

Second Annual Symposium on Personalized Therapies for Breast Cancer

personalized  *therapies*TM
A NEW CONCEPT IN SYMPOSIA *for breast cancer*

JANUARY 24-25, 2009

INTERCONTINENTAL MIAMI HOTEL | MIAMI, FLORIDA

Background photo of FISH-positive breast cancer courtesy of Dr. Michael Press

A completely new concept in breast cancer symposia, integrating molecular diagnostics, personalized surgical and radiation techniques and chemotherapy, hormonal therapy and targeted therapeutics for improving breast cancer patient care

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PROGRAM CO-CHAIRS

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PROGRAM OVERVIEW

For the treatment of breast cancer, the practice of medicine and patient care is now evolving from what has traditionally been a general approach with standardized therapies, to a more personalized therapeutic approach with the selection of therapies specific to patients and their malignancies. The ability to accomplish this is based upon the increasing ability of clinicians to apply the newest and ever expanding clinical, scientific, genetic, and other molecular data used as predictive and prognostic biomarkers for improved therapies and patient outcomes, and a minimization of treatment-induced toxicities. The objective of the *Second Annual Symposium on Personalized Therapies for Breast Cancer* is to further these efforts with an enhanced symposium containing significant new content, many new expert faculty and a more interactive audience-faculty format from last year's program. All Sessions contain at least one major patient case study with multiple-choice treatment care options that the audience selects via the Audience Response System (ARS), and at least one Point-CounterPoint debate whereby the audience votes via ARS. Most of the didactic presentations will include at least one brief patient case study or, one clinical question for the audience to vote upon via ARS. And, finally each Session concludes with a 15-minute "consensus" period where each of the following three questions are asked of the Session's faculty and audience via ARS regarding the particular Session's content to help ensure that this newly presented information can be applied to clinical practice today: 1) Is this a new standard of care? 2) Should it be discussed with your patients? and 3) How can you use it today in your practice?

The content of the *Second Annual Symposium on Personalized Therapies for Breast Cancer* has been modified to reflect the newest clinical and scientific information regarding further personalization of therapies. These are addressed in the following seven Sessions. **Session 1**, "*Personalizing Therapies for the Prevention of Breast Cancer*," addresses: predicting who may develop breast cancer; the use of genetic testing for breast cancer prevention; and the clinical application of SERMS and other strategies to prevent breast cancer. **Session 2**, "*Diagnosis and Molecular Classifications of Breast Cancer for Personalizing Therapies*," reviews several types of molecular tests and their clinical applications, including multi-gene assays and gene expression profiling to help personalize the selection of therapy for breast cancer patients via predictive and prognostic factors. **Session 3**, "*Personalized Approaches to Early Therapy of Breast Cancer*," addresses the latest data on the personalizing of radiation therapy, surgical therapy, and local-regional control, including approaches with neo-adjuvant chemotherapy. **Session 4**, "*Clinical Applications of Personalized Therapies for HER2+ Breast Cancers*," reviews the most current clinical and scientific data on new applications of anti-HER2 strategies, and advances in personalizing clinical anti-HER2 strategies in both the adjuvant and metastatic breast cancer settings. "**Lunch with the Professors**" follows Sessions 4 and 6. This new lunch hour program has been added to enable the audience to further interact with the faculty. Each faculty member is assigned to one table for lunch, and the symposium attendees are invited on a first-come basis to sit and converse with the faculty of their choice for further questions and answers. It also provides an additional 2 hours of CME credit. **Session 5**, "*Clinical Applications of Personalized Therapies for ER+ Breast Cancers*," addresses many new topics including the personalizing or predicting of response to adjuvant endocrine therapy, overcoming resistance to endocrine therapy, the use of SNPs to help personalize the selection of endocrine therapies, and the issue of how elderly patients with breast cancer should be treated. **Session 6**, "*Clinical*

Applications of Personalized Therapies for Triple-Negative Disease," will provide an update on the pathology and biology of this sub-type, and review strategies to personalize therapies with anti-angiogenic and chemotherapeutic approaches. **Session 7**, "*New Developments in the Treatment of Bone Metastases, and the Management of Bone Health and Bone Integrity*." This Session is an entirely new session for this year's symposium because of the significant potential for adjuvant therapeutic applications of drugs that traditionally treated bone metastases, and, the emergence of newer, "targeted" biological approaches for the treatment of bone metastases, and the management of bone integrity and bone health.

