# Breast Cancer Update Issue 2, 2016 (Video Program)

# **CME Information**

# TARGET AUDIENCE

This activity is intended for medical oncologists, hematologists-oncologists and other healthcare providers involved in the treatment of breast cancer (BC).

## **OVERVIEW OF ACTIVITY**

BC remains the most frequently diagnosed cancer in women, and in 2016 in the United States alone the disease will culminate in an estimated 246.660 new cases and 40.890 deaths. 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 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. In fact, as the field of oncology is challenged to improve the precision with which it therapeutically targets malignant cells, biomarker-driven treatment algorithms have become the "norm" for many tumor types, particularly BC. Although the diagnosis and treatment of BC remain, in many ways, more advanced than in other solid tumors, challenging issues in the basic management of this disease continue to require refinement.

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. To provide clinicians with therapeutic strategies to address the disparate needs of patients with BC, this program features information on the latest research developments and is designed to assist medical oncologists, hematologists-oncologists and other healthcare professionals with the formulation of up-to-date strategies for the care of patients with BC.

# LEARNING OBJECTIVES

- Establish an evidence-based algorithm for the treatment of hormone-sensitive advanced BC, including the use of endocrine, biologic and chemotherapeutic agents.
- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and investigational targeted treatments.

- Recognize the evolving application of biomarkers and multigene assays in BC management, and effectively use these tools to refine or individualize treatment plans for patients.
- Recognize the recent FDA approval of palbociclib for ER-positive metastatic BC, and discern how this agent can be optimally integrated into clinical practice.
- Develop an understanding of the mechanisms of action, available data and potential clinical roles of late-stage investigational compounds in preparation for their potential introduction into BC clinical practice.

#### **ACCREDITATION STATEMENT**

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Successful completion of this CME activity enables the participant to earn up to 1.5 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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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/BCU216/Video/CME**.

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Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-theart 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: Lilly; Consulting Agreements:

AstraZeneca Pharmaceuticals LP, Genentech BioOncology, Novartis Pharmaceuticals Corporation, Pfizer Inc, Roche Laboratories Inc; **Contracted Research:** AstraZeneca Pharmaceuticals LP, Genentech BioOncology, Lilly, Novartis Pharmaceuticals Corporation, Pfizer Inc, Roche Laboratories Inc.

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**Board of Directors:** Syndax Pharmaceuticals Inc; **Contracted Research:** Lilly; **Scientific Advisory Board:** Nektar, Radius Health Inc, Symphogen A/S.

**EDITOR** — **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, Agendia Inc, Amgen Inc, Ariad Pharmaceuticals Inc, Array BioPharma Inc, Astellas Pharma Global Development Inc, AstraZeneca

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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

Last review date: January 2017

Expiration date: January 2018

# Select Publications

A phase III randomized double-blind, placebo controlled study of alpelisib in combination with fulvestrant for men and postmenopausal women with hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment. NCT02437318

Adams S et al. Phase Ib trial of atezolizumab in combination with *nab*-paclitaxel in patients with metastatic triple-negative breast cancer (mTNBC). *Proc ASCO* 2016; Abstract 1009.

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

Augusto L et al. Prognostic and predictive value of circulating ESR1 mutations in metastatic breast cancer patients (mBC) progressing under aromatase inhibitor (AI) treatment. *Proc ASCO* 2016; Abstract 511.

Blum JL et al. Interim joint analysis of the ABC (Anthracyclines in Early Breast Cancer) phase III trials (USOR 06-090, NSABP B-46I/USOR 07132, NSABP B-49 [NRG Oncology]) comparing docetaxel + cyclophosphamide (TC) v anthracycline/taxanebased chemotherapy regimens (TaxAC) in women with high-risk, HER2-negative breast cancer. *Proc ASCO* 2016;Abstract 1000.

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.

Conlon N et al. Is there a role for Oncotype DX testing in invasive lobular carcinoma? Breast J 2015;21(5):514-9.

Dickler MN et al. MONARCH1: Results from a phase II study of abemaciclib, a CDK4 and CDK6 inhibitor, as monotherapy, in patients with HR+/HER2- breast cancer, after chemotherapy for advanced disease. *Proc ASCO* 2016; Abstract 510.

Dickler MN et al. A first-in-human phase 1 study to evaluate the oral selective estrogen receptor degrader GDC-0810 (ARN810) in postmenopausal women with estrogen receptor positive (ER+), HER2- advanced/metastatic breast cancer. *Proc* AACR 2015; Abstract CT231.

Finn RS et al. PALOMA-2: Primary results from a phase III trial of palbociclib (P) with letrozole (L) compared with letrozole alone in postmenopausal women with ER+/HER2- advanced breast cancer (ABC). *Proc ASCO* 2016; Abstract 507.

Fribbens C et al. Plasma ESR1 mutations and the treatment of estrogen receptor-positive advanced breast cancer. *J Clin Oncol* 2016;34(25):2961-8.

Goss PE et al. A randomized trial (MA.17R) of extending adjuvant letrozole for 5 years after completing an initial 5 years of aromatase inhibitor therapy alone or preceded by tamoxifen in postmenopausal women with early-stage breast cancer. *Proc* ASCO 2016; Abstract LBA1.

Harris LN 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. *J Clin Oncol* 2016;34(10):2460-7.

Love N et al. HER2 and estrogen receptor status drive decisions regarding the use of neoadjuvant chemotherapy. *Proc ASCO* 2015; Abstract P1-14-20.

Nanda R et al. **Pembrolizumab in patients with advanced triple-negative breast cancer: Phase Ib KEYNOTE-012 study.** *J Clin Oncol* 2016;34(21):2460-7.

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.

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.

Rugo HS et al. Effect of a proposed trastuzumab biosimilar compared with trastuzumab on overall response rate in patients with ERBB2 (HER2)-positive metastatic breast cancer: A randomized clinical trial. *JAMA* 2016;[Epub ahead of print].

Sgroi DC et al. Prediction of late distant recurrence in patients with oestrogen-receptor-positive breast cancer: A prospective comparison of the breast-cancer index (BCI) assay, 21-gene recurrence score, and IHC4 in the TransATAC study population. *Lancet Oncol* 2013;14(11):1067-76.

Slamon D et al. Ten year follow-up of BCIRG-006 comparing doxorubicin plus cyclophosphamide followed by docetaxel (AC  $\rightarrow$  T) with doxorubicin plus cyclophosphamide followed by docetaxel and trastuzumab (AC  $\rightarrow$  TH) with docetaxel, carboplatin and trastuzumab (TCH) in HER2+ early breast cancer. San Antonio Breast Cancer Symposium 2015; Abstract S5-04.

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

Turner NC et al. Efficacy of palbociclib plus fulvestrant (P+F) in patients (pts) with metastatic breast cancer (MBC) and ESR1 mutations (mus) in circulating tumor DNA (ctDNA). *Proc ASCO* 2016;Abstract 512.

Zhang Y et al. Validation of a prognostic model integrating Breast Cancer Index (BCI) with tumor size and grade for prediction of distant recurrence in hormone receptor-positive (HR+) breast cancer with 1-3 positive nodes. *Proc ASCO* 2016;Abstract 541.