Interactive Tumor Panel

Clinical Investigators Discuss Emerging Research and Actual Cases of Patients with Breast Cancer

CME Information

TARGET AUDIENCE

This program is intended for medical oncologists, hematology-oncology fellows and other allied healthcare professionals involved in the treatment of breast cancer (BC).

OVERVIEW OF ACTIVITY

BC remains the most frequently diagnosed cancer in women, and in 2019 in the United States alone the disease will culminate in an estimated 268,600 new cases and 41,760 deaths. 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. 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. In conjunction with this approach researchers are actively developing novel agents and immunotherapeutic strategies, with the aim of generating additional benefit, enhancing the efficacy of existing treatments or overcoming resistance to endocrine therapy, chemotherapy or biologic therapy. As such, the pace of change in the field of breast medical oncology has been rapid, and it is expected that a plethora of new data will continuously be disseminated requiring ongoing efforts to keep medical professionals informed.

These video proceedings from a CME symposium held during the 2019 ASCO Annual Meeting feature discussions with leading researchers with an expertise in BC regarding actual cases from their practices and the published data that drive clinical decision-making for patients in those and diverse other situations. By providing information on the latest research developments and their potential application to 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.

LEARNING OBJECTIVES

- Consider published data to guide the use of biomarkers and genomic classifiers in assessing risk and customizing therapy for patients with hormone receptor-positive BC in the adjuvant and extended adjuvant settings.
- Appraise available and emerging research evidence to individualize the selection and duration of neoadjuvant, adjuvant and extended adjuvant therapy for patients with HER2-overexpressing early BC.
- Develop an evidence-based algorithm for the treatment of advanced hormone receptor-positive pre- and postmenopausal BC, including endocrine, biologic and chemotherapeutic agents.
- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing and investigational targeted treatments.
- Appraise published efficacy and safety data with the use of PARP inhibitors for patients with metastatic BC harboring a BRCA1/2 mutation, and consider the diagnostic and therapeutic implications of these findings on nonresearch care.
- Appraise recently presented Phase III data supporting the FDA approval of anti-PD-L1 antibody therapy combined with chemotherapy for newly diagnosed PD-L1-positive metastatic triple-negative BC, and use this information to identify patients who may be appropriate for this approach in clinical practice.
- Develop an understanding of the mechanisms of action of, available data with and potential clinical roles of other investigational compounds to facilitate referral for clinical trial opportunities or participation in expanded access programs.

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Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 2.75 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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MODERATOR — **Dr Love** is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following commercial interests: AbbVie Inc, Acerta Pharma — A member of the AstraZeneca Group, Adaptive Biotechnologies, Agendia Inc, Agios Pharmaceuticals Inc, Amgen Inc, Ariad Pharmaceuticals Inc, Array BioPharma Inc, Astellas Pharma Global Development Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Dendreon Pharmaceuticals Inc, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech, Genmab, Genomic Health Inc, Gilead Sciences Inc, Guardant Health, 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, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, Natera Inc, Novartis, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Prometheus Laboratories Inc, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sandoz Inc, a Novartis Division, Sanofi Genzyme, Seattle Genetics, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro, Teva Oncology, Tokai Pharmaceuticals Inc and Tolero Pharmaceuticals.

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This activity is supported by educational grants from AbbVie Inc, Celgene Corporation, Daiichi Sankyo Inc, Genentech, Genomic Health Inc, Lilly, Merck, Puma Biotechnology Inc and Seattle Genetics.

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: June 2019

Expiration date: June 2020

Select Publications

Hope S Rugo, MD

Geyer CE Jr et al. **Phase III study of trastuzumab emtansine (T-DM1) vs trastuzumab as adjuvant therapy in patients with HER2-positive early breast cancer with residual invasive disease after neoadjuvant chemotherapy and HER2-targeted therapy including trastuzumab: Primary results from KATHERINE.** San Antonio Breast Cancer Symposium 2018;**Abstract GS1-10**.

