RTP ONDEMAND

Breast Cancer, Part I

CME Information

TARGET AUDIENCE

This activity is intended for medical and radiation oncologists, breast and general surgeons, hematology-oncology fellows and other healthcare providers involved in the treatment of breast cancer.

OVERVIEW OF ACTIVITY

Breast cancer remains the most frequently diagnosed cancer in women, and in 2015 in the United States alone the disease will culminate in an estimated 231,840 new cases and 40,290 deaths. Advances in screening and prevention have resulted in a steady down-stage migration at the time of disease presentation, such that only 5% of women have identifiable distant metastases at primary diagnosis. Consequently, the number of individuals living with breast cancer has increased substantially, as has the population "at risk" for recurrent disease. While the diagnosis and treatment of breast cancer remain, in many ways, more advanced than in other solid cancers, challenging issues in the basic management of this disease continue to require refinement.

Published results from ongoing trials lead to the continuing 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, this program uses a discussion with Drs Lisa A Carey and Eric P Winer about treatment controversies and the integration of key data sets into the practical management of breast cancer.

LEARNING OBJECTIVES

- Apply the results of emerging clinical trial data to the best-practice care of patients with breast cancer.
- Assimilate new clinical trial evidence into the therapeutic algorithm for advanced ER-positive postmenopausal breast cancer.
- Appreciate the similarities and differences among existing genomic assays, and use this information to select appropriate platforms to assess risk and individualize therapy for patients with invasive and noninvasive early breast cancer.
- Develop an understanding of emerging efficacy and side-effect data with novel agents and strategies under evaluation for early breast cancer.
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials investigating novel therapeutic agents and strategies.

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 1.25 *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 consists of a video component. To receive credit, the participant should watch the video, complete the Post-test with a score of 75% or better and fill out the Educational Assessment and Credit Form located at ResearchToPractice.com/RTPODBreast115/CME.

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 — 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:

Lisa A Carey, MD
Richardson and Marilyn Jacobs Preyer Distinguished Professor for Breast Cancer Research
Chief, Division of Hematology and Oncology
Physician-in-Chief
North Carolina Cancer Hospital
Associate Director for Clinical Research
Lineberger Comprehensive Cancer Center
Chapel Hill, North Carolina

No real or apparent conflicts of interest to disclose.

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

Contracted 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: AbbVie Inc, Amgen Inc, Astellas Scientific and Medical Affairs Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Pharma Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Dendreon Corporation, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech BioOncology, Genomic Health Inc, Gilead Sciences Inc, ImmunoGen Inc, Incyte Corporation, Janssen Biotech Inc, Jazz Pharmaceuticals Inc, Lilly, Medivation Inc, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, NanoString Technologies, Novartis Pharmaceuticals Corporation, Novocure, Onyx Pharmaceuticals, an Amgen subsidiary, Pharmacyclics Inc, Prometheus Laboratories Inc, Regeneron Pharmaceuticals, Sanofi, Seattle Genetics, Sigma-Tau Pharmaceuticals Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Teva Oncology, Tokai Pharmaceuticals Inc and VisionGate 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.

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.

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Celgene Corporation, Eisai Inc, Foundation Medicine, Genomic Health Inc and Lilly.

Hardware/Software Requirements:
A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later
Adobe Flash Player 10.2 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

Last review date: September 2015

Expiration date: September 2016

Select Publications

Alternate approaches for clinical Stage II or III estrogen receptor positive breast cancer neoadjuvant treatment (ALTERNATE) in postmenopausal women: A Phase III study. NCT01953588

Bachelot T et al. **Randomized phase II trial of everolimus in combination with tamoxifen in patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer with prior exposure to aromatase inhibitors: A GINECO study.** *J Clin Oncol* 2012;30(22):2718-24.

Baselga J et al. **Everolimus plus exemestane for hormone-receptor-positive, human epidermal growth factor receptor-2-negative advanced breast cancer: Overall survival results from BOLERO-2.** *Ann Oncol* 2014;25(12):2357-62.

