

# Breast Cancer<sup>®</sup>

U P D A T E

Conversations with Oncology Investigators  
Bridging the Gap between Research and Patient Care

**FACULTY INTERVIEWS**

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# Breast Cancer®

U P D A T E

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## Breast Cancer Update — A Continuing Medical Education Audio Series

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### OVERVIEW OF ACTIVITY

Breast cancer (BC) continues to be one of the most rapidly evolving fields in medical oncology. 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. Featuring information on the latest research developments along with expert perspectives, this CME activity is designed to assist medical oncologists, hematologist-oncologists and hematology-oncology fellows with the formulation of up-to-date clinical management strategies.

### LEARNING OBJECTIVES

- Develop 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.
- Consider the use of available biomarkers and genomic assays to assess risk and individualize therapy for patients in the neoadjuvant, adjuvant and extended-adjuvant settings.
- 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.
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials investigating novel therapeutic agents and strategies.

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## CME INFORMATION

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## Interview with George W Sledge Jr, MD

### Tracks 1-21

- |                |  |                 |  |
|----------------|--|-----------------|--|
| <b>Track 1</b> | Results of the Phase III MA17R trial: Extended adjuvant letrozole for 5 years after an initial 5 years of aromatase inhibitor (AI) therapy alone or preceded by tamoxifen for early-stage breast cancer (BC) | <b>Track 9</b>  | Perspective on the choice of anthracycline-based versus nonanthracycline-based regimens for HER2-positive early BC           |
| <b>Track 2</b> | Use of the Breast Cancer Index (BCI) in the prediction of late distant recurrence in patients with ER-positive BC  | <b>Track 10</b> | FDA label indication and NCCN guidelines on the use of (neo)adjuvant pertuzumab  |
| <b>Track 3</b> | MINDACT trial: Utility of the 70-gene signature in selecting patients with BC and 0 to 3 positive nodes for adjuvant chemotherapy  | <b>Track 11</b> | Use of neoadjuvant therapy for triple-negative BC (TNBC)   |
| <b>Track 4</b> | Perspective on the ASCO statement on using the 21-gene signature for patients with node-positive BC  | <b>Track 12</b> | Investigation of immune checkpoint inhibitors in TNBC  |
| <b>Track 5</b> | PHEREXA: Results of a Phase III trial of trastuzumab/capecitabine with or without pertuzumab after disease progression on trastuzumab-based therapy for HER2-positive metastatic BC (mBC)                    | <b>Track 13</b> | Androgen receptor expression in primary BC   |
| <b>Track 6</b> | HERITAGE: Results of a Phase III safety and efficacy trial of the proposed trastuzumab biosimilar Myl-14010 for HER2-positive mBC  | <b>Track 14</b> | Investigation of PARP inhibitors in BRCA mutation-positive BC  |
| <b>Track 7</b> | <b>Case discussion:</b> A 62-year-old woman with ER-positive, HER2-positive BC and preexisting peripheral neuropathy receives paclitaxel/trastuzumab   | <b>Track 15</b> | Efficacy and tolerability of palbociclib in combination with letrozole or with fulvestrant for ER-positive mBC               |
| <b>Track 8</b> | Use of anthracycline-based versus nonanthracycline-based therapies for HER2-negative early BC  | <b>Track 16</b> | MONARCH 1: Results of a Phase II trial of the CDK4/6 inhibitor abemaciclib as monotherapy for ER-positive, HER2-negative mBC |
|                |  | <b>Track 17</b> | Use of palbociclib and endocrine therapy in the first-line setting for patients with ER-positive mBC                         |
|                |  | <b>Track 18</b> | Incidence of ESR1 mutations in BC  |
|                |  | <b>Track 19</b> | Treatment for patients with ER-positive BC and disease progression on palbociclib-based therapy                              |
|                |  | <b>Track 20</b> | Use of everolimus/exemestane for patients with ER-positive advanced BC and management of treatment-associated side effects   |
|                |  | <b>Track 21</b> | Investigation of everolimus for HER2-positive mBC  |

