

**Breast Cancer Steering Committee (BCSC)
Clinical Trials Planning Meeting (CTPM)**

**Next Generation Trials for Estrogen Receptor (ER)-positive Breast Cancer
May 14-15, 2012**

**Meeting Co-chairs: Karen Gelmon, M.D. and Fraser Symmans, M.D.
BCSC Co-chairs: Nancy Davidson, M.D. and Tom Buchholz, M.D.**

Introduction/Meeting Description

The National Cancer Institute (NCI) Breast Cancer Steering Committee (BCSC) convened a Clinical Trials Planning Meeting for the Next Generation Trials in Estrogen Receptor (ER)-positive Breast Cancer on May 14 -15, 2012 in Bethesda, MD. The goals of the meeting were to address strategies to improve outcomes from clinical trials of any class of treatment in any stage of ER-positive breast cancer with a scientific focus on overcoming mechanisms of resistance to hormonal therapy. This included developing an understanding of key molecular and genetic ‘drivers’ of ER-positive cancers that may be targeted to improve outcomes and recommending directions for future clinical trials in the treatment of ER-positive breast cancer. The meeting attendees included BCSC members, breast cancer clinicians, clinical trials experts, biostatisticians, translational scientists, basic scientists, patient advocates, FDA staff, and NCI staff.

Background/Importance of Research Topic/Disease/Limitations

Estrogen receptor (ER)-positive breast cancer leads to for the thousands of lives lost per year in the United States.¹ This breast cancer subtype has a relatively good 5-year prognosis; however, individuals with ER-positive breast cancer continue to relapse over time, making ER-positive breast cancer responsible for the majority of breast cancer deaths.² Patients can exhibit *de novo* hormonal resistance or acquired hormonal resistance and there is a need for effective targeted therapies for hormone refractory breast cancer.³ ER-positive breast cancer is comprised of a very heterogeneous group of tumors.³ Understanding the very diverse biology of ER-positive breast cancer, mechanisms by which it becomes resistant to hormonal therapy, and identifying promising targeted agents is a high priority. Efforts are ongoing to define molecular markers that could be used to determine which patients with ER-positive disease benefit from chemotherapy and other therapies in addition to hormonal treatment.⁴⁻¹⁰

Consensus

The current North American Cooperative Group system includes several large adjuvant clinical trials, leaving no space for an additional large randomized adjuvant trial of hormonal therapy due to a limited number of patients and resources. Similarly, the current platform in front line hormonal therapy trials for stage IV disease also leaves no space for trial development.

The Cooperative Groups should utilize smaller pre-operative studies and neoadjuvant trials space to address endocrine response. The Cooperative Groups have committed to a large neoadjuvant trial (ALTERNATE).

Considering all of the patients who are just finishing large adjuvant trials, the registry mechanism, as long as it is linked to a parent trial, should be considered for following patients from those trials so that their data can be used to inform the field and future trials.

For premenopausal women with ER-positive breast cancer, results from the SOFT and TEXT trials should be used to determine the next important questions and to design the next trials.

Recommendations

- There is a need for common definitions/clinical classification for endocrine resistance, considering early stage and metastatic disease.
- There is a need for standardized guidance on biopsies (compulsory and non-compulsory) and specimen storage.
- The next hormone responsive clinical studies should include the following:
 1. Randomized phase II neoadjuvant studies
 2. Variable designs in metastatic setting
 3. Studies of endocrine therapy backbone plus targeted therapy(ies) or alternating between endocrine therapy plus or minus targeted therapy(ies)
 4. Mandatory biopsies of relapsed disease
 5. Integral biomarkers with clinical assay development plan

This Executive Summary presents the consensus arising from the CTPM. These recommendations are not meant to address all clinical contexts, but rather represent priorities for publicly funded clinical research.

Anticipated Action(s)

- Publish white papers for scientific and lay communities including key strategic priorities, both near-term and long-term, for future trials.
- Develop and publish common definitions/clinical classification/lexicon for endocrine resistance, standardized guidance on biopsies (compulsory and non-compulsory) and standardized guidance on specimen storage.
- Design concepts for studies as recommended above with input from Cooperative Group representatives, industry, Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), and Patient Advocates.

