopausal women using anastrozole as adjuvant therapy for hormone receptor-positive early breast cancer — First results.** San Antonio Breast Cancer Symposium 2006; [Abstract 4061](#).

Baehner FL et al. **Quantitative RT-PCR analysis of ER and PR by Oncotype DX indicates distinct and different associations with prognosis and prediction of tamoxifen benefit.** San Antonio Breast Cancer Symposium 2006; [Abstract 45](#).

Watson D et al. **The impact on the recurrence score due to patient variation in the quantitative expression of individual genes or gene groups.** San Antonio Breast Cancer Symposium 2006; [Abstract 6039](#).

Shak S et al. **Relationship between proliferation genes and expression of hormone and growth factor receptors: Quantitative RT-PCR in 10,618 breast cancers.** San Antonio Breast Cancer Symposium 2006; [Abstract 6111](#).

Shak S et al. **Subtypes of breast cancer defined by standardized quantitative RT-PCR analysis of 10,618 tumors.** San Antonio Breast Cancer Symposium 2006; [Abstract 6118](#).

PUBLICATIONS DISCUSSED BY CLIFFORD HUDIS, MD

Dang C et al. **Mature cardiac safety results of dose-dense (DD) doxorubicin and cyclophosphamide (AC) followed by paclitaxel (T) with trastuzumab (H) in HER2/neu overexpressed/amplified breast cancer (BCA).** San Antonio Breast Cancer Symposium 2006; [Abstract 2101](#).

Puhalla S et al. **Phase II randomized adjuvant trial of dose-dense docetaxel (DOC) before or after doxorubicin/cyclophosphamide (AC) in axillary node-positive breast cancer.** San Antonio Breast Cancer Symposium 2006; [Abstract 2104](#).

Shayne M et al. **Dose intensity and hematologic toxicity in older breast cancer patients receiving systemic chemotherapy.** San Antonio Breast Cancer Symposium 2006; [Abstract 6078](#).

Lyman GH et al. **Prospective validation of a risk model for first cycle neutropenic complications in early-stage breast cancer patients receiving adjuvant chemotherapy.** San Antonio Breast Cancer Symposium 2006; [Abstract 6083](#).

Gradishar W et al. **A randomized phase 2 trial of qw or q3w ABI-007 (ABX) vs q3w solvent-based docetaxel (TXT) as first-line therapy in metastatic breast cancer (MBC).** San Antonio Breast Cancer Symposium 2006; [Abstract 46](#).

Link JS et al. **Bevacizumab (Avastin) and albumin bound paclitaxel (Abraxane) treatment in metastatic breast cancer.** San Antonio Breast Cancer Symposium 2006; [Abstract 1095](#).

Schwartzberg LS et al. **Phase II trial of nanoparticle albumin-bound paclitaxel (ABX) + capecitabine (XEL) in first line treatment of metastatic breast cancer (MBC): Interim results.** San Antonio Breast Cancer Symposium 2006; [Abstract 1096](#).

Traina TA et al. **Optimizing chemotherapy administration: A phase I study of biweekly capecitabine dose and schedule based on Norton-Simon mathematical modeling.** San Antonio Breast Cancer Symposium 2006;[Abstract 6077](#).

Wagner LI et al. **Health-related quality of life among patients with metastatic breast cancer receiving paclitaxel versus paclitaxel plus bevacizumab: Results from the Eastern Cooperative Oncology Group (ECOG) study E2100.** San Antonio Breast Cancer Symposium 2006;[Abstract 5078](#).

Cristofanilli M et al. **A phase II combination study of lapatinib and paclitaxel as a neoadjuvant therapy in patients with newly diagnosed inflammatory breast cancer (IBC).** San Antonio Breast Cancer Symposium 2006;[Abstract 1](#).

Chlebowski RT et al. **Mature analysis from the Women's Intervention Nutrition Study (WINS) evaluating dietary fat reduction and breast cancer outcome.** San Antonio Breast Cancer Symposium 2006;[Abstract 32](#).

ADDITIONAL PUBLICATIONS DISCUSSED DURING THE PROGRAM

Albain KS et al. **Global phase III study of gemcitabine plus paclitaxel (GT) vs paclitaxel (T) as frontline therapy for metastatic breast cancer (MBC): First report of overall survival.** *Proc ASCO* 2004;[Abstract 510](#).