## Interview with Maura N Dickler, MD

### Tracks 1-17

- |                |  |                |   |
|----------------|--|----------------|---|
| <b>Track 1</b> | Role of the 21-gene signature for patients with invasive lobular carcinoma   | <b>Track 4</b> | MA17R trial: Outcomes with extended adjuvant letrozole  |
| <b>Track 2</b> | Viewpoint on use of the 70-gene signature as an aid in treatment decision-making in early-stage BC   | <b>Track 5</b> | <b>Case discussion:</b> A 45-year-old woman with previously treated ER-positive invasive ductal carcinoma (IDC) develops disease progression after 2 years of everolimus/exemestane |
| <b>Track 3</b> | Role of genomic assays in determining whether to administer chemotherapy in addition to endocrine treatment for patients with ER-positive BC |                |   |

## Interview with Dr Dickler (continued)

- Track 6** Mechanistic differences among selective ER modulators and selective ER degraders in the treatment of ER-positive BC
- Track 7** Results of a Phase I study of the oral selective ER degrader GDC-0810 in postmenopausal women with ER-positive, HER2-negative mBC
- Track 8** Efficacy of GDC-0810 in patients with ESR1 mutations
- Track 9** Activity and side-effect profile of palbociclib in combination with letrozole for ER-positive mBC
- Track 10** Results of the Phase II MONARCH 1 trial evaluating abemaciclib monotherapy for ER-positive, HER2-negative mBC
- Track 11** Ongoing studies of the CDK4/6 inhibitors palbociclib, abemaciclib and ribociclib in ER-positive BC
- Track 12** Novel PI3K inhibitors (alpelisib, buparlisib, taselisib) under investigation in advanced BC
- Track 13** Activity of everolimus/exemestane for mBC and management of treatment-associated stomatitis and pneumonitis
- Track 14** **Second opinion:** Therapeutic options for ER/PR-positive, HER2-positive mBC and potential role of palbociclib in this setting
- Track 15** **Second opinion:** Potential use of capecitabine after disease progression on multiple trastuzumab-containing regimens
- Track 16** **Second opinion:** Use of intrathecal anti-HER2 therapy
- Track 17** **Case discussion:** A woman with ER-negative, HER2-positive BC initially receives nanoparticle albumin-bound (*nab*) paclitaxel, trastuzumab and pertuzumab

## Interview with Matthew P Goetz, MD

### Tracks 1-16

- Track 1** **Case discussion:** A 55-year-old woman with relapsed/refractory TNBC and no evidence of disease after treatment with eribulin
- Track 2** Sequencing of therapeutic options for mTNBC
- Track 3** Activity of eribulin in patients with mTNBC
- Track 4** Identification of targetable mutations via next-generation sequencing
- Track 5** Targeting the androgen receptor in TNBC
- Track 6** Ongoing clinical trials of novel immunotherapy approaches in mBC
- Track 7** **Case discussion:** A 49-year-old woman with ER-negative, HER2-positive IDC whose disease recurs 2 years after treatment with pertuzumab/trastuzumab/docetaxel
- Track 8** **Case discussion:** A 65-year-old woman with ER/PR-positive, HER2-negative IDC completes 5 years of tamoxifen and receives a BCI assay result indicating a low risk of distant recurrence
- Track 9** Clinical utility of the BCI in predicting risk of distant recurrence
- Track 10** Validation of a prognostic model integrating the BCI with tumor size and grade for prediction of distant recurrence in ER-positive BC with 1 to 3 positive nodes
- Track 11** Perspective on the results of the MA17R trial
- Track 12** Use of the 21-gene signature to guide adjuvant decision-making
- Track 13** Comparison of the 70- and 21-gene signatures
- Track 14** **Case discussion:** A 57-year-old woman with mTNBC receives enzalutamide and taselisib on a clinical trial
- Track 15** Activity of immune checkpoint inhibitors in TNBC
- Track 16** Status of BEAUTY, the Breast Cancer Genome Guided Therapy Study, attempting to identify genomic alterations in patients with high-risk BC recommended for neoadjuvant chemotherapy

## SELECT PUBLICATIONS

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.