References/Literature

1. American Cancer Society: Cancer Facts and Figures 2012. Atlanta, Ga: American Cancer Society, 2012
2. Giuliano M, Schiff R, Osborne CK, et al: Biological mechanisms and clinical implications of endocrine resistance in breast cancer. *Breast* 20 Suppl 3:S42-9, 2011
3. Lim E, Metzger O, Winer E: The Natural History of Hormone Receptor–Positive Breast Cancer. *Oncology*: 26.8, 2012
4. Loi S, Piccart M, Sotiriou C, et al: Predicting prognosis using molecular profiling in estrogen receptor-positive breast cancer treated with tamoxifen. *BMC Genomics*: 9:239, 2008
5. Gökmen-Polar Y and Badve S: Molecular Profiling Assays in Breast Cancer: Are We Ready for Prime Time? *Oncology*: 26.4, 2012
6. Nagaraj G, Ellis M, Ma C: The Natural History of Hormone Receptor–Positive Breast Cancer: Attempting to Decipher an Intriguing Concept. *Oncology*: 26.8, 2012
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8. Liu MC, Dixon JM, Xuan JJ, et al: Molecular signaling distinguishes early ER-positive breast cancer recurrences despite adjuvant tamoxifen. 2011 San Antonio Breast Cancer Symposium. Abstract S1-8. Presented December 7, 2011.
9. Bianchini G, Pusztai L, Iwamoto T, et al: Molecular tumor characteristics influence adjuvant endocrine treatment outcome. 2011 San Antonio Breast Cancer Symposium. Abstract S1-7. Presented December 7, 2011.
10. <http://www.ascopost.com/issues/february-15-2012-supplement/can-molecular-profiling-identify-er-positive-patients-destined-for-relapse.aspx>

**National Cancer Institute Breast Cancer Steering Committee (BCSC)
Clinical Trials Planning Meeting
Next Generation Trials for Estrogen Receptor (ER)-positive Breast Cancer
Monday and Tuesday, May 14-15, 2012**

****Hyatt Regency Bethesda**
One Bethesda Metro Center (7400 Wisconsin Avenue), Bethesda, MD 20814**

AGENDA

DAY 1: MONDAY, MAY 14, 2012

7:30 AM REGISTRATION Cabinet/Judiciary Suite – Conference Level

8:30 AM – 8:35 AM Welcome and Introduction to the NCI Clinical Trials Planning Meeting
Nancy Davidson and Tom Buchholz, BCSC Co-Chairs

8:35 AM – 8:45 AM Charge for the Clinical Trials Planning Meeting
Karen Gelmon and Fraser Symmans, Meeting Co-Chairs

**8:45 AM – 11:50 AM SESSION 1: ENDOCRINE RESISTANCE IN THE CONTEXT OF
BIOLOGICAL MODELS**
Moderator: Kent Osborne

8:45 – 9:05 **Estrogen Receptor and alternative signaling pathways in endocrine resistance**
Kent Osborne

9:05 – 9:25 **Genomic expression and sequence for endocrine resistant tumors**
Matt Ellis

9:25 – 9:35 **API activation: the role of AP-1 in endocrine-resistant breast cancer**
Rachel Schiff

9:35 – 9:45 **ER coregulators**
Steffi Oesterreich

9:45 – 9:55 **Novel ER-ligands in breast cancer pathogenesis**
Donald McDonnell

9:55 – 10:05 **Epigenetics of Hormone Resistance**
Sara Sukumar

10:05 – 10:25 **BREAK**

10:25 – 11:40 **Moderated panel and audience discussion**
Moderator: Kent Osborne
*Panel Members: Matt Ellis, Rachel Schiff, Steffi Oesterreich, Donald McDonnell,
Sara Sukumar, Patty Spears (Patient Advocate)*

11:40 – 11:50 **Session 1 summary**
Steffi Oesterreich, Paul Haluska

11:50 AM – 1:00 PM BREAK

1:00 PM – 3:45 PM SESSION 2: TRANSLATIONAL RESEARCH OF ENDOCRINE RESISTANCE IN HUMAN SUBJECTS
Moderator: Charles Geyer

1:00 – 1:20 **Defining endocrine resistance in the clinical setting**
Stephen Johnston

1:20 – 1:30 **Tissue issues in endocrine resistance**
Fraser Symmans

1:30 – 1:40 **Breast Cancer Pharmacogenomics**
Matt Goetz

1:40 – 2:00 **Dealing with large cohorts to define resistance and translating pathway science to clinical samples**
Mitch Dowsett

2:00 – 2:10 **Expectations for integral versus integrated diagnostics within prospective clinical trial designs**
Mickey Williams

2:10 – 2:20 **Tissue-based research in clinical trials: Patient Advocate perspective**
Mary Lou Smith