EDUCATIONAL NEEDS ASSESSMENT

Breast cancer is the most commonly diagnosed cancer in women in the United States. In 2007, an estimated 180,510 new cases were diagnosed and 40,910 deaths were attributed to breast cancer. Approximately 30% of women diagnosed with early breast cancer will eventually die of their disease. Metastatic breast cancer is incurable and often difficult to treat. Few patients will be long-term survivors. As more is learned about the molecular biology of breast cancer and newer therapies, the evolving personalized approach to treating this malignancy should help physicians improve clinical outcomes and decrease the mortality rate.

Breast cancer risk can today be further characterized using genetic markers. Molecular biology techniques such as genome-wide linkage analysis and positional cloning have led to the identification of and tests for breast cancer susceptibility genes such as BRCA1 and BRCA2. Women with BRCA1 or BRCA2 mutations have a lifetime risk of developing breast cancer of between 50% and 80%. The diagnosis and molecular classifications of breast cancer sub types continue to advance with the commercial availability of more tests, and further developments in molecular testing emerging. All of these tests need to be reviewed, and their specific clinical applications carefully understood. Personalizing radiation therapy, surgical therapy, and local-regional control, including approaches with neo-adjuvant chemotherapy, are also areas of breast cancer treatment where physicians will benefit from the newest information on these topics.

HER2 remains both a vitally important target for some breast cancer therapies, and, a biomarker for poor prognosis. The identification and understanding of novel methodologies used as prognostic factors, or predictive factors for therapies against HER2 is an ongoing need. And the expanding clinical role of anti-HER2 therapy warrants a thorough review and update.

Because estrogen plays a key role in the growth and proliferation in some breast cancers, endocrine therapy is standard treatment in post-menopausal women who are hormone receptor-positive. One of the most challenging aspects of using endocrine therapy is personalizing therapy---determining which patients should receive which therapy and how long should endocrine therapy be used in a specific patient. Another is the challenge in treating patients who may have resistance to endocrine treatment. The use of molecular biomarkers, predictive factors and gene expression profile assays in a personalized approach to breast cancer treatment needs to be further reviewed.

Triple-negative breast cancer is a sub type of breast malignancy that remains very challenging for physicians. With increased understanding of the biology of triple-negative tumors, improvements in clinical outcome may be possible. Because patients with this breast cancer classification do not have good prognosis, an in depth review of how these patients can be optimally treated utilizing the latest results of clinical trials is warranted.

The bone is the most common site of distant metastasis in breast cancer. This past year, new clinical data has emerged with the usage of bisphosphonates to treat bone metastases resulting in an adjuvant treatment of breast cancer itself. And there are several therapeutics in late-stage clinical development to further reduce the risk of skeletal related events. These include strategies to inhibit the RANK Ligand, TGF-beta, cathepsin-K and src. A review of these new strategies and a discussion on how to personalize therapies using these strategies needs to be discussed.

TARGET AUDIENCE

This symposium and corresponding Web-based materials are designed to meet the educational needs of physicians who are involved with the diagnosis and treatment of patients with breast cancer. This includes medical oncologists and hematologist/oncologists, radiation oncologists, surgical oncologists and pathologists. There are neither prerequisites nor relevant system barriers to these activities.

EDUCATIONAL LEARNING OBJECTIVES

At the conclusion of this symposium, and/or after reviewing the enduring materials, participants will be able to:

1. Evaluate the personalized therapeutic approach for the prevention of breast cancer and to help patients prevent the development of breast cancer or breast cancer recurrence.
2. Evaluate the effect of new technologies on the classification and staging of breast cancer and to utilize this new information in the planning of breast cancer treatment.
3. Devise strategies to improve local-regional control of breast cancer through a personalized approach to breast cancer treatment.
4. Assess clinical data regarding the selection of adjuvant treatments of breast cancer and devise treatment strategies utilizing a personalized approach to therapy in patients with early-stage breast cancer to prevent disease recurrence.
5. Analyze the data supporting the use of chemotherapy, targeted therapy, endocrine therapy and radiation therapy in the personalized treatment of patients with advanced disease.
6. Understand new clinical data regarding new approaches to maintaining bone health and to utilize new approaches to prevent skeletal-related events in patients with early-stage breast cancer and in patients with metastatic disease.
7. Evaluate new approaches in identifying patients with triple-negative disease and utilize a personalized approach in the selection of therapies for patients with triple negative breast cancer.