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.

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.

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.

Hortobagyi GN et al. **First-line ribociclib + letrozole for postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2-), advanced breast cancer (ABC).** *Proc ESMO 2016*;Abstract LBA1\_PR.

**MONARCH 2: A randomized, double-blind, placebo-controlled, phase 3 study of fulvestrant with or without abemaciclib, a CDK4/6 inhibitor, for women with hormone receptor positive, HER2 negative locally advanced or metastatic breast cancer.**  
NCT02107703

**MONARCH 3: A randomized, double-blind, placebo-controlled, phase 3 study of nonsteroidal aromatase inhibitors (anastrozole or letrozole) plus LY2835219, a CDK4/6 inhibitor, or placebo in postmenopausal women with hormone receptor-positive, HER2-negative locoregionally recurrent or metastatic breast cancer with no prior systemic therapy in this disease setting.** NCT02246621

**PALbociclib CoLaborative 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 (PALLAS).** NCT02513394

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.

Salunga RC et al. **Evaluation of the analytical performance of the Breast Cancer Index (BCI) assay.** *Proc ASCO 2016*;Abstract 540.

Sanft T et al. **Prospective assessment of the decision-making impact of the Breast Cancer Index in recommending extended adjuvant endocrine therapy for patients with early-stage ER-positive breast cancer.** *Breast Cancer Res Treat 2015*;154(3):533-41.

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.

**Study assessing the efficacy and safety of alpelisib plus fulvestrant in men and postmenopausal women with advanced breast cancer which progressed on or after aromatase inhibitor treatment (SOLAR-1).** NCT02437318

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.

## QUESTIONS (PLEASE CIRCLE ANSWER):

- The Phase III MA17R trial evaluating extension of adjuvant letrozole for 5 years after completion of an initial 5 years of AI therapy alone or preceded by tamoxifen in early-stage BC demonstrated no improvement in disease-free survival with the extension of AI therapy.
  - True
  - False
- The combination of pertuzumab with trastuzumab and docetaxel is FDA approved as \_\_\_\_\_ for patients with HER2-positive \_\_\_\_\_.
  - Adjuvant therapy; early BC
  - Neoadjuvant therapy; early BC
  - First-line therapy; mBC
  - All of the above
  - Both a and b
  - Both b and c
- Data presented at ASCO 2016 from the Phase III PALOMA-2 trial of palbociclib and letrozole versus letrozole alone for patients with ER-positive, HER2-negative advanced BC who had not received prior systemic therapy for their advanced disease demonstrated a statistically significant improvement in the primary study endpoint of progression-free survival (PFS) for patients who received palbociclib.
  - True
  - False
- Single-agent activity has been reported with which of the following CDK4/6 inhibitors in patients with ER-positive, HER2-negative mBC?
  - Abemaciclib
  - Palbociclib
  - Ribociclib
  - None of the above
- Which of the following is the mechanism of action of fulvestrant?
  - Selective estrogen receptor degrader
  - Selective estrogen receptor modulator
  - Both a and b
  - Neither a nor b
- The Phase III MONARCH 2 trial is evaluating \_\_\_\_\_ with or without abemaciclib in patients with ER-positive, HER2-positive locally advanced or metastatic BC.
  - Anastrozole
  - Fulvestrant
  - Letrozole
  - All of the above
- Which of the following toxicities is exhibited to a much greater extent in patients receiving abemaciclib than in those receiving palbociclib for ER-positive mBC?
  - Diarrhea
  - Fatigue
  - Myelosuppression
  - All of the above
- The Phase III BELLE-2 study evaluating fulvestrant with or without buparlisib (BKM120) in postmenopausal women with endocrine-resistant ER-positive, HER2-negative advanced BC reported a significant improvement in PFS for patients with PIK3CA mutations who received buparlisib.
  - True
  - False
- Which of the following PI3K inhibitors is actively under Phase III investigation for patients with endocrine-resistant ER-positive advanced BC?
  - Alpelisib
  - Taselisib
  - Both a and b
  - Neither a nor b
- The goal of the MINDACT trial, for which initial results were recently published, was to evaluate the benefit of genomic profiling with the \_\_\_\_\_ in addition to standard clinical-pathological criteria for patients with early BC and 0 to 3 positive lymph nodes who might safely forgo chemotherapy without compromising outcome.
  - BCI
  - 70-gene signature
  - 21-gene signature



