# Beyond the Guidelines

## Investigator Perspectives on Current Clinical Issues and Ongoing Research in the Management of Early and Advanced Breast Cancer

*A Special Video Supplement*

## CME Information

### TARGET AUDIENCE

This program is intended for medical oncologists, hematologists, hematology-oncology fellows and other healthcare providers involved in the treatment of breast cancer.

### OVERVIEW OF ACTIVITY

Breast cancer (BC) remains the most frequently diagnosed cancer in women, and in 2017 in the United States alone the disease will culminate in an estimated 255,180 new cases and 41,070 deaths. Results from numerous ongoing trials lead to the continual emergence of new therapeutic agents, treatment strategies and diagnostic and prognostic tools. In order to offer optimal patient care — including the option of clinical trial participation — the practicing cancer clinician must be well informed of these advances.

This program features discussions with 2 faculty members after a CME symposium held during the 2017 ASCO Annual Meeting. By providing information on the latest research developments and their potential impact on routine practice, this activity is designed to assist medical oncologists, hematology-oncology fellows and other healthcare providers with the formulation of up-to-date clinical management strategies for patients with BC.

### LEARNING OBJECTIVES

- Compare and contrast expert perspectives on BC treatment recommendations, and use this information to refine or validate existing management strategies.
- Appreciate the similarities and differences among existing genomic assays, and use this information to select an appropriate platform or platforms to assess risk and individualize therapy for patients with hormone receptor-positive BC in the neoadjuvant, adjuvant and extended-adjuvant settings.
- Individualize the selection of evidence-based neoadjuvant and adjuvant chemobiologic regimens for patients with HER2-overexpressing early BC.
- Implement a clinical plan for the management of metastatic HER2-positive BC, incorporating existing and emerging targeted treatments.
- Develop an evidence-based algorithm for the treatment of hormone-sensitive advanced BC, including the use of endocrine, biologic and chemotherapeutic agents.
- Recall the results of pivotal trials introducing effective new BC therapeutic agents, and identify their potential impact on existing treatment algorithms.
- Counsel appropriately selected patients with BC 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 1.75 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

### 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 1.75 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 review the CME information, 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/ASCOBreast17/Interviews/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 conflicts of interest with faculty, planners and managers of CME activities. 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 relevant conflicts of interest, which have been resolved through a conflict of interest resolution process:

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**Advisory Committee:** Advaxis Inc, Bayer HealthCare Pharmaceuticals, Eisai Inc, MacroGenics Inc, Merck, Novartis, Pfizer Inc, Pierian Biosciences, Syndax Pharmaceuticals Inc; **Consulting Agreements:** Celgene Corporation, Coherus BioSciences, G1 Therapeutics, Genentech BioOncology, Lilly, Puma Biotechnology Inc, Sandoz, Novartis, Pfizer Inc, Roche Laboratories Inc; **Contracted Research:** Celgene Corporation, Genentech BioOncology, Novartis, Pfizer Inc.

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**Advisory Committee:** Celgene Corporation, Pfizer; **Contracted Research:** Celgene Corporation, Genentech BioOncology, Merck.

**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, Acerta Pharma, Adaptive Biotechnologies, Agendia Inc, Agios Pharmaceuticals Inc, Amgen Inc, Ariad Pharmaceuticals Inc, Array BioPharma Inc, Astellas Pharma Global Development Inc, AstraZeneca Pharmaceuticals LP, Baxalta Inc, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Pharma Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, CTI BioPharma Corp, Dendreon Pharmaceuticals Inc, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech BioOncology, Genomic Health Inc, Gilead Sciences Inc, Halozyme Inc, ImmunoGen Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Kite Pharma Inc, Lexicon Pharmaceuticals Inc, Lilly, Medivation Inc, a Pfizer Company, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, NanoString Technologies, Natera Inc, Novartis, Novocure, Onyx Pharmaceuticals, an Amgen subsidiary, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Prometheus Laboratories Inc, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seattle Genetics, Sigma-Tau Pharmaceuticals Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro Inc, Teva Oncology and Tokai Pharmaceuticals Inc.

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This activity is supported by educational grants from AbbVie Inc, Agendia Inc, Astellas Pharma Global Development Inc/Medivation Inc, a Pfizer Company, AstraZeneca Pharmaceuticals LP, Genentech BioOncology, Genomic Health, Lilly, Merck, Myriad Genetic Laboratories Inc, Novartis, Puma Biotechnology Inc and Tesaro Inc.

**Hardware/Software Requirements:**
A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 11 or later, Firefox 56 or later, Chrome 61 or later, Safari 11 or later, Opera 48 or later
Adobe Flash Player 27 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

**Last review date:** December 2017

**Expiration date:** December 2018

## Select Publications


Adams S et al. **Phase 2 study of pembrolizumab (pembro) monotherapy for previously treated metastatic triple-negative breast cancer (mTNBC): KEYNOTE-086 cohort A.** *Proc ASCO* 2017;**Abstract 1008**.