Ali SM et al. **Relationship of serum HER-2/neu and serum CA 15-3 in patients with metastatic breast cancer.** *Clin Chem* 2002;48(8):1314-20. [Abstract](#)

Burstein HJ et al. **Trastuzumab and vinorelbine as first-line therapy for HER2-overexpressing metastatic breast cancer: Multicenter phase II trial with clinical outcomes, analysis of serum tumor markers as predictive factors, and cardiac surveillance algorithm.** *J Clin Oncol* 2003;21(15):2889-95. [Abstract](#)

Chan A et al; Navelbine Herceptin Project. **Vinorelbine plus trastuzumab combination as first-line therapy for HER 2-positive metastatic breast cancer patients: An international phase II trial.** *Br J Cancer* 2006;95(7):788-93. [Abstract](#)

Chlebowski RT et al. **Dietary fat reduction and breast cancer outcome: Interim efficacy results from the Women's Intervention Nutrition Study.** *J Natl Cancer Inst* 2006;98(24):1767-76. [Abstract](#)

Chlebowski RT et al. **Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women: The Women's Health Initiative Randomized Trial.** *JAMA* 2003;289(24):3243-53. [Abstract](#)

Clarke CA et al. **Recent declines in hormone therapy utilization and breast cancer incidence: Clinical and population-based evidence.** *J Clin Oncol* 2006;24(33):e49-50. No abstract available

Forbes JF et al. **BCIRG 007: Randomized phase III trial of trastuzumab plus docetaxel with or without carboplatin first line in HER2 positive metastatic breast cancer (MBC).** *Proc ASCO* 2006;[Abstract LBA516](#).

Goss PE et al. **Randomized trial of letrozole following tamoxifen as extended adjuvant therapy in receptor-positive breast cancer: Updated findings from NCIC CTG MA.17.** *J Natl Cancer Inst* 2005;97(17):1262-71. [Abstract](#)

Hudis C et al. **Five year follow-up of INT C9741: Dose-dense (DD) chemotherapy (CRx) is safe and effective.** San Antonio Breast Cancer Symposium 2005;[Abstract 41](#).

Joensuu H et al. **Amplification of erbB2 and erbB2 expression are superior to estrogen receptor status as risk factors for distant recurrence in pT1N0M0 breast cancer: A nationwide population-based study.** *Clin Cancer Res* 2003;9(3):923-30. [Abstract](#)

Land SR et al. **Patient-reported symptoms and quality of life during treatment with tamoxifen or raloxifene for breast cancer prevention: The NSABP Study of Tamoxifen and Raloxifene (STAR) P-2 trial.** *JAMA* 2006;295(23):2742-51. [Abstract](#)

Lipton A et al. **Serum HER-2/neu and response to the aromatase inhibitor letrozole versus tamoxifen.** *J Clin Oncol* 2003;21(10):1967-72. [Abstract](#)

Lipton A et al. **Elevated serum Her-2/neu level predicts decreased response to hormone therapy in metastatic breast cancer.** *J Clin Oncol* 2002;20(6):1467-72. [Abstract](#)

Miller KD et al. **A randomized phase III trial of paclitaxel versus paclitaxel plus bevacizumab as first-line therapy for locally recurrent or metastatic breast cancer: A trial coordinated by the Eastern Cooperative Oncology Group (E2100).** San Antonio Breast Cancer Symposium 2005;[Abstract 3](#).

Mohsin SK et al. **Neoadjuvant trastuzumab induces apoptosis in primary breast cancers.** *J Clin Oncol* 2005;23(11):2460-8. [Abstract](#)

O'Shaughnessy J et al. **Superior survival with capecitabine plus docetaxel combination therapy in anthracycline-pretreated patients with advanced breast cancer: Phase III trial results.** *J Clin Oncol* 2002;20(12):2812-23. [Abstract](#)

Pegram M et al. **Inhibitory effects of combinations of HER-2/neu antibody and chemotherapeutic agents used for treatment of human breast cancers.** *Oncogene* 1999;18(13):2241-51. [Abstract](#)

Press MF et al. **Topoisomerase II-alpha gene amplification as a predictor of responsiveness to anthracycline-containing chemotherapy in the Cancer International Research Group 006 clinical trial of trastuzumab (Herceptin) in the adjuvant setting.** San Antonio Breast Cancer Symposium 2005;[Abstract 1045](#).

Santen RJ et al. **Adaptive hypersensitivity to estrogen: Mechanisms and clinical relevance to aromatase inhibitor therapy in breast cancer treatment.** *J Steroid Biochem Mol Biol* 2005;95(1-5):155-65. [Abstract](#)

Seidman AD et al. **CALGB 9840: Phase III study of weekly (W) paclitaxel (P) via 1-hour (h) infusion versus standard (S) 3h infusion every third week in the treatment of metastatic breast cancer (MBC), with trastuzumab (T) for HER2 positive MBC and randomized for T in HER2 normal MBC.** *Proc ASCO* 2004;[Abstract 512](#).

Slamon D et al. **Phase III randomized trial comparing doxorubicin and cyclophosphamide followed by docetaxel (ACT) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (ACTH) with docetaxel, carboplatin and trastuzumab (TCH) in HER2 positive early breast cancer patients: BCIRG 006 study.** San Antonio Breast Cancer Symposium 2005;[Abstract 1](#).

Spector NL et al. **EGF103009, a phase II trial of lapatinib monotherapy in patients with relapsed/refractory inflammatory breast cancer (IBC): Clinical activity and biologic predictors of response.** *Proc ASCO* 2006;[Abstract 502](#).