METHODS OF PARTICIPATION

The symposium will involve extensive use of interactive techniques, including patient case study discussions, Point-Counterpoint debates and an interactive audience response system throughout the symposium to help engage the learners and to facilitate the use of the most up-to-date adult learning principles. Didactic presenters will present at least one clinical question involving audience participation during their presentations. Attendees will receive a comprehensive DVD-ROM of the program approximately 4 weeks after the symposium, upon request.

The symposium will be published on the Oncology Learning Center (OLC) Web site for one year. Approximately four months after the symposium, those participants who have

volunteered to participate in further, in-depth evaluations of the symposium designed to measure physician practice performance, will be contacted by members of the OLC staff to determine if they have included what they have learned from the symposium into their routine treatment of patients with breast malignancies.

ACCREDITATION STATEMENT

The Oncology Learning Center™, Inc. is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION

The OLC designates this educational activity for a maximum of 13 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Non-physicians may request a Certificate of Attendance.

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SPECIAL MEALS AND REQUESTS

If you have any special requests, or wish to request a certain meal (e.g., vegetarian) please send an E-mail to information@olccme.com.

DISCLOSURE OF UNLABELED USE

This educational activity may contain discussion of published and/or investigational uses of agents that are not indicated by the Food and Drug Administration (FDA). The OLC does not recommend the use of any agent outside of the FDA labeled indications.

DISCLOSURES AND RESOLUTION OF ANY CONFLICTS OF INTEREST

In accordance with the Accreditation Council for Continuing Medical Education Standards for Commercial Support, and the policy of the Oncology Learning Center™, Inc., (OLC), all of its educational activities must demonstrate fair balance, independence from commercial interests, objectivity, scientific rigor, freedom from commercial bias, and, are planned, developed and implemented with scientific rigor. All faculty, authors, editors, OLC staff and planning committee members participating in an OLC-sponsored activity, or who are involved in any control of this activity's content, or who have any communications with the faculty are required to disclose to the audience of participants, in advance of any educational activity, any relevant financial relationships or interests with commercial supporters, including the manufacturers of any commercial products and/or providers of commercial services that are discussed in an educational activity, and, to assist with the resolution of any conflicts of interest before this educational activity can commence.

DISCLOSURE DISCLAIMER

Please be aware there will be additional disclosures received or reviewed after this announcement has been printed, but these will be disclosed to all participants prior to the symposium. These disclosures will be included in a separate handout and distributed to all participants. Any conflicts of interest regarding this symposium will be peer reviewed and resolved prior to the educational activity.

AGENDA

FRIDAY, JANUARY 23, 2009

5:00 PM – 9:00 PM Early On-Site Registration

SATURDAY, JANUARY 24, 2009

7:00 AM – 8:00 AM Buffet Breakfast

7:00 AM – 8:00 AM On-Site Registration

8:00 AM Welcome and Pre-Activity CME Test
GEORGE SLEDGE AND DENNIS SLAMON

SESSION 1

PERSONALIZING THERAPIES FOR THE PREVENTION OF BREAST CANCER

CHAIR: MARK PEGRAM

- 8:10 AM Predicting who will develop breast cancer
MALCOLM PIKE
- 8:30 AM The clinical application of genetic testing for breast cancer prevention
JEFF WEITZEL
- 8:50 AM Drug prevention strategies using SERMS and other agents for patients at high risk of developing breast cancer
POWEL BROWN
- 9:10 AM **Point-Counterpoint:** All patients at high risk for developing breast cancer should receive SERMS prophylactically
PRO: POWEL BROWN, CON: JEFF WEITZEL
- 9:30 AM **Session 1 Case Study**
MARK PEGRAM PRESENTS AND THE AUDIENCE SELECTS TREATMENT STRATEGIES
- 9:45 AM **Panel Discussion, Q & A, and Consensus on the Status of the Data Presented in this Session:**
1. Is it a new standard of care? 2. Should it be discussed with your patients? 3. How can you use it today?
SESSION 1 FACULTY
- 10:00 AM Break