*Breast Cancer Update — Issue 2, 2016*

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**PART 1 — Please tell us about your experience with this educational activity**

**How would you characterize your level of knowledge on the following topics?**

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal
	<b>BEFORE</b>		<b>AFTER</b>	
Results of the Phase III MA17R trial: Extending adjuvant letrozole for 5 years after completion of an initial 5 years of AI therapy alone or preceded by tamoxifen in early-stage BC	4	3	2	1
MONARCH 1: Results of a Phase II trial of the CDK4/6 inhibitor abemaciclib as monotherapy for ER-positive, HER2-negative mBC	4	3	2	1
Clinical utility of the BCI in predicting risk of distant recurrence	4	3	2	1
Ongoing evaluations of the CDK4/6 inhibitors palbociclib, abemaciclib and ribociclib in ER-positive BC	4	3	2	1
Role of the 21-gene signature for patients with invasive lobular carcinoma	4	3	2	1

**Practice Setting:**

- Academic center/medical school     
  Community cancer center/hospital     
  Group practice  
 Solo practice     
  Government (eg, VA)     
  Other (please specify).....

**Approximately how many new patients with breast cancer do you see per year?** ..... patients

**Was the activity evidence based, fair, balanced and free from commercial bias?**

- Yes     
  No     
 If no, please explain: .....

**Please identify how you will change your practice as a result of completing this activity (select all that apply).**

- This activity validated my current practice  
 Create/revise protocols, policies and/or procedures  
 Change the management and/or treatment of my patients  
 Other (please explain): .....

**If you intend to implement any changes in your practice, please provide 1 or more examples:**

.....  
 .....

**The content of this activity matched my current (or potential) scope of practice.**

- Yes     
  No     
 If no, please explain: .....

**Please respond to the following learning objectives (LOs) by circling the appropriate selection:**

4 = Yes    3 = Will consider    2 = No    1 = Already doing    N/M = LO not met    N/A = Not applicable

**As a result of this activity, I will be able to:**

- Develop an evidence-based algorithm for the treatment of hormone-sensitive advanced BC, including the use of endocrine, biologic and chemotherapeutic agents... 4 3 2 1 N/M N/A
- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and investigational targeted treatments... 4 3 2 1 N/M N/A
- Consider the use of available biomarkers and genomic assays to assess risk and individualize therapy for patients in the neoadjuvant, adjuvant and extended-adjuvant settings..... 4 3 2 1 N/M N/A
- Recognize the recent FDA approval of palbociclib for ER-positive metastatic BC, and discern how this agent can be optimally integrated into clinical practice. .... 4 3 2 1 N/M N/A

**EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)**

**As a result of this activity, I will be able to:**

- 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. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials investigating novel therapeutic agents and strategies. . . . . 4 3 2 1 N/M N/A

**Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:**

.....

**Would you recommend this activity to a colleague?**

Yes       No

If no, please explain: .....

**PART 2 — Please tell us about the faculty and editor for this educational activity**

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George W Sledge Jr, MD	4	3	2	1	4	3	2	1
Maura N Dickler, MD	4	3	2	1	4	3	2	1
Matthew P Goetz, MD	4	3	2	1	4	3	2	1
<b>Editor</b>	<b>Knowledge of subject matter</b>				<b>Effectiveness as an educator</b>			
Neil Love, MD	4	3	2	1	4	3	2	1

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