Gianni L et al. **Neoadjuvant chemotherapy with trastuzumab followed by adjuvant trastuzumab versus neoadjuvant chemotherapy alone, in patients with HER2-positive locally advanced breast cancer (the NOAH trial): A randomised controlled superiority trial with a parallel HER2-negative cohort.** *Lancet* 2010;375(9712):377-84.

Martin M et al. **Neratinib after trastuzumab-based adjuvant therapy in HER2-positive breast cancer (ExteNET): 5-year analysis of a randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet Oncol* 2017;18(12):1688-700.

Perez E et al. **Trastuzumab plus adjuvant chemotherapy for human epidermal growth factor receptor 2-positive breast cancer: PLANNED joint analysis of overall survival from NSABP B-31 and NCCTG N9831.** *J Clin Oncol* 2014;32(33):3744-52.

von Minckwitz G et al. **Trastuzumab emtansine for residual invasive HER2-positive breast cancer.** *N Engl J Med* 2019;380(7):617-28.

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Virginia Kaklamani, MD, DSc

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.

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.

Partridge AH et al. **Subtype-dependent relationship between young age at diagnosis and breast cancer survival.** *J Clin Oncol* 2016;34(27):3308-14.

Sparano JA et al. **Clinical and genomic risk to guide the use of adjuvant therapy for breast cancer.** *N Engl J Med* 2019;[Epub ahead of print].

Sparano JA et al. **Impact of clinical risk category on prognosis and prediction of chemotherapy benefit in early breast cancer (EBC) by age and the 21-gene Recurrence Score (RS) in TAILORx.** *Proc ASCO* 2019;**Abstract 503**.

Sparano JA et al. **Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer.** *N Engl J Med* 2018;379(2):111-21.

Sparano JA et al. **TAILORx: Phase III trial of chemoendocrine therapy versus endocrine therapy alone in hormone receptor-positive, HER2-negative, node-negative breast cancer and an intermediate prognosis 21-gene Recurrence Score.** *Proc ASCO* 2018;**Abstract LBA1**.

Fabrice André, MD, PhD

André F et al. **Alpelisib for PIK3CA-mutated, hormone receptor-positive advanced breast cancer.** *N Engl J Med* 2019;380(20):1929-40.

André F et al. **Alpelisib (ALP) + fulvestrant (FUL) for advanced breast cancer (ABC): Results of the phase 3 SOLAR-1 trial.** *Proc ESMO* 2018;**Abstract LBA3_PR**.

Bertucci F et al. **Genomic characterization of metastatic breast cancers.** *Nature* 2019;569(7757):560-4.

Condorelli R et al. **Genomic alterations in breast cancer: Level of evidence for actionability according to ESMO Scale for Clinical Actionability of molecular Targets (ESCAT).** *Ann Oncol* 2019;30(3):365-73.

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

Goetz MP et al. **MONARCH 3: Abemaciclib as initial therapy for advanced breast cancer.** *J Clin Oncol* 2017;35(32):3638-46.

Hamilton E, Infante JR. **Targeting CDK4/6 in patients with cancer.** *Cancer Treat Rev* 2016;45:129-18.

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

Hurvitz SA et al. **Phase III MONALEESA-7 trial of premenopausal patients with HR+/HER2– advanced breast cancer (ABC) treated with endocrine therapy ± ribociclib: Overall survival (OS) results.** *Proc ASCO* 2019;**Abstract LBA1008**.

Select Publications

Juric D et al. **Alpelisib + fulvestrant for advanced breast cancer: Subgroup analyses from the phase III SOLAR-1 trial.** San Antonio Breast Cancer Symposium 2018;**Abstract GS3-08**.

Lindeman GJ et al. **Randomized phase II trial of venetoclax + fulvestrant versus fulvestrant in estrogen receptor+, HER2– locally advanced or metastatic breast cancer following recurrence or progression during or after a CDK4/6 inhibitor: VERONICA.** *Proc ASCO* 2019;**Abstract TPS1108**.