Beck JT et al. **Everolimus plus exemestane as first-line therapy in HR+, HER2– advanced breast cancer in BOLERO-2.** *Breast Cancer Res Treat* 2014;143(3):459-67.

Blum JL et al. **Anthracyclines in early breast cancer: The ABC trials — USOR 06-090, NSABP B-46-I/USOR 07132, and NSABP B-49 (NRG Oncology).** *J Clin Oncol* 2017;35(23):2647-55.

Burke KA et al. **The landscape of somatic genetic alterations in BRCA1 and BRCA2 breast cancers.** San Antonio Breast Cancer Symposium 2016;**Abstract S2-02**.

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.

Chan A et al. **Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): A multicentre, randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet Oncol* 2016;17(3):367-77.

Finn RS et al. **Palbociclib and letrozole in advanced breast cancer.** *N Engl J Med* 2016;375(20):1925-36.

Freedman RA et al. **TBCRC 022: Phase II trial of neratinib + capecitabine for patients (Pts) with human epidermal growth factor receptor 2 (HER2+) breast cancer brain metastases (BCBM).** *Proc ASCO* 2017;**Abstract 1005**.

Gradishar WJ et al. **Phase III study of lapatinib (L) plus trastuzumab (T) and aromatase inhibitor (AI) vs T+AI vs L+AI in postmenopausal women (PMW) with HER2+, HR+ metastatic breast cancer (MBC): ALTERNATIVE.** *Proc ASCO* 2017;**Abstract 1004**.

Harris LN et al. **Use of biomarkers to guide decisions on adjuvant therapy for women with early-stage breast cancer: American Society of Clinical Oncology Clinical Practice Guideline.** *J Clin Oncol* 2016;34(10):1134-50.

Hortobagyi GN et al. **Updated results from MONALEESA-2, a phase 3 trial of first-line ribociclib + letrozole in hormone receptor-positive (HR+), HER2-negative (HER2-), advanced breast cancer (ABC).** *Proc ASCO* 2017;**Abstract 1038**.

Krop I et al. **Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update.** *J Clin Oncol* 2017;35(24):2838-47.

Krop I et al. **A single-arm phase 2 study to assess clinical activity, efficacy and safety of enzalutamide with trastuzumab in HER2+ AR+ metastatic or locally advanced breast cancer.** San Antonio Breast Cancer Symposium 2016;**Abstract P4-22-08**.

Love N et al. **Beyond the guidelines: Clinical investigators' (CI) self-reported use of genomic assays (GA) to assist in decision-making regarding use of neoadjuvant (NA) and adjuvant chemotherapy for patients (pts) with ER-positive/HER2-negative (ER+/HER2-) early breast cancer (BC).** *Proc ASCO* 2017;**Abstract e18187**.

Masuda N et al. **Adjuvant capecitabine for breast cancer after preoperative chemotherapy.** *N Engl J Med* 2017;376(22):2147-59.

Nanda R et al. **Pembrolizumab plus standard neoadjuvant therapy for high-risk breast cancer (BC): Results from I-SPY 2.** *Proc ASCO* 2017;**Abstract 506**.

Robson M et al. **Olaparib for metastatic breast cancer in patients with a germline BRCA mutation.** *N Engl J Med* 2017;377(6):523-33.

Robson ME at al. **OlympiAD: Phase III trial of olaparib monotherapy versus chemotherapy for patients (pts) with HER2-negative metastatic breast cancer (mBC) and a germline BRCA mutation (gBRCAm).** *Proc ASCO* 2017;**Abstract LBA4**.

Schmid P et al. **Atezolizumab in metastatic TNBC (mTNBC): Long-term clinical outcomes and biomarker analyses.** *Proc AACR* 2017;**Abstract 2986**.

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

Tolaney S et al. **Seven-year (yr) follow-up of adjuvant paclitaxel (T) and trastuzumab (H) (APT trial) for node-negative, HER2-positive breast cancer (BC).** *Proc ASCO* 2017;**Abstract 511**.

Turner NC et al. **Final results of a phase 2 study of talazoparib (TALA) following platinum or multiple cytotoxic regimens in advanced breast cancer patients (pts) with germline BRCA1/2 mutations (ABRAZO).** *Proc ASCO* 2017;**Abstract 1007**.

von Minckwitz G et al; APHINITY Steering Committee and Investigators. **Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer.** *N Engl J Med* 2017;377(2):122-31.

von Minckwitz G et al. **APHINITY trial (BIG 4-11): A randomized comparison of chemotherapy (C) plus trastuzumab (T) plus placebo (Pla) versus chemotherapy plus trastuzumab (T) plus pertuzumab (P) as adjuvant therapy in patients (pts) with HER2-positive early breast cancer (EBC).** *Proc ASCO* 2017;**Abstract LBA500**.