SESSION 2

DIAGNOSIS AND MOLECULAR CLASSIFICATIONS OF BREAST CANCER FOR PERSONALIZING THERAPIES

CHAIR: ERIC WINER

- 10:15 AM In which patients with breast cancer are gene expression arrays beneficial as prognostic markers today?
CHARLES PEROU
- 10:30 AM Clinical applications of gene expression profiling-based prediction of complete pathologic response to neo-adjuvant taxane/FAC chemotherapy in breast cancer
LAJOS PUSZTAI
- 10:50 AM **Point-Counterpoint:** Use the 70-gene microarray assay versus the 21-gene panel assay for testing ER+, node-negative breast cancer
FOR 70-GENE MICROARRAY ASSAY: ERIC WINER,
FOR 21-GENE PANEL ASSAY: GEORGE SLEDGE
- 11:10 AM **Session 2 Case Study**
ERIC WINER PRESENTS AND THE AUDIENCE SELECTS TREATMENT STRATEGIES

- 11:30 AM **Panel Discussion, Q & A, and Consensus on the Status of the Data Presented in this Session:**
1. Is it a new standard of care? 2. Should it be discussed with your patients? 3. How can you use it today?
SESSION 2 FACULTY

- 11:45 AM-12:45 PM **Lunch with the Professors:** Each of today's faculty members will be assigned a separate lunch table so that the symposium participants can further interact with a faculty member on his/her presentation or topic
ALL PARTICIPANTS AND ALL OF THE DAY'S FACULTY

SESSION 3

PERSONALIZED APPROACHES TO EARLY THERAPY OF BREAST CANCER

CHAIR: LORI PIERCE

- 12:45 PM Individualizing local-regional control with neo-adjuvant chemotherapy
ELEFTHERIOS MAMOUNAS
- 1:05 PM Personalizing radiation therapy
LORI PIERCE
- 1:25 PM Personalizing surgical therapy
KELLY HUNT
- 1:45 PM **Point-Counterpoint:** T[a taxane]+ C[a platinum]+ H[an anti-HER2] should replace anthracycline-based therapies for adjuvant therapy of HER2-positive breast cancer
PRO: TBD, CON: TBD
- 2:05 PM **Session 3 Case Study**
LORI PIERCE PRESENTS AND THE AUDIENCE SELECTS TREATMENT STRATEGIES
- 2:20 PM **Panel Discussion, Q & A, and Consensus on the Status of the Data Presented in this Session:**
1. Is it a new standard of care? 2. Should it be discussed with your patients? 3. How can you use it today?
SESSION 3 FACULTY
- 2:35 PM Break

SESSION 4

CLINICAL APPLICATIONS OF PERSONALIZED THERAPIES FOR HER2+ BREAST CANCERS

CHAIR: DENNIS SLAMON

- 2:50 PM Personalized approaches to selecting targeted therapies and chemotherapies for metastatic HER2+ breast cancer patients
DENNIS SLAMON
- 3:10 PM Predictors of response and personalized approaches to selecting patients for adjuvant and neo-adjuvant anti-HER2 therapy for HER2 breast cancer
CARLOS ARTEAGA
- 3:30 PM The relationship between HER2 expression and response to taxane-based therapies
TBD
- 3:50 PM **Point-Counterpoint:** Adjuvant anti-HER2 therapy should be considered for HER2-negative patients?
PRO: HYMAN MUSS, CON: MICHAEL PRESS

- 4:10 PM **Point-Counterpoint:** A taxane plus an alkylating agent should replace anthracycline-based therapies for adjuvant therapy of HER2-negative breast cancer
PRO: DENNIS SLAMON, CON: TBD
- 4:30 PM **Session 4 Case Study**
DENNIS SLAMON PRESENTS AND THE AUDIENCE SELECTS TREATMENT STRATEGIES
- 4:45 PM **Panel Discussion, Q & A, and Consensus on the Status of the Data Presented in this Session:**
1. Is it a new standard of care? 2. Should it be discussed with your patients? 3. How can you use it today?
SESSION 4 FACULTY
- 5:00 PM **DINNER "On Your Own"**

SUNDAY, JANUARY 25, 2009

SESSION 5

CLINICAL APPLICATIONS OF PERSONALIZED THERAPIES FOR ER+ BREAST CANCERS

CHAIR: EDITH PEREZ

- 8:00 AM What are the molecular predictors of response to adjuvant endocrine therapy?
W. FRASER SYMMANS
- 8:20 AM Are there personalized strategies for overcoming resistance to endocrine therapy?
CRAIG JORDAN
- 8:40 AM Personalized approaches to treating patients with ER+ breast cancer using single nucleotide polymorphisms (SNPs)
DAVID FLOCKHART
- 8:50 AM **Point-Counterpoint:** Systemic therapy for the elderly should be identical to that for younger patients
PRO: EDITH PEREZ, CON: TBD
- 9:10 AM **Session 5 Case Study**
EDITH PEREZ PRESENTS AND THE AUDIENCE SELECTS TREATMENT STRATEGIES
- 9:30 AM **Panel Discussion, Q & A, and Consensus on the Status of the Data Presented in this Session:**
1. Is it a new standard of care? 2. Should it be discussed with your patients? 3. How can you use it today?
SESSION 5 FACULTY
- 9:50 AM BREAK

