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**

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**
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**
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 **Pharmacogenetics update**
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 **Patient advocate perspective on tissue-based research in clinical trials**
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**

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

8:10 AM – 11:20 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 – 9:55 **BREAK**

9:55 – 11:10 **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)

11:10 – 11:20 **Session 3 summary**
Cliff Hudis, Edith Perez

11:20 AM – 12:30 PM **SESSION 4: BREAK-OUT GROUP DISCUSSIONS**
Objective: prioritize strategies for clinical trials

1. **Biological strategy and targeted therapy**
   Chair: Jim Ingle

2. **Translational research**
   Chair: Dan Hayes

3. **Clinical trial strategies**
   Chair: Gabe Hortobagyi

12:30 PM – 1:30 PM BREAK

1:30 PM – 3:00 PM **SESSION 5: REPORT-OUT, DISCUSSION AND ACTION PLAN**
Moderator: Nancy Davidson

1:30 – 1:40 **Report-out from biological strategy and targeted therapy break-out group**
Chair: Jim Ingle

1:40 – 1:50 **Report-out from translational research break-out group**
Chair: Dan Hayes

1:50 – 2:00 **Report-out from clinical trial strategies break-out group**
Chair: Gabe Hortobagyi

2:00 – 2:45 **Moderated panel and audience discussion of priorities and post-meeting action plan**
Moderator: Nancy Davidson
Panelists: 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)

2:45 – 3:00 **Meeting summary and action plan**
Nancy Davidson

3:00 PM **ADJOURN**