Sahebjam S et al. **Assessment of concentrations of abemaciclib and its major active metabolites in plasma, CSF, and brain tumor tissue in patients with brain metastases secondary to hormone receptor positive (HR+) breast cancer.** *Proc ASCO* 2016;**Abstract 526**.

Tolaney S et al. **Abemaciclib for the treatment of brain metastases (BM) secondary to hormone receptor positive (HR+), HER2 negative breast cancer.** *Proc ASCO* 2017;*Abstract 1019*.

Turner NC et al. **Cyclin E1 expression and palbociclib efficacy in previously treated hormone receptor-positive metastatic breast cancer.** *J Clin Oncol* 2019;37(14):1169-78.

Turner NC et al. **Overall survival with palbociclib and fulvestrant in advanced breast cancer.** *N Engl J Med* 2018;379(20):1926-36.

Sara M Tolaney, MD, MPH

Emens LA et al. **IMpassion130: Efficacy in immune biomarker subgroups from the global, randomized, double-blind, placebo-controlled, phase III study of atezolizumab + *nab*-paclitaxel in patients with treatment-naïve, locally advanced or metastatic triple-negative breast cancer.** San Antonio Breast Cancer Symposium 2018;**Abstract GS1-04**.

Hirsch FR et al. **PD-L1 immunohistochemistry assays for lung cancer: Results from phase 1 of the Blueprint PD-L1 IHC Assay Comparison Project.** *J Thorac Oncol* 2017;12(2):208-22.

Kok M et al. **Adaptive phase II randomized trial of nivolumab after induction treatment in triple negative breast cancer (TONIC trial): Final response data stage I and first translational data.** *Proc ASCO* 2018;**Abstract 1012**.

Schmid P et al. **Atezolizumab and *nab*-paclitaxel in advanced triple-negative breast cancer.** *N Engl J Med* 2018;379(22):2108-21.

Schmid P et al. **IMpassion130: Results from a global, randomised, double-blind, phase 3 study of atezolizumab (atezo) + *nab*-paclitaxel (*nab*-P) vs placebo + *nab*-P in treatment-naive, locally advanced or metastatic triple-negative breast cancer (mTNBC).** *Proc ESMO* 2018;**Abstract LBA1_PR**.

Szekely B et al. **Immunological differences between primary and metastatic breast cancer.** *Ann Oncol* 2018;29(11):2232-9.

Tolaney SM et al. **Phase 1b/2 study to evaluate eribulin mesylate in combination with pembrolizumab in patients with metastatic triple-negative breast cancer.** San Antonio Breast Cancer Symposium 2017;**Abstract PD6-13**.

Mark D Pegram, MD

Clynes RA et al. **Inhibitory Fc receptors modulate in vivo cytotoxicity against tumor targets.** *Nat Med* 2000;6(4):443-6.

Fabi A et al. **Efficacy and safety of T-DM1 in the 'common-practice' of HER2+ advanced breast cancer setting: A multicenter study.** *Oncotarget* 2017;8(38):64481-9.

Freedman RA et al. **TBCRC 022: A phase II trial of neratinib and capecitabine for patients with human epidermal growth factor receptor 2-positive breast cancer and brain metastases.** *J Clin Oncol* 2019;37(13):1081-9.

Hamilton E et al. **Efficacy results of a phase 1b study of ONT-380, an oral HER2-specific inhibitor, in combination with capecitabine (C) and trastuzumab (T) in HER2+ metastatic breast cancer (MBC), including patients (pts) with brain metastases (mets).** San Antonio Breast Cancer Symposium 2016;**Abstract P4-21-01**.

Modi S et al. **A phase III, multicenter, randomized, open label trial of trastuzumab deruxtecan (DS-8201a) versus investigator's choice in HER2-low breast cancer.** *J Clin Oncol* 2019 37(15 Suppl).