SESSION 6

CLINICAL APPLICATIONS OF PERSONALIZED THERAPIES FOR TRIPLE-NEGATIVE DISEASE

CO-CHAIRS: LISA CAREY AND CLIFFORD HUDIS

- 10:10 AM Pathology and molecular classification of Triple-Negative Disease
EDI BROGI
- 10:30 AM Personalizing breast cancer therapies using anti-angiogenic strategies
GEORGE SLEDGE
- 10:50 AM Therapeutic individualization with specific chemotherapeutic agents
LISA CAREY

- 11:10 AM **Point-Counterpoint:** All triple-negative patients should receive platinum-based adjuvant therapy
PRO: LISA CAREY, CON: CLIFFORD HUDIS
- 11:30 AM **Session 6 Case Study**
LISA CAREY AND CLIFFORD HUDIS PRESENT AND THE AUDIENCE SELECTS TREATMENT STRATEGIES
- 11:45 AM **Panel Discussion, Q & A, and Consensus on the Status of the Data Presented in this Session:**
1. Is it a new standard of care? 2. Should it be discussed with your patients? 3. How can you use it today?
SESSION 6 FACULTY
- 12:00 PM-1:00 PM **Lunch with the Professors:** Each of today's faculty members will be assigned a separate lunch table so that the symposium participants can further interact with a faculty member on his/her presentation or topic
ALL PARTICIPANTS AND ALL OF THE DAY'S FACULTY

SESSION 7

NEW DEVELOPMENTS IN THE TREATMENT OF BONE METASTASES, AND THE MANAGEMENT OF BONE HEALTH AND BONE INTEGRITY

CHAIR: ALLAN LIPTON

- 1:00 PM Drugs treating bone metastases: are they supportive care agents, therapeutics, or both?
TBD
- 1:20 PM Newer clinical strategies for treating bone metastases
ALLAN LIPTON
- 1:40 PM **Point-Counterpoint:** Drugs treating bone metastases should be offered to patients as an option for adjuvant therapy of breast cancer
PRO: ALLAN LIPTON, CON: TBD
- 2:00 PM **Session 7 Case Study**
ALLAN LIPTON PRESENTS AND THE AUDIENCE SELECTS TREATMENT STRATEGIES
- 2:20 PM **Panel Discussion, Q & A, and Consensus on the Status of the Data Presented in this Session:**
1. Is it a new standard of care? 2. Should it be discussed with your patients? 3. How can you use it today?
SESSION 7 FACULTY
- 2:40 PM **Post-Activity CME Test**
SYMPOSIUM CO-CHAIRS: DENNIS SLAMON AND GEORGE SLEDGE
- 2:50 PM *Adjourn*

FACULTY

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Boston, MA
Co-Chair, Breast Committee,
The Cancer and Leukemia Group B (CALGB)

REGISTRATION



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- Physicians (non-industry): **\$149**
- Nurses, Pharmacists, Other Healthcare Professionals, and Non-profit Organizations (non-industry): **\$149**
- Diagnostic and laboratory industry employees: **\$1,295** (call for group rates)
- Pharmaceutical industry employees: **\$1,795** (call for group rates)
- Fellows: complimentary with letter of status from director

REGULAR REGISTRATION FEES (On or After 12/1/2008)

- Physicians (non-industry): **\$249**
- Nurses, Pharmacists, Other Healthcare Professionals, and Non-profit Organizations (non-industry): **\$249**
- Diagnostic and laboratory industry employees: **\$1,495** (call for group rates)
- Pharmaceutical industry employees: **\$1,995** (call for group rates)
- Fellows: complimentary with letter of status from director

REGISTRANT INFORMATION

First Name	Middle Initial	Last Name
Credentials	Title	
PLEASE CHECK THE APPROPRIATE CATEGORY BELOW:		
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