2:20 – 3:35 **Moderated panel and audience discussion**
Moderator: Charles Geyer
Panel Members: Stephen Johnston, Fraser Symmans, Matt Goetz, Mitch Dowsett, Mickey Williams, Mary Lou Smith (Patient Advocate)

3:35 – 3:45 **Session 2 summary**
Lajos Pusztai, Antonio Wolff

3:45 PM – 3:55 PM BREAK

3:55 PM – 4:10 PM Accrual issues and NCI AccrualNet
Linda Parreco

4:10 PM – 4:40 PM Tackling endocrine resistance – the pharmaceutical industry’s perspective
Stephen Johnston

4:40 PM – 6:00 PM Discussion and wrap-up of day 1
Karen Gelmon and Fraser Symmans

DAY 2: TUESDAY, MAY 15, 2012

7:30 AM REGISTRATION Cabinet/Judiciary Suite – Conference Level

8:00 AM – 8:10 AM **Welcome and charge for day 2**
Karen Gelmon and Fraser Symmans

8:10 AM – 11:00 AM **SESSION 3: ENDOCRINE RESISTANCE IN THE CONTEXT OF PROSPECTIVE CLINICAL TRIALS**
Moderator: Karen Gelmon

8:10 – 8:25 **Defining who are likely cured from current chemotherapy +/- endocrine therapy**
Fabrice Andre

8:25 – 8:40 **Neoadjuvant clinical trial opportunities for ER-positive breast cancer**
Angela Demichele

8:40 – 8:50 **The most pressing loco-regional questions for clinical trials of ER-positive breast cancer**
Marilyn Leitch

8:50 – 9:00 **Addressing compliance in clinical trials of oral therapies**
Dawn Hershman

9:00 – 9:10 **One clinical trial approach to overcome *de novo* endocrine resistance**
Cynthia Ma

9:10 – 9:20 **One clinical trial approach to overcome *acquired* endocrine resistance**
Paul Haluska

9:20 – 9:40 **How do we design the best trials to address endocrine resistance?**
Eric Winer

9:40 – 9:50 **BREAK**

9:50 – 10:50 **Moderated panel and audience discussion**
Moderator: Karen Gelmon
Panel Members: Fabrice Andre, Angela Demichelle, Marilyn Leitch, Dawn Hershman, Cynthia Ma, Paul Haluska, Eric Winer, Liz Frank (Patient Advocate)

10:50 – 11:00 **Session 3 summary**
Cliff Hudis, Edith Perez

11:00 AM – 12:45 PM **SESSION 4: WORKING SESSION**

11:00 – 11:30 **Break-out group charge and audience discussion**
Karen Gelmon and Fraser Symmans

11:30 – 11:45 **Move to break-out rooms**

11:45 – 12:45 **Break-out Group Discussions**

1. Biological strategy and targeted therapy

Location: Susquehanna/Severn/Potomac Suite – Conference Level

Chair: Jim Ingle

2. Translational research

Location: Old Georgetown Room – Conference Level

Chair: Dan Hayes

3. Clinical trial strategies

Location: Cabinet/Judiciary Suite – Conference Level

Chair: Gabe Hortobagyi

12:45 PM – 12:50 PM BREAK

12:50 PM – 2:30 PM SESSION 5: REPORT-OUT, DISCUSSION AND ACTION PLAN

Location: Cabinet/Judiciary Suite – Conference Level

Moderators: Nancy Davidson and Tom Buchholz

12:50 – 1:00 **Report-out from biological strategy and targeted therapy break-out group**

Chair: Jim Ingle

1:00 – 1:10 **Report-out from translational research break-out group**

Chair: Dan Hayes

1:10 – 1:20 **Report-out from clinical trial strategies break-out group**

Chair: Gabe Hortobagyi

1:20 – 2:00 **Moderated panel and audience discussion of priorities and post-meeting action plan**

Moderators: Nancy Davidson and Tom Buchholz

Panelists: Fraser Symmans, Kent Osborne Jim Ingle, Steffi Oesterreich, Paul

Haluska, Dan Hayes, Lajos Pusztai, Antonio Wolff, Karen Gelmon, Gabe Hortobagyi,

Cliff Hudis, Edith Perez, Patty Spears (Patient Advocate)

2:00 – 2:30 **Meeting summary and action plan**

Nancy Davidson and Tom Buchholz

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May 14–15, 2012 | Bethesda, MD

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