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Select Publications

Pegram M et al. **Overcoming resistance to HER2-targeted therapy.** Presentation. ASCO 2018. Available at **https://meetinglibrary.asco.org/record/155386/video**.

Rugo HS et al. **SOPHIA primary analysis: A phase 3 (P3) study of margetuximab (M) + chemotherapy (C) versus trastuzumab (T) + C in patients (pts) with HER2+ metastatic (met) breast cancer (MBC) after prior anti-HER2 therapies (Tx).** *Proc ASCO* 2019;**Abstract 1000**.

Tiffany A Traina, MD

Bardia A et al. **Sacituzumab govitecan-hziy in refractory metastatic triple-negative breast cancer.** *N Engl J Med* 2019;380(8):741-51.

Cardoso F et al. **Characterization of male breast cancer: Results of the EORTC 10085/TBCRC/BIG/NABCG International Male Breast Cancer Program.** *Ann Oncol* 2018;29(2):405-17.

Forero-Torres A et al. **Phase 1 study of the antibody-drug conjugate (ADC) SGN-LIV1A in patients with heavily pretreated metastatic breast cancer.** San Antonio Breast Cancer Symposium 2016;**Abstract P6-12-04**.

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Gucalp A et al. **Phase (Ph) 2 stage 1 clinical activity of seviteronel, a selective CYP17-lyase and androgen receptor (AR) inhibitor, in women with advanced AR+ triple-negative breast cancer (TNBC) or estrogen receptor (ER)+ BC: CLARITY-01.** *Proc ASCO* 2017;**Abstract 1102**.

Gucalp A et al. **Phase II trial of bicalutamide in patients with androgen receptor-positive, estrogen receptor-negative metastatic breast cancer.** *Clin Cancer Res* 2013;19(19):5505-12.

Kim SB et al. **Ipatasertib plus paclitaxel versus placebo plus paclitaxel as first-line therapy for metastatic triple-negative breast cancer (LOTUS): A multicentre, randomised, double-blind, placebo-controlled, phase 2 trial.** *Lancet Oncol* 2017;18(10):1360-72.

Litton JK et al. **Talazoparib in patients with advanced breast cancer and a germline BRCA mutation.** *N Engl J Med* 2018;379(8):753-63.

Litton J et al. **EMBRACA: A phase 3 trial comparing talazoparib, an oral PARP inhibitor, to physician's choice of therapy in patients with advanced breast cancer and a germline BRCA mutation.** San Antonio Breast Cancer Symposium 2017;**Abstract GS6-07**.

Loibl S et al. **Addition of the PARP inhibitor veliparib plus carboplatin or carboplatin alone to standard neoadjuvant chemotherapy in triple-negative breast cancer (BrighTNess): A randomised, phase 3 trial.** *Lancet Oncol* 2018;19(4):497-509.

Modi S et al. **Trastuzumab deruxtecan (DS-8201a) in subjects with HER2-low expressing breast cancer: Updated results of a large phase 1 study.** San Antonio Breast Cancer Symposium 2018;**Abstract P6-17-02**.

Modi S et al. **Phase 1 study of the antibody-drug conjugate SGN-LIV1A in patients with heavily pretreated triple-negative metastatic breast cancer.** San Antonio Breast Cancer Symposium 2017;**Abstract PD3-14**.

Robson ME et al. **OlympiAD final overall survival and tolerability results: Olaparib versus chemotherapy treatment of physician's choice in patients with a germline BRCA mutation and HER2-negative metastatic breast cancer.** *Ann Oncol* 2019;30(4):558-66.

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

Schmid P et al. **AZD5363 plus paclitaxel versus placebo plus paclitaxel as first-line therapy for metastatic triple-negative breast cancer (PAKT): A randomised, double-blind, placebo-controlled, phase II trial.** *Proc ASCO* 2018;**Abstract 1007**.

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