Viale G et al. **Central review of ER, PgR and HER-2 in BIG 1-98 evaluating letrozole vs tamoxifen as adjuvant endocrine therapy for postmenopausal women with receptor-positive breast cancer.** San Antonio Breast Cancer Symposium 2005;[Abstract 44](#).

Vogel VG et al; National Surgical Adjuvant Breast and Bowel Project (NSABP). **Effects of tamoxifen vs raloxifene on the risk of developing invasive breast cancer and other disease outcomes: The NSABP Study of Tamoxifen and Raloxifene (STAR) P-2 trial.** *JAMA* 2006;295(23):2727-41. [Abstract](#)

Vogel CL et al. **Efficacy and safety of trastuzumab as a single agent in first-line treatment of HER2-overexpressing metastatic breast cancer.** *J Clin Oncol* 2002;20(3):719-26. [Abstract](#)

QUESTIONS (PLEASE CIRCLE ANSWER):

- After 36 months of follow-up, no statistically significant difference was evident in disease-free survival between the AC → TH and TCH arms in the BCIRG 006 adjuvant trastuzumab trial.
 - True
 - False
- In BCIRG 006, the rate of congestive heart failure was five times higher on the AC → TH arm compared to the TCH arm.
 - True
 - False
- In BCIRG 006, patients with coamplification of HER2 and TOPO II received significantly more benefit from AC → TH compared to TCH.
 - True
 - False
- In the EFECT study, there was no difference between exemestane and fulvestrant in progression-free survival.
 - True
 - False
- In the ATAC trial, analysis of central laboratory assays demonstrated that progesterone receptor and HER2 were predictive of benefit from anastrozole compared to tamoxifen.
 - True
 - False
- In a population of heavily pretreated women with metastatic breast cancer, the combination of *nab* paclitaxel and bevacizumab resulted in an objective clinical response rate of approximately _____.
 - 20 percent
 - 30 percent
 - 40 percent
 - >50 percent
- In the ATAC trial, patients receiving anastrozole experienced _____ fewer thromboembolic events than those receiving tamoxifen.
 - Seven percent
 - 23 percent
 - 30 percent
 - 40 percent
- Mature analysis of a Phase II trial evaluating dose-dense AC → paclitaxel/trastuzumab revealed one case of congestive heart failure out of 70 treated patients, using the same cardiac monitoring criteria as NSABP-B-31.
 - True
 - False
- A prospective study of 115 randomly selected US community oncology practices with patients older than age 65 revealed that the following features were related to the development of hematologic toxicity:
 - Age
 - Anthracycline-containing chemotherapy
 - Comorbidities > 2
 - Both a and b
 - Both b and c
- A randomized Phase II trial demonstrated that weekly *nab* paclitaxel, compared to every three-week docetaxel at 100 mg/m², resulted in:
 - Higher response rate
 - Increased progression-free survival
 - Both a and b
- Clinical trials have demonstrated benefit from which of the following aromatase inhibitors after five years of tamoxifen?
 - Anastrozole
 - Letrozole
 - Exemestane
 - All of the above

EVALUATION FORM

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GLOBAL LEARNING OBJECTIVES

To what extent does this issue of *Cancer Conference Update* address the following global learning objectives?

- Critically evaluate the clinical implications of emerging clinical trial data in breast cancer treatment and incorporate these data into management strategies in the adjuvant, neoadjuvant, metastatic and preventive settings. 5 4 3 2 1 N/A
- Counsel postmenopausal patients with ER-positive breast cancer about the risks and benefits of adjuvant aromatase inhibitors and of switching to or sequencing aromatase inhibitors after tamoxifen. 5 4 3 2 1 N/A
- Describe and implement an algorithm for treatment of patients with HER2-positive breast cancer in the adjuvant and metastatic settings. 5 4 3 2 1 N/A
- Evaluate the emerging data on various adjuvant chemotherapy approaches and explain the absolute risks and benefits of adjuvant chemotherapy regimens to patients. 5 4 3 2 1 N/A
- Counsel appropriate patients with metastatic disease about selection and sequencing of endocrine therapy and about the risks and benefits of various chemotherapeutic and biologic options. 5 4 3 2 1 N/A

EFFECTIVENESS OF THE INDIVIDUAL FACULTY MEMBERS

Faculty	Knowledge of subject matter	Effectiveness as an educator
John Mackey, MD	5 4 3 2 1	5 4 3 2 1
Peter M Ravdin, MD, PhD	5 4 3 2 1	5 4 3 2 1
Clifford Hudis, 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 N/A
- Related to my practice needs. 5 4 3 2 1 N/A
- Will influence how I practice. 5 4 3 2 1 N/A
- Will help me improve patient care. 5 4 3 2 1 N/A
- Stimulated my intellectual curiosity. 5 4 3 2 1 N/A
- Overall quality of material. 5 4 3 2 1 N/A
- Overall, the activity met my expectations. 5 4 3 2 1 N/A
- Avoided commercial bias or influence. 5 4 3 2 1 N/A

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EVALUATION FORM

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.....

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