Brufsky AM. **Predictive and prognostic value of the 21-gene Recurrence Score in hormone receptor-positive, node-positive breast cancer.** *Am J Clin Oncol* 2014;37(4):404-10.

Dowsett M et al. **Prediction of risk of distant recurrence using the 21-gene Recurrence Score in node-negative and node-positive postmenopausal patients with breast cancer treated with anastrozole or tamoxifen: A TransATAC study.** *J Clin Oncol* 2010;28(11):1829-34.

Finn RS et al. **The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of oestrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18): A randomised phase 2 study.** *Lancet Oncol* 2015;16(1):25-35.

Gnant M et al; Austrian Breast and Colorectal Cancer Study Group. **Predicting distant recurrence in receptor-positive breast cancer patients with limited clinicopathological risk: Using the PAM50 Risk of Recurrence score in 1478 postmenopausal patients of the ABCSG-8 trial treated with adjuvant endocrine therapy alone.** *Ann Oncol* 2014;25(2):339-45.

Goetz M et al. **MONARCH 3: A randomized phase III study of anastrozole or letrozole plus abemaciclib, a CDK4/6 inhibitor, or placebo in first-line treatment of women with HR+, HER2-locoregionally recurrent or metastatic breast cancer (MBC).** *Proc ASCO* 2015;**Abstract TPS624.**

Munster PN et al. **Ph IB study of LEE011 and BYL719 in combination with letrozole in ER+, HER2- breast cancer.** Breast Cancer Symposium 2014;**Abstract 143.**

PALLAS: PALbociclib CoLlaborative Adjuvant Study — A randomized Phase III trial of palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+)/human epidermal growth factor receptor 2 (HER2)-negative early breast cancer. NCT02513394

Patnaik A et al. **LY2835219, a novel cell cycle inhibitor selective for CDK4/6, in combination with fulvestrant for patients with hormone receptor positive (HR+) metastatic breast cancer**. *Proc ASCO* 2014;**Abstract 534.**

Piccart M et al. **Everolimus plus exemestane for hormone-receptor-positive, human epidermal growth factor receptor-2-negative advanced breast cancer: Overall survival results from BOLERO-2.** *Ann Oncol* 2014;25(12):2357-62.

Shivers SC et al. **Direct comparison of risk classification between MammaPrint®, Onco*type* DX® and MammoStrat® assays in patients with early stage breast cancer.** San Antonio Breast Cancer Symposium 2013;**Abstract P6-06-02.**

Stover D et al. **Meta-analysis of breast cancer expression data using published gene signatures to reveal key cellular processes implicated in chemosensitivity and resistance.** *Proc ASCO* 2015;**Abstract 509.**

Tamoxifen citrate, letrozole, anastrozole, or exemestane with or without chemotherapy in treating patients with invasive RxPONDER breast cancer. NCT01272037

Tolaney S et al. **A phase Ib study of abemaciclib with therapies for metastatic breast cancer.** *Proc ASCO* 2015;**Abstract 522.**

Tolaney SM et al. **Clinical activity of abemaciclib, an oral cell cycle inhibitor, in metastatic breast cancer.** San Antonio Breast Cancer Symposium 2014;**Abstract P5-19-13.**

Turner N et al. **Palbociclib in hormone-receptor-positive advanced breast cancer.** *N Engl J Med* 2015;373(3):209-19.

Turner N et al. **PALOMA3: A double-blind, phase III trial of fulvestrant with or without palbociclib in pre- and post-menopausal women with hormone receptor-positive, HER2-negative metastatic breast cancer that progressed on prior endocrine therapy.** *Proc ASCO* 2015;**Abstract LBA502.**

Yardley DA et al. **Everolimus plus exemestane in postmenopausal patients with HR(+) breast cancer: BOLERO-2 final progression-free survival analysis.** *Adv Ther* 2013;30(10):870-84.