Cases from the Community

Investigators Provide Their Perspectives on the Practice Implications of Emerging Clinical Research

A Special Video Supplement

CME Information

TARGET AUDIENCE

This activity is intended for medical oncologists, breast cancer surgeons, radiation oncologists and other healthcare professionals involved in the diagnosis and treatment of breast cancer (BC).

OVERVIEW OF ACTIVITY

The current clinical management of BC is multidisciplinary and includes surgical resection of local disease with or without radiation therapy and the treatment of systemic disease (micro- or macroscopic) with cytotoxic chemotherapy, endocrine therapy, biologic therapy or combinations of these approaches. The indication and/or utility of these local and systemic treatment options is largely based on a number of prognostic and predictive risk factors present within the patient or her tumor at the time of diagnosis. Increasingly, an emphasis is being placed on a "personalized medicine" approach that promises to more effectively identify treatments that will benefit individuals based on specific patient- and disease-related characteristics. The pace of change in the field of breast medical oncology has been rapid, creating an important need for education about the unique mechanisms of action, toxicities and effectiveness of novel agents to properly prepare clinicians for their appropriate use (or potential use) in clinical practice. Several consensus- and evidence-based treatment guidelines are available and aim to assist clinicians with making BC management decisions in the face of this dynamic clinical and research environment, but despite the existence of these tools many areas of controversy persist within academic and community settings.

These highlights from postevent interviews with 2 faculty from a CME meeting held during the San Antonio Breast Cancer Symposium explore the most significant therapeutic advances during the previous year by using the perspectives of these BC experts on challenging cases and questions submitted by clinicians in the community to frame a relevant discussion of how this information has aided in the refinement of current routine clinical practice and ongoing research. This CME activity will help medical oncologists find answers to the individualized questions and concerns that they frequently encounter and in turn provide high-quality cancer care.

LEARNING OBJECTIVES

- Consider available data and the use of biomarkers and genomic assays to assess risk and individualize therapy for patients with hormone receptor-positive BC in the neoadjuvant and adjuvant settings.
- Individualize the selection of evidence-based neoadjuvant and adjuvant chemobiologic regimens for patients with HER2-overexpressing early BC.
- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing and investigational targeted treatments.
- Develop an understanding of the available research data and ongoing trials of investigational CDK4/6 inhibitors and other novel therapies under development for the management of advanced ER-positive BC.
- Recall the scientific rationale and efficacy data with PARP inhibitors for patients with BRCA-mutant BC, and employ this information in the formulation of protocol and nonprotocol treatment recommendations for these individuals.

ACCREDITATION STATEMENT

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CREDIT DESIGNATION STATEMENT

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AMERICAN BOARD OF INTERNAL MEDICINE (ABIM) — MAINTENANCE OF CERTIFICATION (MOC)

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 2.25 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Please note, this program has been specifically designed for the following ABIM specialty: **medical oncology**.

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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 80% or better and fill out the Educational Assessment and Credit Form located at ResearchToPractice.com/SanAntonioBC16/Interviews/CME.

CONTENT VALIDATION AND DISCLOSURES

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process:

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Advisory Committee: Eisai Inc, Pierre Fabre, Seattle Genetics.

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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

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Expiration date: June 2018

Select Publications

A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer. NCT01358877

Albain KS et al. **Prognostic and predictive value of the 21-gene Recurrence Score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: A retrospective analysis of a randomised trial.** *Lancet* Oncol 2010;11(1):55-65.

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

Arpino G et al. **Primary analysis of PERTAIN: A randomized, two-arm, open-label, multicenter phase II trial assessing the efficacy and safety of pertuzumab given in combination with trastuzumab plus an aromatase inhibitor in first-line patients with HER2-positive and hormone receptor-positive metastatic or locally advanced breast cancer.** San Antonio Breast Cancer Symposium 2016;**Abstract S3-04**.

Cardoso F et al. **70-gene signature as an aid to treatment decisions in early-stage breast cancer.** *N Engl J Med* 2016;375(8):717-29.

Dirix LY et al. **Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with locally advanced or metastatic breast cancer: A phase Ib JAVELIN solid tumor trial.** San Antonio Breast Cancer Symposium 2015;**Abstract S1-04**.

Francis PA et al; SOFT Investigators; International Breast Cancer Study Group. **Adjuvant ovarian suppression in premenopausal breast cancer.** *N Engl J Med* 2015;372(5):436-46.

Gianni L et al. **5-year analysis of neoadjuvant pertuzumab and trastuzumab in patients with locally advanced, inflammatory, or early-stage HER2-positive breast cancer (NeoSphere): A multicentre, open-label, phase 2 randomised trial.** *Lancet Oncol* 2016;17(6):791-800.

Gianni L et al. **Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): A randomised multicentre, open-label, phase 2 trial.** *Lancet Oncol* 2012;13(1):25-32.

Gluz O et al. **West German Study Group Phase III PlanB trial: First prospective outcome data for the 21-gene Recurrence Score assay and concordance of prognostic markers by central and local pathology assessment.** *J Clin Oncol* 2016;34(20):2341-9.

Goss PE et al. **Adjuvant lapatinib for women with early-stage HER2-positive breast cancer: A randomised, controlled, phase 3 trial.** *Lancet Oncol* 2013;14(1):88-96.

Hortobagyi GN et al. **Ribociclib as first-line therapy for HR-positive, advanced breast cancer.** *N Engl J Med* 2016;375(18):1738-48.

Love N et al. **HER2 and estrogen receptor status drive decisions regarding the use of neoadjuvant chemotherapy.** San Antonio Breast Cancer Symposium 2015;**Abstract P1-14-20**.

Nanda R et al. **A phase Ib study of pembrolizumab (MK-3475) in patients with advanced triple-negative breast cancer.** San Antonio Breast Cancer Symposium 2014;**Abstract S1-09**.

Pagani O et al. **Are SOFT and TEXT results practice changing and how?** *Breast* 2016;27:122-5.

Pagani O et al; TEXT and SOFT Investigators; International Breast Cancer Study Group. **Adjuvant exemestane with ovarian suppression in premenopausal breast cancer.** *N Engl J Med* 2014;371(2):107-18.

Pan H et al. **Predictors of recurrence during years 5-14 in 46,138 women with ER+ breast cancer allocated 5 years only of endocrine therapy (ET).** *Proc ASCO* 2016;**Abstract 505**.

Robertson J et al. **Fulvestrant 500 mg versus anastrozole 1 mg for hormone receptor-positive advanced breast cancer (FALCON): An international, randomised, double-blind, phase 3 trial.** *Lancet* 2016;388(10063):2997-3005.

Sparano JA et al. **Prospective validation of a 21-gene expression assay in breast cancer.** *N Engl J Med* 2015;373(21):2005-14.

Swain SM et al. **Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer.** *N Engl J Med* 2015;372(8):724-34.

Traina TA et al. **Results from a phase 2 study of enzalutamide (ENZA), an androgen receptor (AR) inhibitor, in advanced AR+ triple-negative breast cancer (TNBC).** *Proc ASCO* 2015;**Abstract 1003**.

Select Publications

Toi M et al. **A phase III trial of adjuvant capecitabine in breast cancer patients with HER2-negative pathologic residual invasive disease after neoadjuvant chemotherapy (CREATE-X, JBCRG-04).** San Antonio Breast Cancer Symposium 2015;**Abstract S1-07**.

Turner NC et al. **Palbociclib in hormone-receptor-positive advanced breast cancer.** *N Engl J Med* 2016;373(17):1672-3.